ISTH GUIDELINES RECOMMEND CABLIVI*

SEE
START
SUPPORT

SEE aTTP†—Diagnosis determined through clinical assessment

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

SUPPORT WITH ADAMTS13—ADAMTS13 test results inform treatment decisions

ISTH TTP Guidelines are the first evidence-based, international guidelines on the diagnosis, treatment, and management of aTTP[1,2]

Treatment recommendations have evolved to include PEX, immunosuppressive therapy, **and CABLIVI**

Initiation of CABLIVI is recommended for **acute aTTP events** (initial and relapsing)

Starting CABLIVI early is believed to have the greatest benefit in the early phase of acute aTTP events (initial or relapsing)

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

*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.

Please see Important Safety Information throughout and Full Prescribing Information.

aTTP=acquired thrombotic thrombocytopenic purpura; ISTH=International Society on Thrombosis and Haemostasis; iTTP=immune thrombotic thrombocytopenic purpura; PEX=plasma exchange; TTP=thrombotic thrombocytopenic purpura.

Cablivi®
caplacizumab-yhdp
Injection 11 mg

ISTH GUIDELINES

RECOMMEND CABLIVI*

See aTTP—Diagnosis determined through clinical assessment[1]

aTTP is a life-threatening blood disorder with considerable morbidity and mortality in the acute phase

Diagnose aTTP through clinical assessment or risk assessment tools prior to ADAMTS13 testing

Clinical assessment†

- Thrombocytopenia (<150 × 10^9/L)
- Evidence of microangiopathic hemolytic anemia
  - –Hb and hematocrit below reference range
  - –Low haptoglobin
  - –Elevated LDH
  - –Presence of schistocytes in peripheral blood smear
- 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

Identifying aTTP is crucial for initiation of an appropriate therapeutic strategy

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†List includes laboratory tests and results only; exclusive of physical symptoms, such as petechiae.

‡ISTH did not appraise the evidence of these 2 tools.

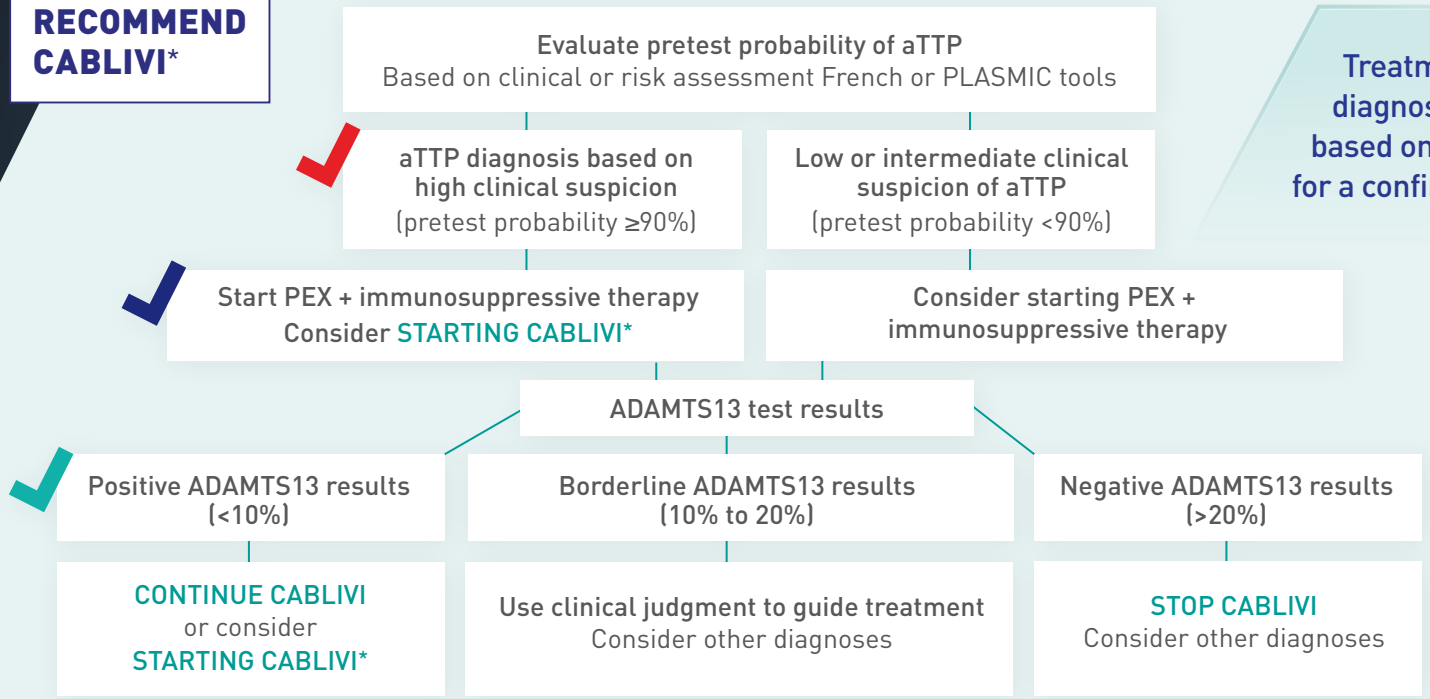
Hb=hemoglobin; LDH=lactate dehydrogenase.

ISTH GUIDELINES

RECOMMEND CABLIVI*

Start CABLIVI*—Consider early administration of CABLIVI in combination with PEX and immunosuppressive therapy[1]

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



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

Adapted from ISTH Guidelines for Diagnosis of TTP.

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IMPORTANT SAFETY INFORMATION (cont'd)

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.

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RECOMMEND CABLIVI*

Support with ADAMTS13—ADAMTS13 test results inform treatment decisions[1]

Timely access to ADAMTS13 results is key to providing optimal care for patients with aTTP

Select US labs testing ADAMTS13 activity, inhibitors, and antibodies

ARUP Labs	800-522-2787
LabCorp	800-334-5161
Machaon Diagnostics	800-566-3462
Mayo Clinic Laboratories	800-533-1710
Quest Diagnostics	866-697-8378
Versiti	800-245-3117 x6250

These listings do not constitute an endorsement by Sanofi and are not included in the ISTH Guidelines. The following is a selection of national laboratories offering ADAMTS13 tests activity, inhibitor, and antibody testing. This is not an exhaustive list of labs that offer one or more of these tests or an endorsement of any lab. Other testing options may be available, including at local or regional laboratories. Content is current as of July 2020, and tests may not be available in all states. Please call laboratory to confirm test availability, sample shipping information, and all other logistics.

Prescribe CABLIVI—the first and only FDA-approved, guideline-recommended therapy for aTTP in combination with PEX and immunosuppressive therapy

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IMPORTANT SAFETY INFORMATION (cont'd)

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.

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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MAT-US-2009642-v3.0-03/2022

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