



# CABLIVI Playbook

## Product Adoption Journey

SANOFI GENZYME 

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

MAT-US-2107812-v1.0-09/2021



# Introduction

---

- **The overarching goal of our CABLIVI ABM team is to provide education to HCPs about aTTP and CABLIVI so they can make informed decisions about their patient’s care and are comfortable using our product.**
- **The purpose of this training is to “walk” you through different types of educational interactions with HCPs:**
  1. Raising aTTP Awareness
  2. Educating on CABLIVI
  3. CABLIVI Access
  4. CABLIVI Acquisition
  5. Educating on the Patient Enrollment Process & Patient Support Services
  6. Patient Discharged from Hospital
  7. CABLIVI Treatment at Home
- **Stages 1-5 will be the focus of this playbook. You will find "tips" and reminders on what happens in each stage to contribute to a seamless fulfillment experience with CABLIVI**

**Important Note:** ABMs have no role in stage 6 or 7 unless requested by appropriate action owner.

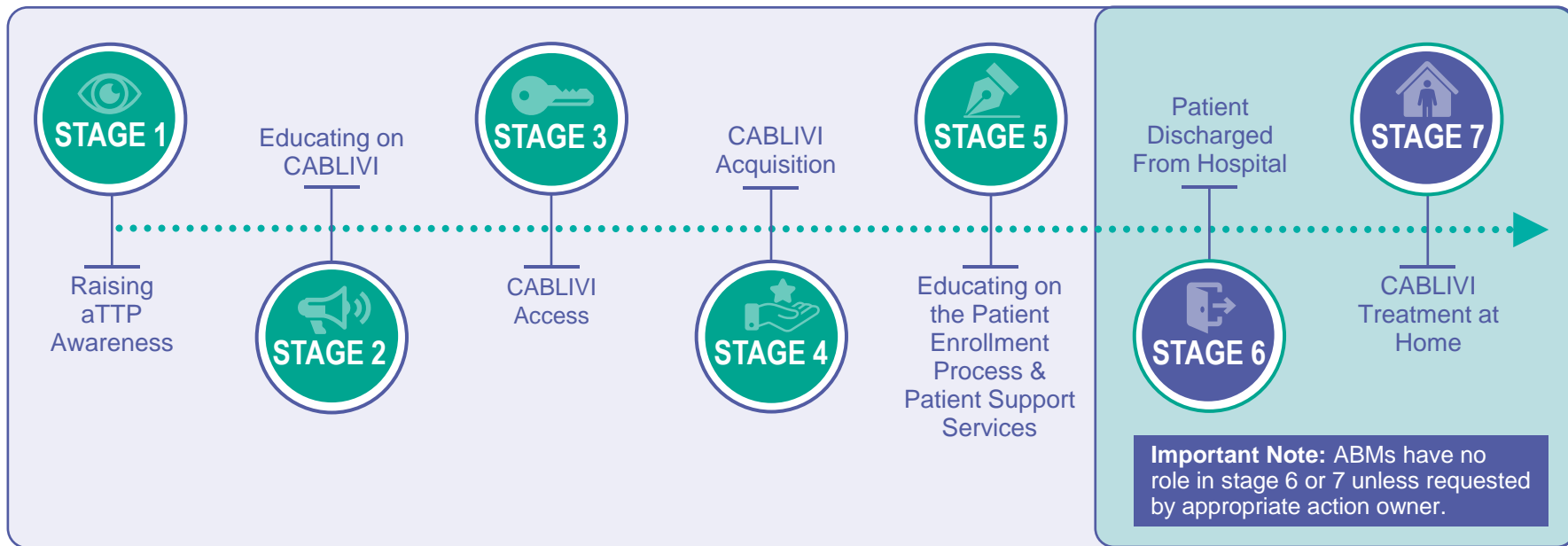


# Important Information

---

- **These materials may be used only to provide essential learning and information to Sanofi Genzyme personnel**
- **Any use of these materials (including excerpts) beyond training purposes is strictly prohibited**
- **The information may not be used to generate material or messaging that will be used externally without further review in accordance with our review processes**
- **You may only use materials PRB-approved for external use when speaking with customers**

# Product Adoption Journey



 **COMPLIANCE**

# Compliance

HOME

Disease  
Awareness  
Materials

CABLIVI  
Branded  
Materials

ISTH Guidelines

Health Care  
Economic  
Information (HCEI)

CABLIVI Patient  
Solutions

**During a disease awareness interaction, you may:**

- Discuss a disease or health condition and/or disease management;
- Encourage awareness of signs of the disease or health condition; or

**Do NOT mention or suggest any drug, and do not include any representation or suggestion relating to a particular drug**

**Reminder: Unbranded messages should not be combined with messages about CABLIVI unless included in a PRB-approved document.**

Disease Awareness  
Material Example



HCP Disease Awareness  
Brochure  
(MAT-US-2019998)

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

# Compliance

HOME

Disease Awareness Materials

CABLIVI Branded Materials

ISTH Guidelines

Health Care Economic Information (HCEI)

CABLIVI Patient Solutions

Provide approved messaging and information to support customer interactions.

**Important Note:** During any product discussion, you are required to provide the appropriate fair balance/Important Safety Information (ISI) for CABLIVI.

## CABLIVI Branded Material Example

In the fight against aTTP,  
**A STRONG START CAN MAKE A DIFFERENCE**

ISTH GUIDELINES RECOMMEND CABLIVI\*

aTTP diagnosed → HOME  
CABLIVI + PEX + Immunosuppression

Purpura • Thrombocytopenia • Organ involvement MAHA

The first and only FDA-approved therapy for adults with aTTP in combination with PEX and immunosuppressive therapy<sup>12</sup>

\*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. In de novo patients where no reasonable access to ADAMTS13 activity testing is available, the Guidelines do not recommend CABLIVI, however, treatment of a patient previously diagnosed with aTTP could be safely undertaken on clinical grounds without the need for a confirmatory ADAMTS13 test.<sup>12</sup>

**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 anaphylaxis.

**Please see Important Safety Information and full Prescribing Information.**

aTTP=acquired thrombotic thrombocytopenic purpura; ISTH=International Society on Thrombosis and Haemostasis; MAHA=microangiopathic hemolytic anemia; PEX=plasma exchange.

Cablivi.  
caplacizumab-yhdp  
Injection

CABLIVI Core Visual Aid  
MAT-US-2101322-v1.0-03/2021

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

# Compliance



Disease Awareness Materials

CABLIVI Branded Materials

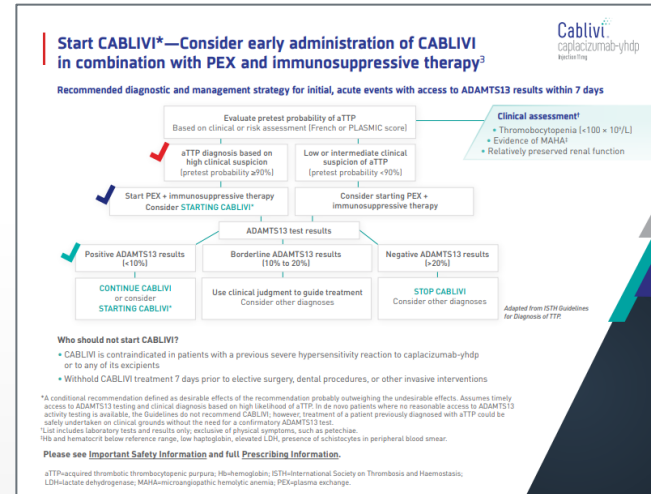
ISTH Guidelines

Health Care Economic Information (HCEI)

CABLIVI Patient Solutions

## ISTH Guideline Example

- ISTH (International Society for Thrombosis and Haemostasis) published guidelines for the diagnosis and treatment of TTP in August of 2020
- The recommendations for the use of CABLIVI are conditional recommendations
- For conditional recommendations, the Panel believes that the desirable effects of following the recommendation probably outweigh 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 (immune-mediated TTP)
- Be sure to review Who should NOT START CABLIVI with customers
- Remember to review important efficacy and safety information with customers



CABLIVI Core Visual Aid  
MAT-US-2101322-v1.0-03/2021

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

Disease Awareness Materials

CABLIVI Branded Materials

ISTH Guidelines

Health Care Economic Information (HCEI)

CABLIVI Patient Solutions

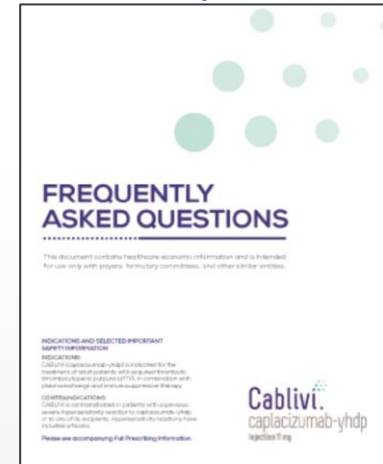
Some of our materials contain health care economic information that is approved for use with payers, formulary committees and other, similar entities who have knowledge and expertise in the area of health care economic analysis carrying out their responsibilities for the selection of drugs for coverage and reimbursement. Materials that contain HCEI are not appropriate for use with a general HCP audience with no P&T responsibilities.

### Important Reminder:

The Economic Backgrounder and the Frequently Asked Questions Brochure have been approved for use by ABMs in detailing customers who are treating physicians or other HCPs who independently are also a hospital formulary decision maker, and you are speaking to them in that capacity. An HCP attestation form must be completed before engaging in a discussion. Please reach out to your manager for this document.

When speaking with a customer, you should never use the difference between the cost of CABLIVI and the customer's reimbursement as a reason for the customer to purchase and prescribe CABLIVI. This is sometimes referred to as "marketing the spread" and is prohibited.

### Health Care Economic Information (HCEI) Material Example



Frequently Asked Questions  
MAT-US-2023916-v1.0-01/2021



Disease Awareness Materials

CABLIVI Branded Materials

ISTH Guidelines

Health Care Economic Information (HCEI)

CABLIVI Patient Solutions

**Important Reminder:** The services offered through CABLIVI PATIENT SOLUTIONS should not be used as a selling tool. Do not make promises of support for specific patients as there are eligibility requirements that will need to be assessed (eg, “You can be assured that Sanofi will pick up the patient’s copay once he is discharged because we cover all co-pays”).

## CABLIVI Patient Solutions Example

**Transition from hospital to home with CABLIVI**

Financial and educational assistance with  
**CABLIVI PATIENT SOLUTIONS**

**SPECIALTY PHARMACY SERVICES**

- For patients who obtain their medication through Biologics by McKesson:
- The specialty pharmacy coordinates direct-to-home shipment of CABLIVI for a seamless transition upon discharge
- Nurses are available to provide ongoing support and answer questions about CABLIVI
- Pharmacists are available 24 hours a day, 7 days a week
- CABLIVI Patient Solutions help is available Monday through Friday, 8:00 AM to 8:00 PM ET

**FINANCIAL ASSISTANCE**

- Support is available to cover the cost of CABLIVI co-pay or co-insurance up to \$25,000 for qualified, commercially insured patients\*
- CABLIVI will be provided at no cost to eligible underinsured or uninsured patients<sup>1</sup>

**SUPPLEMENTAL TRAINING**

- Clinical educators<sup>2</sup> are available to provide:
- Supplemental education on how to self-administer CABLIVI
- Support in setting up a plan for administering therapy
- Additional at-home support after hospital discharge
- Answers to questions about CABLIVI

\*Not valid for CABLIVI 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. Not valid where prohibited by law. Savings may vary depending on patients' out-of-pocket costs. Upon registration, patient will receive all program details.  
<sup>1</sup>Approval is not guaranteed. Sanofi Genzyme reserves the right to modify or discontinue the programs at any time.  
<sup>2</sup>CABLIVI clinical educators are paid to provide educational services. They don't provide medical advice. Patients should always consult

**Please see [Important Safety Information](#) and full [Prescribing Information](#).**

DoD=Department of Defense; VA=Veterans Affairs.

