The first and only FDA-approved therapy for adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy[1]

HOSPITAL GUIDE FOR CABLIVI

From Inpatient to Home Administration

This guide is intended to highlight key information related to procurement of, and patient access to, CABLIVI. This overview informs various stakeholders involved in the care of patients receiving CABLIVI beginning with treatment initiation in the hospital to self-administration at home upon discharge.

INDICATIONS AND SELECTED IMPORTANT SAFETY INFORMATION

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.

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 additional Important Safety Information on page 6, and accompanying Full Prescribing Information.

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caplacizumab-yhdp
Injection 11 mg

Ensuring Patient Access to CABLIVI

aTTP is a medical emergency warranting rapid diagnosis and treatment.[2,3] Treatment with CABLIVI is initiated in combination with plasma exchange and immunosuppressive therapy when appropriate.[1]

CABLIVI adminstration occurs in two phases:

First dose given upon the initiation of plasma exchange

Continue therapy outpatient after discharge from the hospital

ACCESS SUPPORT:

We're With You From the Start

CABLIVI Patient Solutions provides support for your patients as they transition from hospital to home.

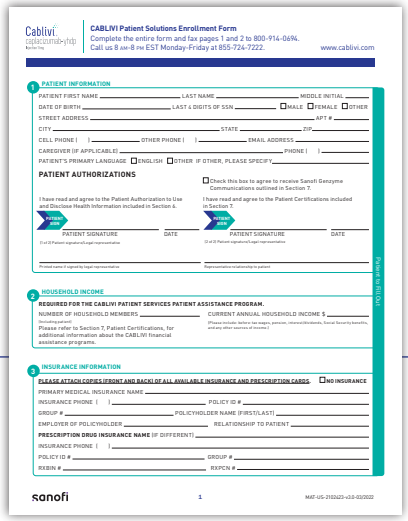
CABLIVI Patient Enrollment Form

You and your patient should complete the CABLIVI Patient Enrollment Form as soon as treatment is initiated to be eligible to receive support services upon discharge.

When completing the form, note that there are 2 pages that need to be completed and faxed to 1-800-914-0694.

- Note that patients need to opt in in order for their enrollment to be processed
  - Patients should read sections 6 & 7 of the CABLIVI Patient Enrollment Form carefully, and then sign where applicable in section 1.
- In Section 1, patients have the ability to opt-in to receive relevant Sanofi communications (not required).

The form can be downloaded from **www.CabliviHCP.com**.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CABLIVI Patient Solutions Enrollment Form
Complete the entire form and fax pages 1 and 2 to 800-914-0694.
Call us 8 AM–8 PM EST Monday–Friday at 855-724-7222.
www.cablivi.com

1 PATIENT INFORMATION
PATIENT FIRST NAME ____ LAST NAME ____ MIDDLE INITIAL ____
DATE OF BIRTH ____ LAST 4 DIGITS OF SSN ____ ☐MALE ☐FEMALE ☐OTHER
STREET ADDRESS ____ APT # ____
CITY ____ STATE ____ ZIP ____
CELL PHONE ( ) ____ OTHER PHONE ( ) ____ EMAIL ADDRESS ____
CAREGIVER (IF APPLICABLE) ____ PHONE ( ) ____
PATIENT'S PRIMARY LANGUAGE ☐ENGLISH ☐OTHER IF OTHER, PLEASE SPECIFY ____

PATIENT AUTHORIZATIONS

I have read and agree to the Patient Authorization to Use and Disclose Health Information included in Section 6.
PATIENT SIGNATURE ____ DATE ____
(1 of 2) Patient signature/Legal representative
Printed name if signed by legal representative

☐Check this box to agree to receive Sanofi Genzyme Communications outlined in Section 7.
I have read and agree to the Patient Certifications included in Section 7.
PATIENT SIGNATURE ____ DATE ____
(2 of 2) Patient signature/Legal representative
Representative relationship to patient

2 HOUSEHOLD INCOME
REQUIRED FOR THE CABLIVI PATIENT SERVICES PATIENT ASSISTANCE PROGRAM.
NUMBER OF HOUSEHOLD MEMBERS ____ CURRENT ANNUAL HOUSEHOLD INCOME $ ____
Please refer to Section 7, Patient Certifications, for additional information about the CABLIVI financial assistance programs.
[Please include: before-tax wages, pension, interest/dividends, Social Security benefits, and any other sources of income.]

3 INSURANCE INFORMATION
PLEASE ATTACH COPIES (FRONT AND BACK) OF ALL AVAILABLE INSURANCE AND PRESCRIPTION CARDS. ☐NO INSURANCE
PRIMARY MEDICAL INSURANCE NAME ____
INSURANCE PHONE ( ) ____ POLICY ID # ____
GROUP # ____ POLICYHOLDER NAME (FIRST/LAST) ____
EMPLOYER OF POLICYHOLDER ____ RELATIONSHIP TO PATIENT ____
PRESCRIPTION DRUG INSURANCE NAME (IF DIFFERENT) ____
INSURANCE PHONE ( ) ____
POLICY ID # ____ GROUP # ____
RXBIN # ____ RXPCN # ____

Please fill in BLOCK

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The preferred, most-efficient way to submit is by faxing a completed enrollment form (which includes Rx) to **1-800-914-0694**. If fax is not an option, call **1-855-724-7222** for additional information.

