Cablivi®
caplacizumab-yhdp
Injection 11 mg

ISTH GUIDELINES RECOMMEND CABLIVI* — SEE START SUPPORT

GUIDANCE FOR THE DIAGNOSIS AND TREATMENT OF TTP[1,2]

ISTH TTP Guidelines are **the first evidence-based, international guidelines** on the diagnosis, treatment, and management of aTTP†

For patients with aTTP experiencing an acute event (initial or relapsing), the ISTH recommends using CABLIVI*

Identifying aTTP is crucial for initiation of an appropriate therapeutic strategy

SEE aTTP†—Diagnosis determined through clinical assessment

CLINICAL ASSESSMENT‡

- **Thrombocytopenia** (<100 x 10^9/L)
- **Evidence of MAHA**§
- **Relatively preserved renal function**

OR

RISK ASSESSMENT TOOLS‖

Available risk assessment tools include:

- **PLASMIC score**
- **French score**

The higher the risk assessment score the more likely patients have severe ADAMTS13 deficiency and aTTP

‡List includes laboratory tests and results only; exclusive of physical symptoms, such as petechiae.
§Hb and hematocrit below reference range, low haptoglobin, elevated LDH, presence of schistocytes in peripheral blood smear.
‖ISTH did not appraise the evidence of these 2 tools.

START CABLIVI*—Consider early administration of CABLIVI in combination with PEX and immunosuppressive therapy

Recommended diagnostic and management strategy for acute events with access to ADAMTS13 results within 7 days

aTTP diagnosis based on high clinical suspicion (pretest probability ≥90%)	**Start PEX + immunosuppressive therapy Consider STARTING CABLIVI***
Low or intermediate clinical suspicion of aTTP (pretest probability <90%)	**Consider starting PEX + immunosuppressive therapy**

Who should not start CABLIVI?

- CABLIVI is contraindicated in patients with a previous severe hypersensitivity reaction to caplacizumab-yhdp or to any of its excipients
- Withhold CABLIVI treatment 7 days prior to elective surgery, dental procedures, or other invasive interventions

SUPPORT WITH ADAMTS13—ADAMTS13 test results inform treatment decisions

<10%	10%–20%	>20%
CONTINUE CABLIVI or consider STARTING CABLIVI*	**Use clinical judgment to guide treatment** and consider other diagnoses	STOP CABLIVI and consider other diagnoses

Treatment of relapses for a patient previously diagnosed with aTTP could be started safely based on clinical grounds without the need for a confirmatory ADAMTS13 test

*A conditional recommendation defined as desirable effects of the recommendation probably outweighing the undesirable effects. Assumes timely access to ADAMTS13 testing and clinical diagnosis based on high likelihood of aTTP. If ADAMTS13 testing is not available, do not add CABLIVI.

†The ISTH TTP Guidelines refer to aTTP as iTTP.

INDICATIONS:

CABLIVI (caplacizumab-yhdp) is indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:

CABLIVI is contraindicated in patients with a previous severe hypersensitivity reaction to caplacizumab-yhdp or to any of its excipients. Hypersensitivity reactions have included urticaria.

WARNINGS AND PRECAUTIONS:

Hemorrhage:

- CABLIVI increases the risk of bleeding. In clinical studies, severe bleeding adverse reactions of epistaxis, gingival bleeding, upper gastrointestinal hemorrhage, and metrorrhagia were each reported in 1% of subjects. Overall, bleeding events occurred in approximately 58% of patients on CABLIVI versus 43% of patients on placebo.
- In the postmarketing setting cases of life-threatening and fatal bleeding were reported in patients receiving CABLIVI.
- 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.
- Avoid concomitant use of CABLIVI with antiplatelet agents or anticoagulants. If clinically significant bleeding occurs, interrupt use of CABLIVI. Von Willebrand factor concentrate may be administered to rapidly correct hemostasis. If CABLIVI is restarted, monitor closely for signs of bleeding.
- Withhold CABLIVI for 7 days prior to elective surgery, dental procedures or other invasive interventions. If emergency surgery is needed, the use of von Willebrand factor concentrate may be considered to correct hemostasis. After the risk of surgical bleeding has resolved, and CABLIVI is resumed, monitor closely for signs of bleeding.

ADVERSE REACTIONS:

The most common adverse reactions (>15% of patients) were epistaxis (29%), headache (21%) and gingival bleeding (16%).

CONCOMITANT USE OF ANTICOAGULANTS OR ANTIPLATELET AGENTS:

Concomitant use of CABLIVI with any anticoagulant or antiplatelet agent may increase the risk of bleeding. Avoid concomitant use when possible. Assess and monitor closely for bleeding with concomitant use.

PREGNANCY:

There are no available data on CABLIVI use in pregnant women to inform a drug associated risk of major birth defects and miscarriage.

- **Fetal/neonatal adverse reactions:** CABLIVI may increase the risk of bleeding in the fetus and neonate. Monitor neonates for bleeding.
- **Maternal adverse reactions:** All patients receiving CABLIVI, including pregnant women, are at risk for bleeding. Pregnant women receiving CABLIVI should be carefully monitored for evidence of excessive bleeding.

Please see accompanying Full Prescribing Information.

aTTP=acquired thrombotic thrombocytopenic purpura; Hb=hemoglobin; ISTH=International Society on Thrombosis and Haemostasis; iTTP=immune thrombotic thrombocytopenic purpura; LDH=lactate dehydrogenase; MAHA=microangiopathic hemolytic anemia; PEX=plasma exchange; TTP=thrombotic thrombocytopenic purpura.

References: 1. Zheng XL, Vesely SK, Cataland SR, et al. ISTH guidelines for the diagnosis of thrombotic thrombocytopenic purpura. *J Thromb Haemost*. 2020;(jth.15006). doi:10.1111/jth.15006 **2.** Zheng XL, Vesely SK, Cataland SR, et al. ISTH guidelines for treatment of thrombotic thrombocytopenic purpura. *J Thromb Haemost*. 2020;(jth.15010). doi:10.1111/jth.15010

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