CABLIVI Core Visual Aid

MAT-US-2101322-v1.0-03/2021



STAGE 1

# Raising aTTP Awareness

[+ HOME](#)

**Who** is involved in this stage?

- Hematologist/Oncologist (Hem/Onc)
- Nephrologist
- Emergency Medicine Physician
- Transfusion Medicine Specialist / Apheresis/Blood Bank Manager/Nurse
- Internist
- Hospitalist
- Critical Care Specialist
- Pathologist
- Pharmacist
- Clinical Pharmacist
- Patient Navigator / Case Manager / Charge Nurse
- Discharge Nurse
- Purchasing / Procurement
- Hospital Administration

**What** happens in this stage?

**Why** is this stage so important?

Tips to **Remember**

**What** questions or objections may arise?

HCPs can be found in various locations within a hospital



[+ KEY STAKEHOLDERS](#)

[+ aTTP CONSIDERATIONS](#)

[+ IDN](#)

Select each button to learn more

# aTTP Considerations



**Hematologist/Oncologist:** The specialist who will be responsible for overall care of patients with blood disorders including aTTP. While the patient is in the ICU, their role will likely be limited to consultation, but once the patient is released to a unit/floor, or discharged, they will become the point-of-care for that patient. The hematologist will also likely be the HCP responsible for a lot of patient communication.

**Nephrologist:** A specialist who will be consulted in the event the patient with aTTP experiences loss of renal function. They may also run apheresis

**Emergency Medicine Physicians:** HCPs who will typically be the first in the hospital to assess the patient presenting with aTTP. They will be responsible for performing a workup on the patient and gathering the clinical symptoms to see who would need to be consulted based on symptomology and transferring the patient to either the ICU or floor as needed.

**Transfusion Medicine Specialist / Apheresis/Blood Bank Manager/Nurse:** HCPs and support staff responsible for acute care of aTTP patients with blood/plasma transfusion needs. Acute care is challenging to fit into schedules that often include donor and patient services, so careful planning of PEX is important.



# aTTP Considerations



**Internist:** (PCP) Post-discharge, the PCP may be responsible for general care of the patient with aTTP and may be in the best position to monitor for signs of recurrence. In addition, the Hematologist/Oncologist may monitor the patient for the first six months post-discharge.

**Hospitalist:** An HCP who may manage patients with aTTP in either the general hospital setting, or the ICU, depending on the staffing structure at any hospital.

**Critical Care Specialist:** An ICU-based physician, who is most typically responsible for treatment decisions for a patient with aTTP in acute care. They will usually follow hospital-approved goals and measures for managing patients with aTTP in the ICU, in conjunction with the ICU team and relevant consultant specialists.


**Pathologist:** A specialist who will be working with the care team to determine the cause of symptoms and differentially diagnose aTTP. In some hospitals, the pathologist may be part of the PEX team (which is part of the Transfusion Medicine department) and influence hematologists prescribing decisions.

**Purchasing / Procurement / Hospital Administration:** Functions that may be important for accessing institutions and key stakeholders. It is important to understand credentialing requirements and rules around educational and promotional activities within an institution.

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

# Hematologist or Hematologist / Oncologist (Hem/Onc)

---

- Hematologists and Hem/Oncs are medical doctors who specialize in the diagnosis and treatment of diseases of the blood and blood system, such as anemia, blood-clotting disorders, and leukemia. These physicians may also order blood transfusions, diagnose blood disorders, and perform procedures such as bone marrow aspiration and biopsy
  - Hematologists may be internists or pathologists who further specialize in disorders of the blood. Hematologists can be board-certified in hematology through the Board of Internal Medicine or the American Board of Pathology, which are recognized by the American Board of Medical Specialties
  - Hem/Oncs complete training in hematology and additional training in medical oncology and are trained to diagnose and treat cancerous blood disorders and cancers. These physicians are double-boarded in hematology and medical oncology
- 

# Hospitalist

---



Hospitalists are medical doctors who specialize in hospital care, providing treatment in place of a primary care physician. They usually are general internists, family medicine doctors, pulmonologists, or other specialists.



# Emergency Medicine Physician



- Emergency medicine specialists, commonly called ER doctors, are medical doctors who specialize in emergency care. They can diagnose and treat many medical emergencies and can refer people to other health professionals for further treatment
- Emergency medicine specialists may further specialize in one area of medicine, such as sports medicine
- Emergency medicine doctors can be board-certified through the Board of Emergency Medicine, which is recognized by the American Board of Medical Specialties

# Internist



- An internist is a medical doctor who specializes in the care of adults. People might choose an internist as their primary doctor for regular checkups and treating illnesses
- Internists can further specialize in areas such as:
  - Allergy or immunology (immune system diseases)
  - Cardiology (diseases and conditions of the heart and blood vessels)
  - Endocrinology (diseases of the endocrine glands, which regulate hormones)
  - Gastroenterology (diseases of the digestive system)
  - Geriatric medicine (conditions and diseases in older adults)
  - Hematology (diseases of the blood and blood system)
  - Infectious disease (complex infections)
  - Nephrology (diseases of the kidney and urinary system)
  - Oncology (cancer)
  - Pulmonology (lung diseases such as asthma, emphysema, and pneumonia)
  - Rheumatology (immune system diseases and diseases of the joints)
  - Sports medicine (the treatment of injuries to the bones, muscles, joints, tendons, or ligaments that result from physical activity)
- Internists can be board-certified by the American Board of Internal Medicine, which is recognized by the American Board of Medical Specialties



# Nephrologist



- Nephrologists are medical doctors who specialize in the diagnosis and treatment of diseases of the kidneys, such as inflammation of the kidneys, chronic kidney disease, or cancer
- Nephrologists may further specialize in treating certain age groups. Nephrologists may consult with people for short-term illnesses or procedures, such as for a kidney biopsy. Or they may care for people who have long-term (chronic) kidney problems or who are on dialysis
- Nephrologists can be board-certified in nephrology through the American Board of Internal Medicine, which is recognized by the American Board of Medical Specialties

# Pathologist



- Pathologists are medical doctors who specialize in the examination of tissue and blood samples to diagnose disease and who perform autopsies
- Pathologists analyze and evaluate all tissues removed from people by such procedures as surgery or biopsy. They are also in charge of the clinical laboratories that analyze blood and body fluid samples. For example, when a person has a mole removed or has a Pap test, a pathologist examines the specimen to determine the diagnosis. Pathologists would be the ones looking for schistocytes on a blood smear
- Treatment decisions are often made based on the pathology report
- Pathologists can be board-certified in a number of subspecialties through the American Board of Pathology, which is recognized by the American Board of Medical Specialties

# Pharmacist



- Pharmacists are licensed health professionals who prepare, dispense, and provide advice about both prescription and nonprescription medicines. They are specialists in mechanism of action, indications, use, dosage, side effects, and interaction with other substances. They help ensure the safe use of medicines in people of all ages
- While a pharmacist may hold a bachelor's, master's, or doctorate degree in pharmacy, today, entry level practicing pharmacists all have a PharmD (doctorate degree in pharmacy). The Department of Pharmacy may have the following positions: Director of Pharmacy, Clinical Pharmacist, Pharmacy Clinical Coordinator, Pharmacy Buyer, etc. Inquiring about the hospitals' Pharmacy Residency Program is a great way to find those individuals who may benefit from education on CABLIVI
- A pharmacist provides integrated pharmacy operational services including:
  - Pharmaceutical services throughout medical center
  - Participates in pharmacy operations and medication dispensing
  - Responsible for managing the hospital's formulary (Director of Pharmacy)

# Clinical Pharmacist



- A clinical pharmacist will have a PharmD and will also have completed a residency in a specific area, such as hematology and are integral in the disease state management of patients
- Clinical pharmacists are involved with the care of patients at all phases of their treatment; from assessment to treatment decisions, medication management, symptom management and supportive care
- A clinical pharmacist provides direct patient-centered care in partnership with physicians, nurses, and other hospital personnel. Duties and responsibilities include:
  - Leads assigned patient service lines, clinical areas, and therapeutic programs
  - Delivers direct patient care and clinical practice
  - Medications management
  - Facilitates experiential education and practice advancement

# Patient Navigator / Case Manager / Charge Nurse

---

- A nurse/patient navigator acts as the conduit between the patient and clinical care staff. They help navigate the patient through the treatment process by connecting them to resources and information to make informed decisions
- Nurse navigators help their patients throughout the treatment process. Below are some of the roles nurse navigators perform:
  - **Education:** One of the primary roles of a nurse navigator is to provide expert information to patients
  - **Monitors symptoms:** As a middleman between the patient and care team, the navigator records a patient's symptoms
  - **Provides clinical resources:** The navigator helps equip their patient with information about other clinical options that may not be available locally
  - **Community resources:** This benefit connects patients to community resources
- Nurse navigators typically have a Bachelor of Science in Nursing (BSN) or Associate Degree in Nursing (ADN) as well as a registered nursing license
- Typically, these navigators are the individuals who oversee the completion of the patient enrollment form and may benefit from education on CABLIVI patient services

# Critical Care Specialist



- Critical care medicine specialists (also called intensivists) are medical doctors who specialize in the care of people who are in an intensive care unit (ICU)
- In some areas, when a person is very ill and has to spend time in an ICU, he or she is cared for by a critical care medicine specialist. After the person is transferred out of the ICU to a regular hospital unit, another doctor or health professional assumes care
- Most critical care specialists are pulmonologists (specializing in lung disease), cardiologists (specializing in heart disease), or neurologists (specializing in brain and nerve diseases). Critical care specialists may also first specialize in another area of medicine (such as anesthesiology, internal medicine, or pediatrics) and then hold a subspecialist certificate in critical care medicine
- Critical care medicine specialists can be board-certified through one of the Boards recognized by the American Board of Medical Specialties (such as the American Board of Internal Medicine)

# Discharge Nurse



- Registered nurses (RNs) provide treatment, counseling, and health education. They provide assessment, plan and implement care, and evaluate outcomes
- Nurses work as part of a health care team in a variety of environments, often under the supervision of a doctor. Most nurses work in hospitals. Others work in settings such as community or public health, outpatient care, nursing education, occupational health, nursing home agencies, hospice programs, schools, and student health clinics
- A registered nurse (RN) may hold either a bachelor of science in nursing (BSN) from a 4-year university or an associate degree in nursing (ADN) from a 2-year college. All graduates must successfully pass the Registered Nurse Licensing Examination to become licensed to practice as a professional RN. Graduation from a state-accredited program is a prerequisite to taking the licensing examination. A registered nurse must hold a current license in the state in which he or she practices. Licensing requirements are managed by individual state boards of nursing
- A discharge planning nurse is a RN who may not have been working directly with the patient during their stay at the hospital. Therefore, this nurse must work closely with the patient's doctors and nurses to ensure that there is a plan for discharge and that everyone involved knows what they are. They must also discuss these plans with family members of the patient, especially if they have some role to play regarding the patient's further healing. Essentially, the discharge planning nurse serves as a connection between in-patient care and follow-up or out-patient care. They help to make sure that the patient and their family understand exactly what to do after discharge to prevent injury and encourage healing. They are a crucial part of proper patient care

# Transfusion Medicine Specialist / Apheresis/ Blood Bank Manager/Nurse



- The role of the clinical nurse is to provide personalized, humanistic, and comprehensive nursing care to plasmapheresis patients
- In clinical practice, the plasmapheresis nurse has to be an effective practitioner able to establish and maintain high quality evidence-based nursing services and to work with the multidisciplinary team to ensure that patients receiving plasma exchange have access to specialist care, knowledge and expertise
- The apheresis nurse ensures that patients understand their disease, treatment options and support services in conjunction with the responsible doctors (Hematologists, Nephrologists or others) and provide effective coordination for patients undergoing plasma exchange within the hospital
- The apheresis nurse in the plasma exchange procedure facilitates effective communication between the multidisciplinary team and the patients and their families. The goal to ensure the patient and the families understand the treatment and answer any of their concerns
- The Apheresis clinic/staff may be a part of the Transfusion Medicine department or sometimes it could be part of the blood banking department
- Apheresis may be provided through a mobile apheresis company, like the Red Cross, Davita, Vitalent, Community Blood Centers, and these companies are outside of the hospital. However, training can be offered to their apheresis nurses, and they are great resources of information for hospitals where aTTP is seen

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.