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Cablivi Patient Solutions supports patients by offering the following services:

1. Financial support for eligible patients

Sanofi offers financial assistance to cover the cost of CABLIVI co-pay or co-insurance for your qualified, commercially insured patients up to the program maximum amount.* CABLIVI can be provided at no cost to eligible underinsured or uninsured patients.†

2. Benefits verification

A summary of benefits is faxed to the healthcare provider. This may include information such as:

- Insurance coverage for CABLIVI
- Determination of patient's out-of-pocket costs, including deductibles, co-insurance, and/or co-pays
- Eligibility for Cablivi Patient Solutions financial assistance
- Identify the need for prior authorization

3. Supplemental training

Clinical educators are available to provide additional support in the home after hospital discharge. They can provide additional education on how to self-administer CABLIVI, support patients in setting up a plan for administering therapy, and answer questions about CABLIVI.‡

4. Post-discharge follow-up and support

- Call from Therapeutic Education Manager on days 7 and 14‡

If a prior authorization is required, the insurer may need additional information from the patient's physician such as:

- Confirmatory diagnosis with ADAMTS13[3]
- Explanation of medical necessity
- Response to therapy
- Medical literature including guidelines
- CABLIVI prescribing information
- Chart notes

If denied:

Consider pursuing an appeal if the prior authorization is denied

*Cablivi's co-pay/co-insurance program is not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, VA, DoD, Tricare, or similar federal or state programs including any state pharmaceutical assistance programs and is not valid where prohibited by law. Sanofi retains the right to modify or terminate the program at any time without notice. Savings may vary depending on patients' out-of-pocket costs and participants will receive all program details upon registration. Additional terms and conditions apply.

†Approval is not guaranteed.

‡Cablivi Clinical Educators and Therapeutic Education Managers are paid to provide educational services by Sanofi and do not provide medical advice. Patients should always consult their doctor with any questions or concerns regarding their medical condition or healthcare needs.

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

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.

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DISCHARGE AND BEYOND:

Services Provided by CABLIVI Patient Solutions for Discharge/At-home Use

To ensure patient access throughout the home administration phase of treatment, CABLIVI Patient Solutions offers fulfillment and other support services. Sanofi has made CABLIVI available through one specialty pharmacy (SP) for home delivery of the additional outpatient doses. CABLIVI will be shipped directly to the patient's home by Biologics SP for patient self-administration beginning at discharge.

Biologics SP Support for Patients

Cablivi is available exclusively through Biologics Specialty Pharmacy. The pharmacy team will verify insurance coverage and provide 24/7 access to a clinical pharmacist.

What patients can expect:

- CABLIVI Patient Solutions Case Manager will communicate with the hospital to discuss patient discharge
- Biologics Specialty Pharmacy facilitates prior authorization, where appropriate
- Biologics Specialty Pharmacy team member will call the patient to schedule home delivery and refill shipments
- CABLIVI Patient Solutions Case Manager is available to assist you and your patient with other program benefits

CABLIVI treatment should continue for 30 days following the last daily plasma exchange. If, after the initial treatment course, sign(s) of persistent underlying disease such as suppressed ADAMTS13 activity levels remain present, treatment may be extended for a maximum of 28 days.[1]

SELECTED 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.

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.

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HOSPITAL PROCUREMENT:

CABLIVI Pharmacy Ordering Information

CABLIVI is available through a network of authorized specialty distributors for hospital acquisition. It is up to your institution to determine the procurement option that works best for your practice or facility.

Authorized Specialty Distributors (SDs) for Hospital Inpatient Acquisition			
Cardinal SPD	**ASD**	**McKesson SD**	**BioCare SD**
1-855-855-0708	1-800-746-6273	1-877-625-2566	1-800-304-3064

Given the unpredictable nature of aTTP, a consignment model may be a consideration for some hospitals to manage inventory and reduce carrying costs. Your institution can arrange for a consignment agreement with these specialty distributors (listed above) if there is not one already in place.

How Supplied/Storage and Handling[1]

How product is supplied	1 carton containing: - 1 single-dose vial containing 11 mg of CABLIVI - 1 mL Sterile Water for Injection, USP, prefilled glass syringe [diluent for CABLIVI] - 1 sterile vial adapter - 1 sterile hypodermic needle [30 gauge] - 2 individually packed alcohol swabs
Storage	• Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton • Do not freeze • Unopened vials may be stored in the original carton at room temperature up to 30°C (86°F) for up to 2 months • Do not return CABLIVI to the refrigerator after it has been stored at room temperature
NDC	• NDC 58468-0225-1
Dimensions	**Length:** 6.42 in • **Width:** 4.02 in • **Height:** 1.50 in • **Weight:** 0.22 lb

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Please see accompanying Full Prescribing Information.

References: 1. CABLIVI (caplacizumab-yhdp) [prescribing information]. Cambridge, MA: Genzyme Corporation. **2.** Joly BS, Coppo P, Veyradier A. Thrombotic thrombocytopenic purpura. *Blood*. 2017;129(21):2836-2846. **3.** Scully M, Hunt BJ, Benjamin S, et al; for British Committee for Standards in Haematology. Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies. *Br J Haematol*. 2012;158(3):323-335. **4.** Centers for Medicare & Medicaid Services. Glossary. https://www.cms.gov/glossary?term=fiscal+year&items_per_page=10&viewmode=grid. Accessed February 11, 2021. **5.** Centers for Medicare & Medicaid Services. *Federal Register*. Department of Health and Human Services. 42 CFR Parts 405, 3312, 313, 417, 476, 480,484, and 495. Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long- Term Care Hospital Prospective Payment System and Final Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access. 2020;85(182):58432-59107. **6.** Centers for Medicare & Medicaid Services. FY 2021 IPPS Final Rule Home Page. https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipps-final-rule-home-page. Accessed February 11, 2021.

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Reminders when filling out CABLIVI Patient Enrollment Forms:

Make sure all applicable fields are complete and accurate

Be sure to sign the form

Fax the completed form to
1-800-914-0694

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