# Integrated Delivery Networks



- Sometimes called organized providers, integrated health systems, and corporatized providers, Integrated Delivery Networks (IDNs) are health systems in which providers are affiliated with a parent company. IDNs consist of medical groups, facilities, labs, and one or more acute care hospitals and associated outpatient facilities, and provide a continuum of care including different disease states
- Some familiar IDNs include The Mayo Clinic, The Cleveland Clinic, Partners Healthcare, Memorial Sloan Kettering Cancer Center, and HCA. There are approximately 1000 IDNs in the US
- Providers and/or facilities that are not affiliated with an IDN or PN are said to be independent

Integrated Delivery Network (IDN)



# Integrated Delivery Networks



## “If you have seen one IDN, you have seen one IDN”

- A small number of IDNs operate nationally
- The majority operate regionally or, in some cases, locally
- The three largest IDNs—Hospital Corporation of America, CommonSpirit Health, and the Department of Veterans Affairs—may include hundreds of hospitals each
- Smaller, regional IDNs may have just several dozen hospitals, and local IDNs have even fewer
- Some are groups of hospitals, others cover the entire continuum of care
- Some are integrated more or less in name only, such as when a hospital buys a neighboring facility or two, but just uses them for referrals, with little effort at integrating clinical or back-office operations
- Other IDNs are truly, fully integrated, including patient care protocols, human resources, and finance

# Integrated Delivery Networks

## Taking a Different Strategic Approach...



- One of the most dramatic differences with IDNs is a movement towards a more centralized decision-making process
- One estimate finds as many as 80% of IDNs with policies and practices that are applied at the individual entity level were often drafted at the ownership level rather than at the operational level
- Other IDNs impose corporate decisions and mandates systemwide. That means buying decisions are being moved away from physicians and replaced with administrators, where institutional objectives are increasingly at the top of the agenda
- This paradigm change also means that business considerations may carry as much weight in IDN purchasing decisions as do clinical considerations. As a result, decisions on purchasing medications may move away from physicians with a potential emphasis on administrator opinions
- If you become aware that drug usage and selection at an institution is dependent on an IDN decision, you may want to start with an IDN Pharmacy Stakeholder to gain a better understanding of this dynamic



**IDN PHARMACY  
STAKEHOLDER**

*Select to learn more*

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

# Integrated Delivery Networks



As part of the centralized decision-making process, keep in mind that the Pharmacy Director position in an IDN may go by many titles such as the following:

- System Director of Clinical Pharmacy Services, Pharmacy Operations and Clinical Services
- Director, Pharmacy Strategic Sourcing
- Clinical Pharmacy Manager
- Regional Manager, Clinical Pharmacy Services
- SVP Chief Pharmacy Officer
- Division Director, Clinical Pharmacy Services



**Note:** It is important for you to be aware of the IDN affiliations of your accounts and the level of involvement they have in local decisions; however, you should have a discussion with your manager before contacting individuals at the IDN level because your actions can have impact on the broader business for Sanofi.

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.



STAGE 1

# Raising aTTP Awareness



## Who is involved in this stage?

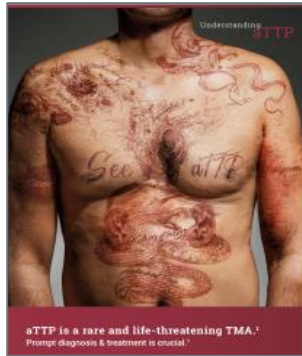
## What happens in this stage?

## Why is this stage so important?

## Tips to Remember

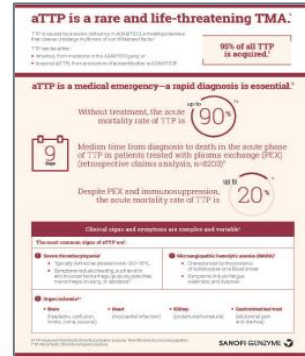
## What questions or objections may arise?

This is an excellent opportunity for you, the ABM, to raise the awareness surrounding the impact of aTTP on patients, clinical signs and symptoms of aTTP, and the importance of early diagnosis. Here are the key materials for disease awareness.



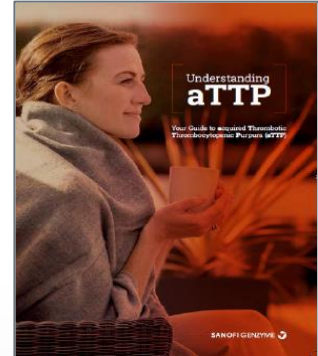
HCP Disease Awareness Brochure  
SAUS.CAPL.18.12.7262

This resource outlines patient demographics as well as pathophysiology and clinical signs and symptoms of aTTP and can be used as a detail aid and a leave behind. Can only be distributed in print.



HCP Disease Awareness Flash Card  
SAUS.CAPL.18.10.6214(1)

A tool that includes disease background and emphasizes the importance of early diagnosis as well as differentiators between aTTP and other TMAs. Can be used as a detail aid and a leave behind and can be distributed in print or Veeva email form.



Patient Disease Awareness Brochure  
SAUS.CAPL.18.12.7163

This resource can be given to the HCP to provide to their patient as a guide to help understand their aTTP diagnosis. Can only be used as a leave behind and can be distributed in print or Veeva email form.



# Raising aTTP Awareness



**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

**Tips to Remember**

**What** questions or objections may arise?

Focus on these disease awareness resources to raise aTTP awareness.

**aTTP is a rare and life-threatening thrombotic microangiopathy (TMA)**

**aTTP is a medical emergency – a rapid diagnosis is essential**

**Raising the awareness around aTTP is critical**

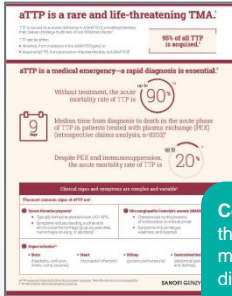
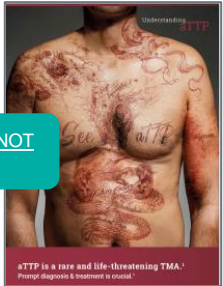
The data speaks volumes...

- A retrospective claims analysis of 8203 hospitalizations with TTP showed a mortality rate for TTP as high as 90% without any treatment
- Mortality remains high despite patients receiving PEX and immunosuppressive therapy, up to 20% of patients die
- In a retrospective claims analysis of 8203 hospitalizations with TTP, the median time from diagnosis to death in TTP patients treated with PEX who passed away during the study (N=613) was 9 days
- Approximately 50% of patients experienced a recurrence within 30 days of stopping PEX. (retrospective review of French Reference Centre for TMA registry, N = 388)
- TTP can be either inherited or acquired. 95% of all TTP is acquired

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

HCP Disease Awareness Brochure  
SAUS.CAPL.18.12.7262

**Compliance Watch Out:** This piece CANNOT be combined with a branded discussion.



HCP Disease Awareness Flash Card  
SAUS.CAPL.18.10.6214(1)

**Compliance Watch Out:** Only unbranded piece that can be used on the same call as branded materials, must be used BEFORE a branded discussion with appropriate transition between unbranded and branded topics.



# Raising aTTP Awareness

[+ HOME](#)

**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

Tips to Remember

**What** questions or objections may arise?

**There is disease state information included in both our branded and nonbranded materials, but we have specific approved messaging and rules around branded and unbranded discussions:**

- You cannot transition from a branded discussion to unbranded discussion
- You must only use disease state messaging that has been approved for use with branded discussion (such as those messages included in your CABLIVI Core Visual Aid and CABLIVI In-Service Slide Deck)
- You cannot use the HCP Disease Awareness Brochure in a branded discussion. Unbranded discussion with this tool must be on a separate visit
- You may initiate a call with the HCP Disease Awareness Flashcard and then transition to a branded discussion as the disease state messages included in that piece are allowed in the context of a branded discussion, but you must start the call with the flashcard, appropriately transition to a branded call, and cannot transition back



# Raising aTTP Awareness

[+ HOME](#)

**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

Tips to **Remember**

**What** questions or objections may arise?

## Potential Reasons a Diagnosis May Be Delayed

- Clinical signs of aTTP are similar to other systemic disorders that present with MAHA and thrombocytopenia (other TMAs, HUS, aHUS)
- Disease is relatively rare; many healthcare providers have limited experience diagnosing and managing TTP and there is a considerable amount of variation employed among practicing specialists who manage these patients
- Physicians not feeling confident in the clinical diagnosis and wanting the ADAMTS13 confirmatory diagnosis





# Educating on CABLIVI

[+ HOME](#)

**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

**Tips to Remember**

**What** questions or objections may arise?

- Hematologist/Oncologist (Hem/Onc)
- Nephrologist
- Emergency Medicine Physician
- Transfusion Medicine Specialist / Apheresis/Blood Bank Manager/Nurse
- Internist
- Hospitalist
- Critical Care Specialist
- Pathologist
- Pharmacist
- Clinical Pharmacist
- Patient Navigator / Case Manager / Charge Nurse
- Discharge Nurse
- Purchasing / Procurement
- Hospital Administration

HCPs can be found in various locations within a hospital



[+ KEY STAKEHOLDERS](#)

[+ CABLIVI CONSIDERATIONS](#)

[+ IDN](#)

Select each button to learn more

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

# CABLIVI Considerations



**Hematologist / Oncologist (Hem/Onc):** As an HCP who will prescribe CABLIVI at some point in the product adoption journey, most likely outside the ICU, they should understand the benefits and risks of CABLIVI in appropriate aTTP patients. The hematologist will want to see the ADAMTS13 test results.

**Nephrologist:** This specialist would be consulted on TMAs and in the event the patient with aTTP experiences loss of renal function. They also may run apheresis.

**Emergency Medicine Physician:** May benefit from education on potential signs and symptoms of aTTP as may be involved in the initial diagnosis of new or relapsing patients. May benefit from awareness and education on CABLIVI.

**Transfusion Medicine Specialist / Apheresis/Blood Bank Manager/Nurse:** May benefit from education on CABLIVI dosage in an aTTP patient, to align with medication and procedure scheduling.

**Internist:** Post-discharge, this PCP may be responsible for general care of the CABLIVI patient with aTTP. The PCP may want to understand the benefits and risks of CABLIVI in appropriate aTTP patients. In addition, the Hematologist / Oncologist may monitor the patient for the first six months post-discharge.

**Hospitalist:** At some point, this HCP may be involved with the care of a patient receiving CABLIVI, most likely inside the ICU. They may want to understand the benefits and risks of CABLIVI in aTTP patients.

**Critical Care Specialist:** As an HCP who may prescribe CABLIVI should the patient be treated in the ICU; they may want to understand the benefits and risks of CABLIVI in appropriate aTTP patients.

**Pathologist:** Involved in diagnosis and testing, this specialist may be interested in the use of ADAMTS13 testing and other earlier indicators of aTTP.



# CABLIVI Considerations



**Pharmacist:** May play a role in formulary approval and ordering. They will be interested in the hospital acquisition cost for CABLIVI. May be involved in preparation of the dose of CABLIVI for administration.

**Clinical Pharmacist:** As an HCP who will play an integral role in recommending the use of CABLIVI in aTTP patients, they may be interested in learning about the clinical trial data, efficacy, and safety profile of CABLIVI. They may work closely with the Hematologist / Oncologist to treat the patients on the floor and may be involved in educating the patient on the product and the process for self-administration upon discharge. May be involved in preparation of the dose of CABLIVI for administration.

**Nurse / Patient Navigator / Case Manager / Charge Nurse:** As a navigator, the nurse will help their CABLIVI patients throughout the treatment process, which may include completing the patient enrollment form. They may benefit from education on CABLIVI Patient Solutions and the enrollment form.

**Discharge Nurse:** Ensure that patient is ready for discharge. They may benefit from education on the CABLIVI patient solutions and the enrollment form.

**Purchasing / Procurement:** May be interested in education on the indications for CABLIVI usage, and expected number of annual patients with aTTP, and CABLIVI hospital acquisition cost and potential CABLIVI utilization.

**Hospital Administration:** Can be decision makers or incremental influencers in the process of helping physicians get the products they need/want in the hospital along with the processes necessary for their use. These include administrators in the clinical departments involved in the care of patients with aTTP as well as other departments like quality, billing, procurement, etc.

# Purchasing / Procurement



- The main goal of any hospital purchasing department is to deliver high-quality goods and solutions while reducing costs. They play a central role in negotiating, soliciting bids, and creating purchase orders. They also review requisitions for goods and services from various departments
- A hospital purchasing agent will spend a significant amount of time analyzing price proposals, financial reports, and other data to determine fair market pricing. Day-to-day activities and responsibilities include:
  - Negotiating and administering contracts with suppliers and vendors
  - Monitoring shipments of purchased goods
  - Analyzing data to maintain budgetary restraints. May be involved in Value Analysis process that looks at financial implications of new products that are being considered for formulary review or general acquisition
- What impacts decisions in hospital buying? It varies across different hospitals. For example, community hospitals have different needs versus a large healthcare system. The former's volume will be smaller, and they may be more price sensitive. Whereas larger healthcare systems often have more negotiating power. But outside of price, there are more criteria considered for making a purchase, including:
  - Vendor relationships: many hospitals have preferred vendor agreements with rebates
  - Urgency of need for the product
  - Quality of goods and services (reliability, warranties, etc.)
  - Risk factors: will new goods or services disrupt certain workflows?
  - Compliance: hospitals deal with a variety of regulations, so any product or solution they choose must be compliant
  - Manage the vendor credentialing in program within institutions and control hospital access



# Hospital Administration



- There are departments within an institution that include key decision makers involved in the process of getting the products physicians need or want to use available in the hospital. Some of these key stakeholders may include titles such as:
  - Director, Transfusion Services
  - Service Line Directors (e.g., Hematology, ICU, etc.)
- Other administrative functions to consider engaging in the hospital include those who might be focused on quality measures, such as:
  - Utilization Review Team - interested in utilization of services and products, looks at length of stay, may do some quality measures
  - Quality Improvement Coordinator - may assist in the development and implementation of quality programs at the department level
- In addition to healthcare resource utilization, institutions are interested in reducing preventable hospital readmissions to improve health care and lower costs. In 2012, the Centers for Medicare & Medicaid Services introduced the Hospital Readmissions Reduction Program (HRRP) which began reducing Medicare payments for certain hospitals with excess 30-day readmissions for patients with several conditions. This program does not apply to aTTP as it is a rare disease, however, institutions and providers still have a goal of reducing avoidable readmissions.

# Hospital Administration



- Medical billing and coding is the process of identifying diagnoses, medical tests, treatments, and procedures found in clinical documentation and then transcribing this patient data into standardized codes to bill government and commercial payers for hospital / physician reimbursement
- Medical billers and coders are the health care professionals in charge of processing patient data, such as treatment records and related insurance information. Both medical billing and medical coding professionals are involved in the medical reimbursement cycle, working together to ensure that health care providers are accurately and efficiently paid for the services they perform
- The primary job of a medical coder is to review clinical documentation to extract and translate billable information into medical codes using CPT®, ICD-10-CM, and HCPCS Level II classification systems. Medical classification, or medical coding, is the process of translating medical reports into codes used within the health care industry. The use of medical codes helps summarize medical services and reports. These medical code sets help medical coders document the patient conditions and describe the health care procedure(s) performed to treat their conditions
- Medical billing is the process of submitting and following up on claims with health insurance companies to receive payment for services rendered by a health care provider. The medical biller needs to understand how to read medical records and, like the medical coder, be familiar with CPT®, HCPCS Level II, and ICD-10-CM codes. Medical billing translates a healthcare service into a medical billing claim

**IMPORTANT REMINDER:** The ABMs' involvement with medical billing and coding is limited to providing the CABLIVI Billing and Coding Guide. ABMs should not be further involved in a hospital's billing and coding and should have no involvement in the billing or coding of individual patients or a hospital's implementation of the information in the CABLIVI billing and coding guide.

# Integrated Delivery Networks



- Sometimes called organized providers, integrated health systems, and corporatized providers, Integrated Delivery Networks (IDNs) are health systems in which providers are affiliated with a parent company. IDNs consist of medical groups, facilities, labs, and one or more acute care hospitals and associated outpatient facilities, and provide a continuum of care including different disease states
- Some familiar IDNs include The Mayo Clinic, The Cleveland Clinic, Partners Healthcare, Memorial Sloan Kettering Cancer Center, and HCA. There are approximately 1000 IDNs in the US
- Providers and/or facilities that are not affiliated with an IDN or PN are said to be independent

Integrated Delivery Network (IDN)



# Integrated Delivery Networks



## “If you have seen one IDN, you have seen one IDN”

- A small number of IDNs operate nationally
- The majority operate regionally or, in some cases, locally
- The three largest IDNs—Hospital Corporation of America, CommonSpirit Health, and the Department of Veterans Affairs—may include hundreds of hospitals each
- Smaller, regional IDNs may have just several dozen hospitals, and local IDNs have even fewer
- Some are groups of hospitals, others cover the entire continuum of care
- Some are integrated more or less in name only, such as when a hospital buys a neighboring facility or two, but just uses them for referrals, with little effort at integrating clinical or back-office operations
- Other IDNs are truly, fully integrated, including patient care protocols, human resources, and finance



# Integrated Delivery Networks

## Taking a Different Strategic Approach...



- One of the most dramatic differences with IDNs is a movement towards a more centralized decision-making process
- One estimate finds as many as 80% of IDNs with policies and practices that are applied at the individual entity level were often drafted at the ownership level rather than at the operational level
- Other IDNs impose corporate decisions and mandates systemwide. That means buying decisions are being moved away from physicians and replaced with administrators, where institutional objectives are increasingly at the top of the agenda
- This paradigm change also means that business considerations may carry as much weight in IDN purchasing decisions as do clinical considerations. As a result, decisions on purchasing medications may move away from physicians with a potential emphasis on administrator opinions
- If you become aware that drug usage and selection at an institution is dependent on an IDN decision, you may want to start with an IDN Pharmacy Stakeholder to gain a better understanding of this dynamic



**IDN PHARMACY  
STAKEHOLDER**

*Select to learn more*

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

# Integrated Delivery Networks



As part of the centralized decision-making process, keep in mind that the Pharmacy Director position in an IDN may go by many titles such as the following:

- System Director of Clinical Pharmacy Services, Pharmacy Operations and Clinical Services
- Director, Pharmacy Strategic Sourcing
- Clinical Pharmacy Manager
- Regional Manager, Clinical Pharmacy Services
- SVP Chief Pharmacy Officer
- Division Director, Clinical Pharmacy Services



**Note:** It is important for you to be aware of the IDN affiliations of your accounts and the level of involvement they have in local decisions; however, you should have a discussion with your manager before contacting individuals at the IDN level because your actions can have impact on the broader business for Sanofi.

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.



# Educating on CABLIVI

[HOME](#)

## Who is involved in this stage?

## What happens in this stage?

## Why is this stage so important?

## Tips to Remember

## What questions or objections may arise?

- This is an excellent opportunity for you to communicate the mechanism of action, safety, and efficacy of CABLIVI.
- In addition, it is critical to stress the importance of early diagnosis dovetailing off your previous conversations about the aTTP disease state.
- In the fight against aTTP, a strong start can make a difference.
- Also, this is a great place to communicate that the ISTH guidelines for aTTP include CABLIVI (conditional recommendation).

Here are the key materials for CABLIVI brand awareness.

**Important Note:** During any call, you are required to provide the full approved indication and fair balance/important safety information for CABLIVI.

**In the fight against aTTP, A STRONG START CAN MAKE A DIFFERENCE**

**ISTH GUIDELINES RECOMMEND CABLIVI\***

**The first and only FDA-approved therapy for adults with aTTP in combination with PEX and immunosuppressive therapy<sup>1,2</sup>**

\*A conditional recommendation defined as desirable effects of the recommendation probably outweighing the undesirable effects. Assumes timely access to ADAMTS-1 testing and clinical diagnosis based on high likelihood of aTTP in de novo patients where no earlier data access to ADAMTS-1 testing is available. The guideline does not recommend CABLIVI, however, treatment of a patient previously diagnosed with aTTP could be safely undertaken on clinical grounds without the need for confirmatory ADAMTS-1 testing.

**INDICATIONS:**  
CABLIVI (caplacizumab-yhnd) 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-yhnd or to any of its ingredients. Hypersensitivity reactions have included urticaria.

**Please see Important Safety Information and full Prescribing Information.**

<sup>1</sup>TTP/acquired thrombotic thrombocytopenic purpura, ISTH International Society on Thrombosis and Haemostasis, Melkersson epistaxis/hemolytic anemia, PEX/plasma exchange.

**Cablivi**  
caplacizumab-yhnd  
Injection

**CABLIVI Core Visual Aid  
MAT-US-2101322-v1.0-03/2021**

## Other Resources

[Example ABM Account Plan](#)

[Definitive Healthcare – Hospital Profile](#)

[Customer Mapping Tool](#)

Select each button to learn more



# Educating on CABLIVI



**Who is involved in this stage?**

**What happens in this stage?**

**Why is this stage so important?**

**Tips to Remember**

**What questions or objections may arise?**



**CABLIVI In-Service Slide Deck**  
MAT-US-2100195-v1.0

Presentation describing aTTP and its current treatment options as well as the efficacy, safety, and dosing of CABLIVI and information outlining the recently published ISTH Guidelines.

Can only be used as a presented detail aid.

**Important Note:** During any call, you are required to provide the full approved indication and fair balance/important safety information for CABLIVI.



**ISTH Flashcard**  
MAT-US-2009642/MAT-US-2019605

A detail aid used to update HCPs on the ISTH Guidelines for the diagnosis and treatment of TTP and how they relate to use of CABLIVI.

Can be distributed in print or Veeva email form.



**CABLIVI Pivotal Study Reprint Carrier**  
SAUS.CAPL.19.01.0028(1)

Reprint carrier containing the 2019 Scully et al paper is focused on the efficacy and safety of CABLIVI in the HERCULES trial.

Must report transfer of value, unless at a large congress with more than 50 attendees not invited by Sanofi.

Can only be distributed in print.

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

# Example ABM Account Plan



Est. aTTP cases/year	Pts treated with CABLIVI® 2019/2020	Volume LTD (kits) 2019/2020	2020 CABLIVI Patient Goal	Access to CABLIVI (Yes/No)	On Formulary (Yes/No)	Stocked/Consigned/Neither	Adoption Rating <small>1=Strongly Negative, 5=Strong Adoption</small>	Primary Challenge <small>Access, Cost, Formulary, Reserve for severe, Satisfied w/ current care</small>	Secondary Challenge <small>Access, Cost, Formulary, Reserve for severe, Satisfied w/ current care</small>

Account Description	Account Status	Recent & Pending Activity
Internal Classification		
Specialty Distributor		
Specialty Pharmacy		

Account Goal/Opportunities	Plan/Needs	Treater	Role	Notes
Account Obstacles	Plan/Needs			

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.



# Example ABM Account Plan



Key Stakeholder	Title	Role	Within Account Role Rank	Formulary Role? Y/N	Key Stakeholder Influencers (accounts + Individuals)	Influencer For (accounts, region + individuals)	Planned Conference Attendance

ADAMTS13 Insource/Outsource	
Diagnosis Score Used (eg, PLASMIC/French/None)	

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

# Definitive Health Care



The screenshot displays two overlapping web browser windows from the Definitive Health Care platform.

The background window is titled "Commercial Claims - Physician" and shows the "Physician Diagnosis Analytics" page. It includes a search bar, navigation tabs, and a "Physician Diagnosis by Provider" section. The "View By" dropdown is set to "Physician" and the "Claim Year" is 2020. A list of physicians is visible, including RUSKMAN, Edge Moore, Mary Abbott, David Miller, Katie GARDINER, Enderick Jones, Nisreen Shahid, and Sarah Carroll.

The foreground window is titled "Hospital Profile" for Tufts Medical Center. It shows the "Medical Claims" tab with a table of diagnoses by ICD-10 code. The search criteria include "ICD-10 Code (Rendering Provider)" set to "M311" and "Claim Year" set to "2021 through July".

ICD-10 CODE	ICD-10 CODE	ICD-10 DESCRIPTION	# ACTUAL DIAGNOSES	% ACTUAL DIAGNOSES	# ACTUAL UNIQUE PATIENTS	# ACTUAL PRIMARY DIAGNOSES	% ACTUAL PRIMARY DIAGNOSES	# ACTUAL UNIQUE PATIENTS (PRIMARY DIAGNOSES)	ACTUAL CHARGES (PRIMARY DIAGNOSES)	% ACTUAL CHARGES	CHARGE/CLAIM (ACTUAL)
M311	4460	Thrombotic microangiopathy	23	100.0 %	5	9	100.0 %	2	\$7,734	100.0 %	\$689

ICD-10 CODE	RENDERING PROVIDER	DEFINITE ID	RENDERING PROVIDER TYPE	# ACTUAL DIAGNOSES	% ACTUAL DIAGNOSES	# ACTUAL UNIQUE PATIENTS	# ACTUAL PRIMARY DIAGNOSES	% ACTUAL PRIMARY DIAGNOSES	# ACTUAL UNIQUE PATIENTS (PRIMARY DIAGNOSES)	ACTUAL CHARGES (PRIMARY DIAGNOSES)	% ACTUAL CHARGES	CHARGE/CLAIM (ACTUAL)
M311	Paul Minkov	1447341204	Physician	9	0.0 %	1	5	0.0 %	1	\$4,116	0.0 %	\$923
M311	JOSEB SERRANO	1144523630	Physician	1	0.0 %	1	1	0.0 %	1	\$1,830	0.0 %	\$1,830
M311	Luigi Pa	1083727911	Physician	1	0.0 %	1	1	0.0 %	1	\$343	0.0 %	\$343
M311	Julian Sui	1245658392	Physician	1	0.0 %	1	1	0.0 %	1	\$378	0.0 %	\$378
M311	Abdullah Elm	1285740969	Physician	1	0.0 %	1	1	0.0 %	1	\$667	0.0 %	\$667

Definitive Healthcare is a comprehensive database on hospitals, physicians, and other healthcare providers. Sanofi has unlimited user license to Definitive Health.

You can use this tool to:

- Profile hospitals and health systems
- Conduct provider analytics using claims data
- Identify key stakeholders and decision makers within an institution

The best (and quickest) way to get users access is to reach out directly to [support@definitivehc.com](mailto:support@definitivehc.com) and ask for access stating you are a Sanofi employee.

Definitive Health provides weekly trainings on the database and will send an email once you receive your username/password.

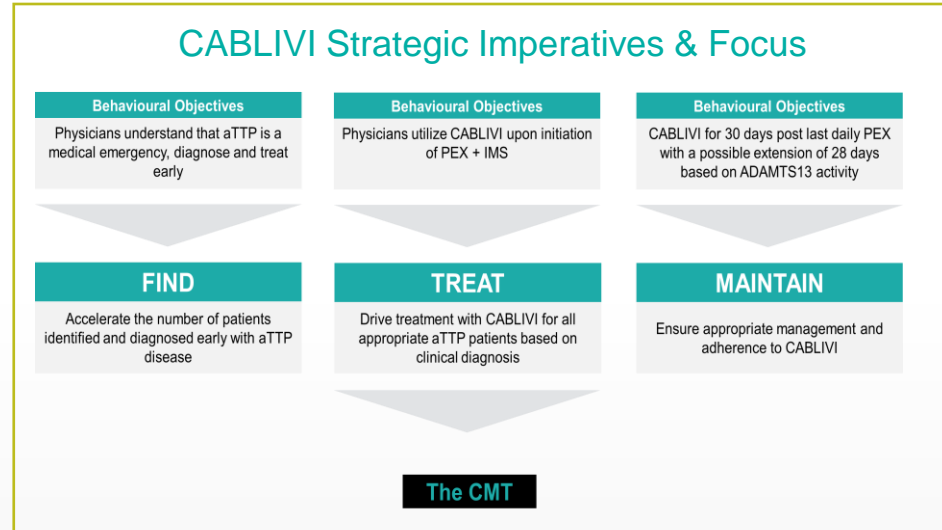
FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

# Customer Mapping Tool (CMT)



## What Is Customer Mapping?

- Customer Maps are visual models using objective and subjective inputs that show the interests of different groups and the people who may impact a project or decision
- These maps help us understand how our customers may (or may not) be connected to each other
- This information can be used to help us improve our account planning, targeting, reach, and resource allocation



CMT supports the TREAT strategic imperative by supporting CABLIVI account planning and execution.



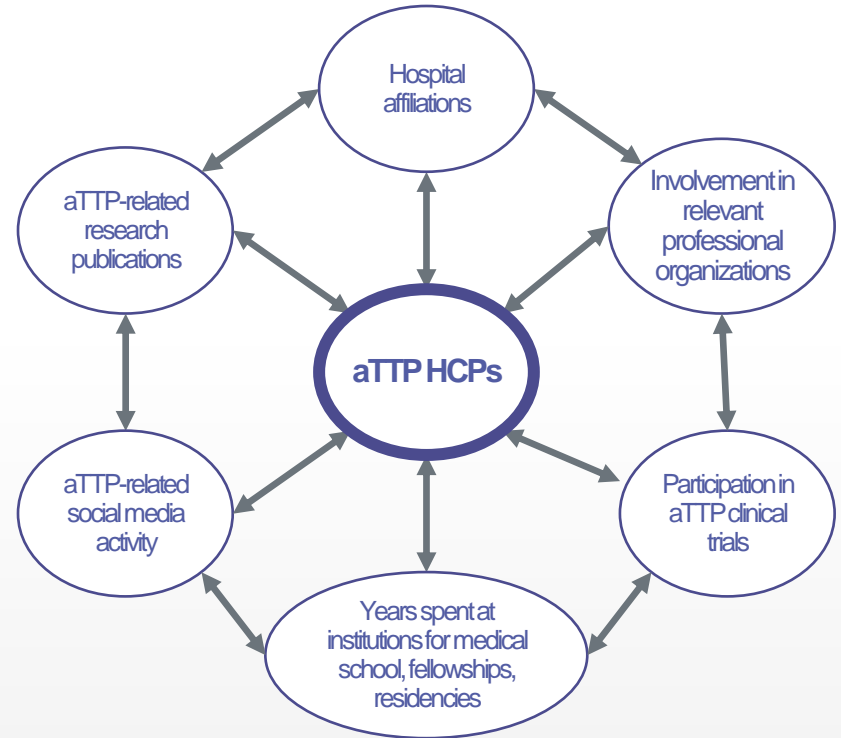
# Customer Mapping Tool (CMT)



## What is the CMT?

An interactive tool for exploring data about individual HCPs to help call plan:

- Identify connections among physicians based on background and aTTP-related activity
- Understand the nature of influence individual HCPs have relevant to aTTP
- Other sources of influence (eg, guidelines, national & international associations, web sites, etc)



# Customer Mapping Tool (CMT)



Icons detail specific connections between HCPs based on Sanofi account, medical background and current ATP work

## Legend

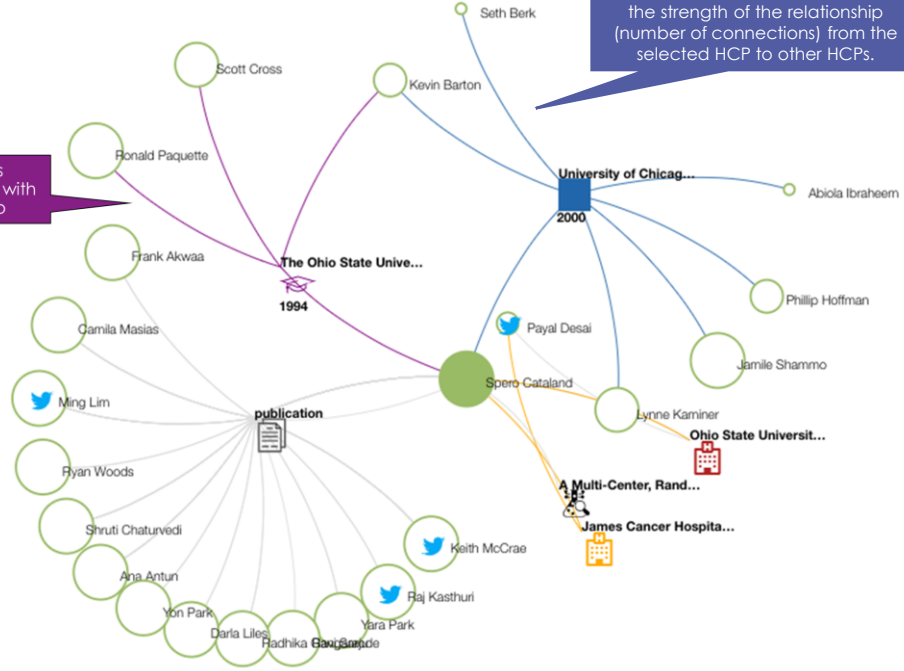
- This physician
- Connected physician
- Sanofi account
- Other hospital affiliation
- Fellowship/Residency
- Medical school
- Clinical trial
- Journal publication
- Twitter

## Actions

- **Click** a node to freeze/unfreeze
- **Drag** to reposition
- **Double click** to select an HCP
- **Search** to find an HCP
- **Right click** an HCP to suggest edits

Color of line indicates nature of relationship with HCP at center of map

The line thickness is an indicator of the strength of the relationship (number of connections) from the selected HCP to other HCPs.





# Educating on CABLIVI



**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

**Tips to Remember**

**What** questions or objections may arise?

**This is your opportunity to differentiate the addition of CABLIVI versus PEX and Immunosuppressive Therapy alone in patients with aTTP.**

### Key Messages:

- In the fight against aTTP, a strong start can make a difference
- CABLIVI is the first and only FDA-approved therapy for adults with aTTP in combination with PEX and immunosuppressive therapy
- Each aTTP episode can be unpredictable with microthrombi risks
- Triple threat of aTTP deserves a triple therapy regimen with CABLIVI + PEX + IS
- ISTH Guidelines recommend CABLIVI based on a high likelihood of aTTP and timely access to ADAMTS13 testing (conditional recommendation)

**Important Note:** During any call, you are required to provide the full approved indication and fair balance/important safety information for CABLIVI.

**CABLIVI Core Visual Aid  
MAT-US-2101322-v1.0-03/2021**



# Educating on CABLIVI



## Who is involved in this stage?

## What happens in this stage?

## Why is this stage so important?

## Tips to Remember

## What questions or objections may arise?

- aTTP is a rare disease. Therefore, your hospital may not see many patients on an annual basis and many potential stakeholders may have limited or no awareness of aTTP or experiences with CABLIVI
- Effectively utilizing Definitive Healthcare, the customer mapping tool, and your account plan will be critical to your success in locating the key stakeholders to assist in the aTTP decision-making process and ultimately, CABLIVI utilization.
- For total account management, focus broadly within the targeted account.

**Important Note:** During any call, you are required to provide the full approved indication and fair balance/important safety information for CABLIVI.

**In the fight against aTTP, A STRONG START CAN MAKE A DIFFERENCE**

**ISTH GUIDELINES RECOMMEND CABLIVI**

**The first and only FDA-approved therapy for adults with aTTP in combination with PEX and immunosuppressive therapy<sup>1,2</sup>**

<sup>1</sup>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. In de novo patients where no reasonable access to ADAMTS13 activity testing is available, the guidelines do not recommend CABLIVI; however, treatment of a patient previously diagnosed with aTTP could be safely undertaken on clinical grounds without the need for a confirmatory ADAMTS13 test.<sup>2</sup>

**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.

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

**Important Safety Information:**  
aTTP/acquired thrombotic thrombocytopenic purpura, ISTH International Society on Thrombosis and Haemostasis, MAHA/acquired hemolytic uremic syndrome, PEX/plasma exchange.

**Cablivi. caplacizumab-yhdp injection**

**CABLIVI Core Visual Aid**  
**MAT-US-2101322-v1.0-03/2021**



# Educating on CABLIVI



**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

**Tips to Remember**

**What** questions or objections may arise?

Introducing a new therapy can be challenging. Your key stakeholders may have questions and concerns about CABLIVI utilization in their institution, especially if they see no reason to change from their current treatment for aTTP.

The **ABM CABLIVI FAQ Document** is a great internal resource to assist and navigate you through anticipated questions about CABLIVI access.

Here are few topics that you may want to review in this document:

- PEX + Immunosuppressive Therapy is fine in managing patients through an episode of aTTP, why should I add CABLIVI?
- I don't need to use CABLIVI, I am already using Rituximab
- I'm reserving the use of CABLIVI to severe patients
- Why should CABLIVI be dosed for 30 days following last daily plasma exchange?
- Could you explain the cost of CABLIVI to me?

**Important Note:** During any call, you are required to provide the full approved indication and fair balance/important safety information for CABLIVI.



ABM CABLIVI FAQ Document  
MAT-US-2016294-v2.0-12/2020



# CABLIVI Access

[+ HOME](#)

**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

Tips to **Remember**

**What** questions or objections may arise?

- Hematologist/Oncologist
- Emergency Medicine Physician
- Hospitalist
- Intensivist
- Pharmacist
- Clinical Pharmacist
- Purchasing / Procurement



# CABLIVI Access

[+ HOME](#)

**Who is involved in this stage?**

**What happens in this stage?**

**Why is this stage so important?**

**Tips to Remember**

**What questions or objections may arise?**

**CABLIVI access for your hospital will be critical for CABLIVI utilization. Typically, the first step is to better understand your hospital's formulary processes. Here are steps to consider, questions to ask, and other supportive resources:**

1. Understand if formulary approval needed
2. Each hospital has a formulary process and set schedule
  - Find out what the process is for that specific hospital and when meetings are scheduled
  - Are there any subcommittees? (For example—HemOnc, financial committee)
  - Are urgent formulary requests allowable?
3. Education for formulary consideration
  - Find a physician who supports use of CABLIVI and wants to use it in the hospital
  - Provide Data/Formulary Kit for Clinical Evaluation
  - RBADs support may be needed for Value/Cost Analysis component of review
4. Follow-up questions to ask about product access during formulary approval process or if CABLIVI is not on formulary
  - During the formulary process and prior to approval are providers able to access CABLIVI if a patient presents?
  - How do they order emergency drug? How fast can they get access?
  - What else needs to be completed to ensure ease of use for a product used during medical emergencies?
5. Will the account stock or consign product?
6. HCPs who are likely to initiate the formulary process for CABLIVI:
  - Hematologists, Hem/Oncs
  - Clinical Pharm D
  - Director, Pharmacy

[+ Formulary Process Questions](#)

[+ CABLIVI Formulary Kit](#)

[+ Other Resources](#)

[+ Budget Impact Model \(BIM\)](#)

*Select each button to learn more*

**Note:** If formulary won't be considered, determine if there an exception process for access.

# CABLIVI Access



When working with your account customers, consider the following questions to gain greater insight into their formulary needs and process.

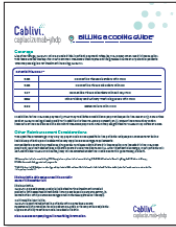
## FORMULARY PROCESS

1. Can you describe how therapies for ultra-rare diseases are managed through P&T?
2. How are formulary decisions made?
  - Independent of other hospitals (independent hospital or decentralized IDN/group)
  - Hospital follows a central formulary (IDN or another group)
3. What is the process for formulary review?
4. How often does P&T meet?
5. Does the product also require review by a Value Analysis Committee?
6. What is the role of the hospital pharmacy in P&T review and approval?
7. Who in your institution is tasked with review of a product?
8. Do you have P&T subcommittees (example: Hem/Onc, financial committee, etc)?
9. How long does it usually take for a product to be reviewed and approved by P&T?
10. What is the procedure for using products that are not on formulary?
11. For those accounts that say they do not need Cablivi added to formulary: what is the process for using a non-formulary product and what kind of delay could that create?
12. During the formulary process and prior to approval are providers able to access Cablivi if a patient presents?
13. What are the criteria for therapies to be considered by P&T as "urgent care"?
14. For urgent treatment situations, what is the time required to gain access to the product for non-formulary/ non-P&T treatment approvals?
15. What else needs to be completed to ensure ease of use for a product used during medical emergencies?

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.



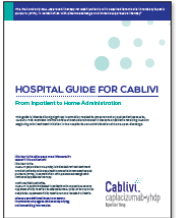
# CABLIVI Access



## Billing & Coding Guide

4 pages

Communicate billing and coding information

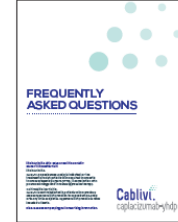


## Hospital Guide

8 pages

Communicate ordering and PSP information

## CABLIVI Formulary Kit



## FAQs

12 pages

Pre-empt and address anticipated questions from customers



## Pricing Sheet

1 page

Communicate pricing and ordering information

**Leave-behind ONLY to Economic Decision Makers. The formulary kit MUST NOT be distributed to HCPs unless they are identified as a hospital economic decision maker.**

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

# CABLIVI Access



For Formulary Decision Makers

The first and only FDA-approved therapy for adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange (PEX) and intravenous immunoglobulin

**CABLIVI (CAPLIZUMAB-YHDP) AND HEALTHCARE UTILIZATION**

See how taking CABLIVI to first-line intravenous immunoglobulin treatment can help impact hospital utilization compared with standard of care once

This brochure contains health care economic information and is intended for use with formulary decision maker committees only.

**INDICATION AND SELECTED INFORMATION**  
**SAFETY INFORMATION**  
**CONTRAINDICATIONS**  
**IMPORTANT SAFETY INFORMATION**

**Cablivi**  
 caplizumab-yhdp  
 Biogen Inc.

**CABLIVI Economic Background**  
 SAUS.CAPL.19.01.0346(1)  
 PI Needed: PI is included in packet

**Resource Summary:** This is a resource that can be used to educate hospital P&T formulary decision makers on CABLIVI healthcare economic data from HERCULES trial to inform hospital formulary decision making.

**Understanding CABLIVI coverage**

**IN THE HOSPITAL**      **AT HOME**

**CABLIVI + PEX + IMMUNOGLOBULIN THERAPY**      **OPTIONAL TREATMENT EXTENSION**

Variable LOS in hospital\*      CABLIVI for 30 days post daily PEX†      Up to 18 additional days (if needed) ††

at least 30 days of treatment post daily PEX, or the absence of PEX/IVIG/ECMO; the number treatment days with CABLIVI was 28 days

**Insurance coverage**

**Insurance coverage**      **Outpatient costs are primarily managed by third-party insurance**

**CABLIVI patient access support**

Provides financial assistance for eligible patients to enable access to CABLIVI. Eligible patients covered by commercial health insurance are eligible for the CABLIVI in-patient assistance program (up to \$25,000 per patient per calendar year) or the CABLIVI outpatient assistance program (up to \$25,000 per patient per calendar year).

**INDICATIONS:** CABLIVI (caplizumab-yhdp) is indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and intravenous immunoglobulin therapy.

**CONTRAINDICATIONS:** CABLIVI is contraindicated in patients with a previous severe hypersensitivity reaction to caplizumab-yhdp or to any of its excipients, hypersensitivity reactions to human albumin, or hypersensitivity reactions to any of the excipients.

Please see Important Safety Information and Full Prescribing Information.

**Understanding CABLIVI Coverage Flashcard**  
 MAT-US-2101320-v1.0-02/2021  
 PI needed: YES

**Resource Summary:** This is a customer facing aid to reactively respond to customer questions/objections regarding cost, reimbursement, and coverage for CABLIVI.

**FREQUENTLY ASKED QUESTIONS**

This document contains health care economic information and is intended for use only with payers, formulary committees, and other similar entities.

**INDICATIONS AND SELECTED INFORMATION**  
**SAFETY INFORMATION**  
**CONTRAINDICATIONS**

**Cablivi**  
 caplizumab-yhdp  
 Biogen Inc.

**Frequently Asked Questions**  
 MAT-US-2023916-v1.0-01/2021  
 PI needed: No, PI is included in packet

**Resource Summary:** This is a purchasing decision maker facing aid to pre-empt and address anticipated questions from purchasing decision makers related to clinical attributes, cost, coverage, reimbursement, distribution, and manufacturer sponsored patient and provider support services. This resource is also part of the CABLIVI Formulary Kit.

# CABLIVI Access



## Budget Impact Model (BIM) – RBAD Only

- Used to help economic decision makers understand the financial implications of adopting CABLIVI into clinical practice for the treatment of aTTP
- Can only be presented by trained RBADs and then only to economic decision makers such as P&T members or advisors in their area of specialty to the P&T Committee
- Target Audience:
  - Economic decisions makers for the entity involved in the selection of products for purchase, coverage, or reimbursement could include:
    - C-Suite, finance, hospital administrators who negotiate with payers, billing departments, personnel involved in quality measures, P&T committee members and value analysis

**In your CABLIVI discussions, you may realize that your decision-making audience may benefit from a Budget Impact Model presentation. Contact your respective RBAD for this request.**



# CABLIVI Access

[+ HOME](#)

**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

**Tips to Remember**

**What** questions or objections may arise?

This stage is critical in securing CABLIVI in your institution. Many questions and processes will be revealed with respect to “how” products are reviewed, assessed, and ultimately approved for use in the hospital.

This is a great opportunity for you to familiarize yourself with the key decision makers and how they process certain types of information to make their decisions.





# CABLVI Access

[+ HOME](#)

**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

Tips to **Remember**

**What** questions or objections may arise?

**Compliance Note:** *Certain materials and information, including health care economic information, are only appropriate to be provided to payers and other economic decision makers. These materials and information may only be provided to the following individuals: payers, formulary committee members (eg, pharmacy and therapeutics committees), drug information centers, technology assessment committees, and pharmacy benefit managers.*

*If you have questions about distributing such documents and information, including health care economic information, please ask your manager. Always remember to look at the audience the marketing piece is approved for to determine if the information can be shared with a specific individual.*

*Sanofi employees must not offer anything of value (such as a contract for services) as a reward or inducement to a Customer for the purchase, prescription, recommendation or formulary placement of a Company product.*



# CABLIVI Access



**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

**Tips to Remember**

**What** questions or objections may arise?

## Potential reasons for not allowing access to CABLIVI

- Satisfied with current standard of care
- Reserve CABLIVI for severe patients
- Cost concerns
- Access may be dependent on decisions at the IDN level
- Confidence in transition of care to home treatment
- Reservation of prescribing CABLIVI upon clinical diagnosis while waiting for ADAMTS13 results
- Not having the ADAMTS13 test readily available
- Being placed on order sets in hospital EMR system

*The **ABM CABLIVI FAQ Document** is a great internal resource to assist and navigate you through anticipated questions and potential objections to CABLIVI access. Review this document to be better prepared to handle these potential questions and objections.*

**Important Note:** During any call, you are required to provide the full approved indication and fair balance/important safety information for CABLIVI. Also, you should have no involvement in the implementation of CABLIVI into the hospital's EMR system.





# CABLIVI Acquisition

[+ HOME](#)

**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

Tips to **Remember**

**What** questions or objections may arise?

- Director of Pharmacy / Pharmacy Buyer
- Purchasing / Procurement
- Hematologist/Oncologist
- Emergency Medicine Physicians
- Hospitalist
- Critical Care Specialist



STAGE 4

# CABLIVI Acquisition

+ HOME

Who is involved in this stage?

What happens in this stage?

Why is this stage so important?

Tips to Remember

What questions or objections may arise?

## WHAT HAPPENS POST FORMULARY?

### Institution Driven Activities (ie, issues for the institution to consider once a product is on formulary)

- After formulary approval, what else does the hospital need to do to be able to use it? Does CABLIVI need to be:
  - Added to the CPOE (Computerized Physician Order Entry) pharmacy pick list, MAR (Medicine Administration Record), bar code system?
  - Added to EMR including electronic clinical decision support tools? Added to aTTP order set?
  - Stocked/Consigned?
- Are there protocols or standard operating procedures (SOPs) in place to define how CABLIVI should be used in the institution?
- What specific departments need to be informed of formulary approval and the protocol/SOP around the use of CABLIVI? What is that process for informing?
- If CABLIVI is approved to dispense through a Hospital Owned Specialty Pharmacy, is there a communication system in place between the Hospital Inpatient Pharmacy and Outpatient Specialty Pharmacy to ensure CABLIVI is available at discharge?

**Note: If formulary won't be considered, determine if there is an exception process for access.**

**Compliance Note:** Institution-driven activities are listed here for your background but should be completed by the hospital staff, not a Sanofi employee. You may mention these considerations to customers who would like to use CABLIVI at their institution to let them know these action items might be required. Sanofi employees are not permitted to assist in any task or provide any service to implement formulary processes other than what is listed on this slide.

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.







# CABLIVI Acquisition

[+ HOME](#)

**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

**Tips to Remember**

**What** questions or objections may arise?

## ABM questions to understand processes:

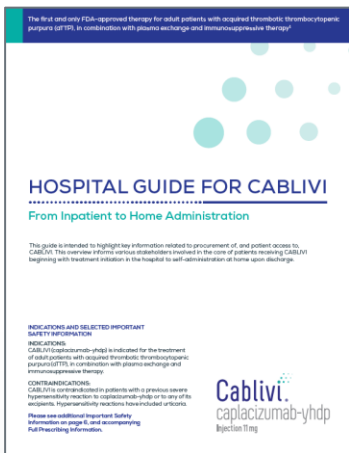
1. Once CABLIVI is on formulary, what education happens with the staff, including the weekend staff? Can CABLIVI be started on the weekends?
  - Is the weekend staff aware of CABLIVI, how to dose, how to enroll a patient in patient services, etc?
  - Is there a process in place at the pharmacy to ensure product availability or accessibility during the weekend?
2. Once CABLIVI is on formulary at a hospital, is it automatically on formulary at the other hospitals that are part of the system? Are there additional steps/processes that need to occur?
3. How do products become part of the system treatment guidelines?

[+ Other Resources](#)

*Select to learn more*

**Compliance Note:** Institution-driven activities are listed here for your background but should be completed by the hospital staff, not a Sanofi employee. You may mention these considerations to customers who would like to use CABLIVI at their institution to let them know these action items might be required. Sanofi employees are not permitted to assist in any task or provide any service to implement formulary processes other than what is listed on this slide.

# CABLIVI Acquisition



**Hospital Guide for CABLIVI**  
SAUS.CAPL.19.03.1418(2) 09/19

A guide highlighting key information related to the procurement of and patient access to CABLIVI. Can be distributed in print or Veeva email form.



**CABLIVI Pricing Sheet**  
MAT-US-2102422-v1.0-04/2021  
PI needed: No

Resource Summary: A guide to pricing and ordering of CABLIVI. Can be distributed in print or Veeva email form.



**CABLIVI In-Service Slide Deck**  
MAT-US-2100195-v1.0

Presentation describing aTTP and its current treatment options as well as the efficacy, safety, and dosing of CABLIVI and information outlining the recently published ISTH Guidelines.

Can only be used as a presented detail aid.

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.



# CABLIVI Acquisition



## Reactive for customer requests for access to distribute CABLIVI via their hospital owned pharmacy:

- Use approved talking points to inform customer of why we chose to work with one Specialty Pharmacy
- All requests should be escalated to your manager as well as your RBAD (no request will be denied)

When a hospital owned pharmacy dispenses for outpatient use, the Prescription section of enrollment form should not be filled out.

# CABLIVI Acquisition



## Talking Points for Hospital Specialty Pharmacy Distribution Requests:

- Yes, your hospital's pharmacy can have access to CABLIVI through any specialty distributor with access to CABLIVI.
- According to incidence rates of aTTP, it is estimated that 200 hospitals with apheresis centers treat approximately 1700 cases per year in the US, and CABLIVI is a product used in combination with PEX and IS therapy during acute episodes of aTTP.
- Sanofi has worked hard to develop a distribution model that can best support the treatment needs of all CABLIVI patients. We contracted with one specialty pharmacy to provide CABLIVI at-home prescriptions. The specialty pharmacy will assist patients with access to CABLIVI, including a patient welcome kit, benefits verification, insurance navigation, and adherence and compliance support.
- Sanofi carefully considered a wide range of distribution options and concluded that, for this extremely rare disease, patients will be best served by a specialty pharmacy that has training and experience with aTTP patients and CABLIVI.

**Note:** You should inform the physician or other HCP that all patients can enroll in CABLIVI Patient Solutions regardless of where they get their outpatient prescription (must complete CABLIVI Patient Solutions Enrollment Form). Services offered through CABLIVI Patient Solutions include financial assistance to eligible patients and supplemental injection training.



# CABLIVI Acquisition

[+ HOME](#)

**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

Tips to **Remember**

**What** questions or objections may arise?

- This stage is critical in acquiring CABLIVI
- The question of whether or not to stock CABLIVI should be an internal decision based on what makes most sense for your hospital and the clinicians who will be involved in treating patients with aTTP
- aTTP is a rare condition and a medical emergency. Hospitals are unable to predict when they may see the next patient. Having the product on hand in the hospital will prevent any delays in initiating treatment
- Your hospital should consider stocking or consigning CABLIVI, so it is on hand when it's needed most. 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 their practice or facility



# CABLIVI Acquisition

[+ HOME](#)

**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

**Tips to Remember**

**What** questions or objections may arise?

## Stock/Consign Talking Points

- Given the unpredictable nature of aTTP, a stocking and/or consignment model may be a consideration for some hospitals to help prevent any delays in initiating treatment
- CABLIVI is available through a network of authorized specialty distributors (SDs) for the hospital inpatient acquisition
- Hospitals and health systems can obtain CABLIVI for inpatient use by placing an order to stock and/or consign through one of the following authorized SDs below

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

- It is up to the institution to determine the procurement option that works best for its practice or facility

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.



# CABLIVI Acquisition

[+ HOME](#)

**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

**Tips to Remember**

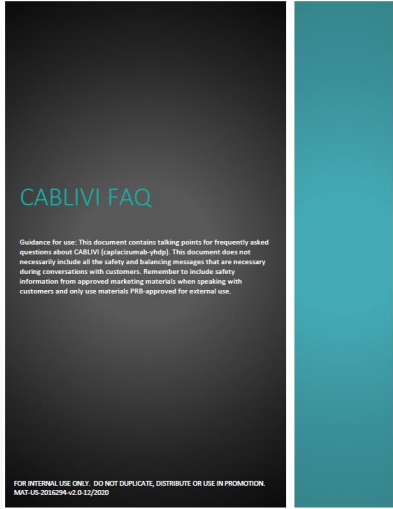
**What** questions or objections may arise?

## Potential Customer Questions

- Could you explain the cost of CABLIVI to me?
- What is the rationale for placing CABLIVI on hospital formulary or building out a protocol since it such a rare disease?
- If CABLIVI can be obtained overnight or on the weekend, why would I want to stock or consign the product at my hospital?
- Will the hospital incur all of the cost of CABLIVI?
- Will the patient receive CABLIVI as an outpatient if I order on the inpatient side?
- Why are you working with a single specialty pharmacy?
- Can I buy CABLIVI so my hospital's SP can provide all product to our patients?

*Now that your hospital is ready to order CABLIVI, there may be many questions.*

*The **ABM CABLIVI FAQ Document** is a great internal resource to assist and navigate you through anticipated questions and potential objections to CABLIVI acquisition. Review this document to be better prepared to handle these potential questions and objections.*



**Important Note:** During any call, you are required to provide the full approved indication and fair balance/important safety information for CABLIVI.

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

**ABM CABLIVI FAQ Document  
MAT-US-2016294-v2.0-12/2020**



# Educating on the Patient Enrollment Process & Patient Support Services

[+ HOME](#)

**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

Tips to **Remember**

**What** questions or objections may arise?

- Hematologist/Oncologist
- Hospitalist
- Critical Care Specialist
- Nurse / Patient Navigator / Case Manager / Charge Nurse
- Clinical Pharmacist





# Educating on the Patient Enrollment Process & Patient Support Services

[+ HOME](#)

**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

**Tips to Remember**

**What** questions or objections may arise?

- aTTP is a medical emergency warranting rapid diagnosis and treatment. Treatment with CABLIVI is initiated in combination with plasma exchange and immunosuppressive therapy when appropriate
- CABLIVI Patient Solutions offers certain programs to eligible patients. While ABMs should not be involved in an individual patient's application nor use of these services, some HCPs may benefit from education on these patient support programs so they can inform CABLIVI patients of the programs. Remember that these support programs cannot be used as a sales tool to influence the decision to prescribe CABLIVI

[+ CABLIVI Patient Enrollment Form](#)

*Select the button to learn more*

**CABLIVI administration occurs in two phases:**



Initiated in the hospital with PEX and Immunosuppressive Therapy



Continue therapy outpatient after discharge from the hospital

# Educating on the Patient Enrollment Process & Patient Support Services



## CABLIVI Patient Enrollment Form

If a patient is going to apply for programs offered by CABLIVI Patient Services, it is advisable to submit the CABLIVI Patient Enrollment Form as soon as treatment is initiated to increase the chance that patients can receive the requested support services upon discharge. The form can be downloaded from CABLIVI.com.\*

The following information is collected on the enrollment form:

1. Patient Information (patient fills out)
2. Insurance Information (patient fills out)
3. Prescriber Information (prescriber fills out)
4. Prescription Information (prescriber fills out)
5. Authorization to Release Health Information (patient consent)
6. Optional Patient Consent Opt-Ins for:
  - Patient Services Support
  - Financial Assistance Programs
  - Sanofi Genzyme Communications

\* As an option, ABMs can email the enrollment form from within a VEEVA rep triggered email AND using our new Outlook email template as an attachment. For outlook email refer to your manager or CABLIVI Marketing for current template.

The image shows a sample of the CABLIVI Patient Solutions Enrollment Form. The form is titled 'CABLIVI Patient Solutions Enrollment Form' and includes contact information for CABLIVI. It is divided into several sections: 1. PATIENT EDUCATION SERVICES, 2. FINANCIAL ASSISTANCE PROGRAMS, 3. PATIENT INFORMATION, 4. INSURANCE INFORMATION, and 5. PRESCRIBER INFORMATION. Each section contains various fields for patient and prescriber details, including name, address, phone, email, and insurance information. There are also checkboxes for patient consent and optional opt-ins. The form is branded with the Sanofi Genzyme logo at the bottom.



FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

# Educating on the Patient Enrollment Process & Patient Support Services



## CABLIVI Patient Enrollment Form

If a patient is going to apply for programs offered by CABLIVI Patient Services, it is advisable to submit the CABLIVI Patient Enrollment Form as soon as treatment is initiated to increase the chance that patients can receive the requested support services upon discharge. The form can be downloaded from CABLIVI.com.\*

The following information is collected on the enrollment form:

1. Patient Information (patient fills out)
2. Insurance Information (patient fills out)
3. Prescriber Information (prescriber fills out)
4. Prescription Information (prescriber fills out and signs)
5. Authorization to Release Health Information (patient or legal representative signature for consent)
6. Optional Patient Consent Opt-Ins for:
  - Patient Services Support
  - Financial Assistance Programs
  - Sanofi Genzyme Communications

**TIP:** Find a champion of the enrollment form who is willing to take ownership every time and if possible, even before the first time CABLIVI is used. This will make the enrollment process more seamless.

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.

The image shows the CABLIVI Patient Solutions Enrollment Form. It is a multi-section document with the following parts:

- Header:** CABLIVI logo, CABLIVI Patient Solutions Enrollment Form, and contact information: 17000 West 15th, Suite 100, Denver, CO 80202-3144, Phone: 800-734-7222, www.cablivi.org.
- Section 1: PATIENT EDUCATION SERVICES** (with a '1' icon) and **FINANCIAL ASSISTANCE PROGRAMS** (with a '5' icon). Includes text about service availability and financial assistance options.
- Section 2: PATIENT INFORMATION** (with a '1' icon). Fields include: PATIENT FIRST NAME, LAST NAME, DATE OF BIRTH, SEX, STREET ADDRESS, CITY, STATE, ZIP, CELL PHONE, HOME PHONE, PREScriBER TYPE (Primary, Secondary, Other), and PATIENT'S PRIMARY LANGUAGE.
- Section 3: INSURANCE INFORMATION** (with a '2' icon). Includes checkboxes for 'PLEASE ATTACH COPIES (FRONT AND BACK) OF ALL AVAILABLE INSURANCE AND PRESCRIPTION CARDS' and 'NO INSURANCE'. Fields include: PRIMARY MEDICAL INSURANCE NAME, POLICY ID #, GROUP #, EMPLOYER OF POLYHOLDER, CURRENT ADDRESS, CITY, STATE, ZIP, and SECONDARY MEDICAL INSURANCE NAME.
- Section 4: PRESCRIBER INFORMATION** (with a '3' icon). Fields include: PRESCRIBER NAME, GROUP FAX #, OFFICE CONTACT NAME, SPECIALTY, OFFICE CONTACT EMAIL, CITY, STATE, ZIP, HOSPITAL & CLINIC (DATE), HOSPITAL NAME, HOSPITAL CONTACT NAME, CITY, STATE, ZIP, PHONE, FAX, HOSPITAL CASE MANAGER NAME, and HOSPITAL CASE MANAGER PHONE.
- Footer:** SANOFI GENZYME logo and document number: 1647-08-2017Rev. v1.0-08/2020.

# Educating on the Patient Enrollment Process & Patient Support Services



## CABLIVI Patient Enrollment Form

If a patient is going to apply for programs offered by CABLIVI Patient Services, it is advisable to submit the CABLIVI Patient Enrollment Form as soon as treatment is initiated to increase the chance that patients can receive the requested support services upon discharge. The form can be downloaded from CABLIVI.com.\*

The following information is collected on the enrollment form:

1. Patient Information (patient fills out)
2. Insurance Information (patient fills out)
3. Prescriber Information (prescriber fills out)
4. Prescription Information (prescriber fills out)
5. Authorization to Release Health Information (patient consent)
6. Optional Patient Consent Opt-Ins for:
  - Patient Services Support
  - Financial Assistance Programs
  - Sanofi Genzyme Communications

The image shows the CABLIVI Patient Solutions Enrollment Form. It is a multi-section document with the following parts:

- Header:** CABLIVI logo, CABLIVI Patient Solutions Enrollment Form, and contact information: 7700 West 16th Street, Suite 100, Denver, CO 80202. Phone: 800-734-7222. www.cablivi.org
- Section 1: PATIENT EDUCATION SERVICES** (with a '1' icon) and **FINANCIAL ASSISTANCE PROGRAMS** (with a '5' icon). Includes text about service availability and financial assistance.
- Section 2: PATIENT INFORMATION** (with a '1' icon). Fields include: PATIENT FIRST NAME, LAST NAME, DATE OF BIRTH, SEX, STREET ADDRESS, CITY, STATE, ZIP, CELL PHONE, HOME PHONE, PREScriber INFO, and PATIENT'S PRIMARY LANGUAGE.
- Section 3: INSURANCE INFORMATION** (with a '2' icon). Includes a checkbox for 'NO INSURANCE' and fields for primary and secondary medical insurance names, policy IDs, and group numbers.
- Section 4: PRESCRIBER INFORMATION** (with a '3' icon). Fields include: PRESCRIBER NAME, GROUP/TAX ID, OFFICE CONTACT NAME, ADDRESS, CITY, STATE, ZIP, HOSPITAL/CLINIC/EMERGENCY, HOSPITAL NAME, HOSPITAL CONTACT NAME, ADDRESS, CITY, STATE, ZIP, HOSPITAL CASE MANAGER NAME, and HOSPITAL CASE MANAGER PHONE.
- Footer:** SANOFI GENZYMÉ logo, page number 1, and document ID: 1647-08-2017Rev. v1.0-08/2020.

# Educating on the Patient Enrollment Process & Patient Support Services



- CABLIVI Patients Solutions and Biologics Specialty Pharmacy will be the main points of contact for follow-up outside the hospital staff

## CABLIVI PATIENT SOLUTIONS can provide patients financial and educational assistance

SPECIALTY PHARMACY SERVICES	SUPPLEMENTAL TRAINING
<p>For patients who obtain their medication through Biologics by McKesson:</p> <ul style="list-style-type: none"><li>• The specialty pharmacy coordinates direct-to-home shipment of CABLIVI for a seamless transition upon discharge</li><li>• Nurses are available to provide ongoing support and answer questions about CABLIVI</li><li>• Pharmacists are available 24 hours a day, 7 days a week</li><li>• CABLIVI Patient Solutions help is available Monday through Friday, 8:00 AM to 8:00 PM ET, at 1-855-724-7222</li></ul>	<p>Clinical educators* are available to provide:</p> <ul style="list-style-type: none"><li>• Supplemental education on how to self-administer CABLIVI</li><li>• Support in setting up a plan for administering therapy</li><li>• Additional at-home support after hospital discharge</li><li>• Answers to questions about CABLIVI</li></ul>

\*CABLIVI clinical educators are paid to provide educational services. They don't provide medical advice. Patients should always consult their physicians with any healthcare needs.

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.



# Educating on the Patient Enrollment Process & Patient Support Services



## CABLIVI Treatment Guide

Can also be used as a stand-alone resource.



## Reminder Magnet



## CABLIVI Welcome Kit

SAUS.CAPL.19.10.5429 10/19

PI needed: YES

### Resource Summary:

The CABLIIVI Welcome Kit was designed for patients and their caregivers to better understand aTTP and their experience with CABLIIVI.



## Wallet Card

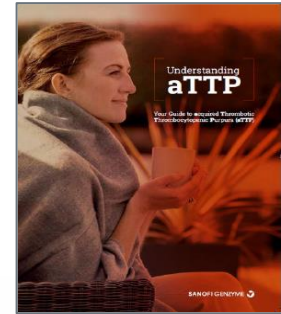


## CABLIVI at Home: How to Self-Administer

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.



## CABLIVI Patient Solutions Brochure



## Patient Disease Awareness Brochure

SAUS.CAPL.18.12.7163

PI needed: No

This resource can be given to the HCP to provide to their patient as a guide to help understand their aTTP diagnosis.

Can only be used as a leave behind and can be distributed in print or Veeva email form.

HCPs can inform their patients to go to <https://www.CABLIVI.com/atp/how-to-take-CABLIVI> learn how to take CABLIIVI



# Educating on the Patient Enrollment Process & Patient Support Services



**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

**Tips to Remember**

**What** questions or objections may arise?

This stage is quite important. Educating HCPs on how to complete the form helps to ensure that if a patient wants to apply for any of the following programs, those HCPs can help the patient complete the form properly and in a timely manner.

- Financial support for eligible patients
- Benefits verification via Biologics
- Supplemental training
- Post discharge follow-up and support via Biologics

**Submit the enrollment form as soon as the patient is prescribed CABLIVI, to ensure your patient has access to the following services:**

- 1. Financial support for eligible patients**  
Sanofi Genzyme offers financial assistance to cover the cost of CABLIVI co-pay or co-insurance for your qualified, commercially insured patients.\* CABLIVI can be provided at no cost to eligible underinsured or uninsured patients.†
- 2. Benefits verification via Biologics, the exclusive specialty pharmacy provider for Cablivi**  
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 Sanofi Genzyme's Financial Assistance
  - Need for prior authorization
  - Assistance, where appropriate, with facilitation of 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 via Biologics**
  - Calls from nurse on days 7 and 14
  - Access to a pharmacist every day, from 8am to 8pm, for questions about CABLIVI

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

- Confirmatory diagnosis with ADAMTS13<sup>§</sup>
- 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

\*This offer is not valid for prescriptions paid, in whole or in part, by Medicaid, Medicare, Veterans Affairs, Department of Defense, TRICARE, or similar federal programs.  
†Approval is not guaranteed.  
‡Cablivi Clinical Educators are paid to provide educational services by Sanofi Genzyme and do not provide medical advice. Patients should always consult their doctor with any questions or concerns regarding their medical condition or healthcare needs.



# Educating on the Patient Enrollment Process & Patient Support Services

[+ HOME](#)

**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

**Tips to Remember**

**What** questions or objections may arise?

## New CABLIVI Order Alert

1. Alert from account or CABLIVI Insights e-mail
2. Find point of contact at account. If no point of contact, start with procurement at account or pharmacy buyer
3. Upon confirmation of contact:
  - Confirm active patient or stock/consign/restock, etc.
  - Offer or provide product information
  - Walk through enrollment form, patient support services
  - Review dosing & administration

### Important Reminder

During conversations, do not discuss specific patients, even in the abstract. Focus on education on the process in general and the importance of certain steps in the process. Do not discuss the process in terms of specific patients, even if you don't know or are not using the patient's name. If the account has questions relating to specific patients, refer them to CABLIVI Patients Solutions.

When discussing the Enrollment Form process, emphasize:

- Quicker the better
- Be as thorough as possible when completing
- Remind contact to ensure that patient or family member signs appropriate places
- Discharge date is critical – even estimated is better than none
- Account should not fill out Rx portion of enrollment form if dispensing from hospital-owned pharmacy. The prescription section is for dispenses from Biologics Specialty Pharmacy only

### Important Reminder

You should never fill out any forms for an account or instruct the account about specific information to put into the form. You may discuss the enrollment form generally, but it is the account's responsibility to fill it in with accurate information.





# Educating on the Patient Enrollment Process & Patient Support Services

 HOME

Who is involved in this stage?	What happens in this stage?	Why is this stage so important?	Tips to Remember	What questions or objections may arise?
--------------------------------	-----------------------------	---------------------------------	------------------	---

## New Patient Order Checklist

*The following are activities that a rep should take when they are alerted of a new product order.*

- 1. Call the hospital inpatient pharmacy to get Clinical Pharmacist or Buyer contact information**
  - Goal: Get connected with the prescribing physician or Case Manager to provide product education and enrollment form
  - Reminder: It should be made clear to all customers that you are not seeking any patient information
- 2. Send Veeva emails with enrollment form and product information to respective contacts from above. We now have an Outlook email template where you can attach the enrollment form. Inform the contact/HCP that the enrollment form is available on CABLIVI.com**
  - Reminder: Inform them that a discharge date is needed to initiate the enrollment process
  - Other resources to send HCPs: CVA, Hospital Guide, Dosing Card, Enrollment Form
  - Other resources to send Pharmacy/Finance: Billing and Coding Guide, Dosing Card, Hospital Guide, CVA, Economic Backgrounder, Enrollment Form
- 3. Contact RBAD to discuss order and inform on expected enrollment form submission**
- 4. If outpatient product will be dispensed through Hospital Owned Pharmacy, Contact Hospital Specialty Pharmacy to review product information and support services available to the patient through CABLIVI Patient Solutions**
- 5. Send CABLIVI Patient Welcome Kit to hospital contact and/or hematologist/Social Worker for their patients**

**TIP:** When you receive an order alert, a TEM may contact you to ask about contacts for reaching out to the nursing staff to offer them education. Be prepared to discuss with the TEM any necessary information for this process.



FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.



# Educating on the Patient Enrollment Process & Patient Support Services

 HOME

Who is involved in this stage?	What happens in this stage?	Why is this stage so important?	Tips to Remember	What questions or objections may arise?
--------------------------------	-----------------------------	---------------------------------	------------------	---

## When the patient is discharged from the hospital:

- CABLIVI Patient Solutions (Hub) will be their primary contact at Sanofi Genzyme
- Supplemental Training is provided by Ashfield
- Note:
  - Paid product is dispensed and managed by Biologics
  - PAP/IAP Product is dispensed and managed by RX Crossroads
  - Customer questions about patient cases should be referred to the appropriate entity above.
- TEMs may have a role in this stage

**Important Note:** The services offered through the hub should not be used as a selling tool. Do not make promises of support for specific patients, as there are eligibility requirements that need to be assessed.

If additional questions about patient access arise (e.g., copay eligibility, OOP expense for patients, etc.), please refer HCPs to CABLIVI Patient Solutions. You should not answer any questions about a specific patient's eligibility to participate in a CABLIVI access program or their out-of-pocket costs.



# Educating on the Patient Enrollment Process & Patient Support Services

[+ HOME](#)

**Who** is involved in this stage?

**What** happens in this stage?

**Why** is this stage so important?

**Tips to Remember**

**What** questions or objections may arise?

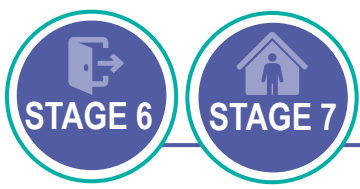
**This stage is quite important. Educating HCPs on how to complete the form helps to ensure that if a patient wants to apply for any of the following programs, those HCPs can help the patient complete the form properly and in a timely manner.**

- Financial support for eligible patients
- Benefits verification via Biologics
- Supplemental training
- Post discharge follow-up and support via Biologics

**In addition to the potential questions that may arise, here are a few points to keep in mind:**

- Even though the hospital owned pharmacy has requested to dispense CABLIVI for outpatient use, they may not have the payer contract to do so. In this case, the hospital owned pharmacy may contact Biologics SP to fulfill the outpatient order
- Since this action would not be pre-arranged, but more of an internal hospital pharmacy decision, the outpatient prescription request may come to Biologics SP on the same day as patient discharge
- If this should happen, depending on “when” the CABLIVI outpatient prescription is sent to Biologics SP, there may not be adequate time for proper full benefits investigation for coverage of the outpatient prescription

FOR INTERNAL USE ONLY. DO NOT DUPLICATE, DISTRIBUTE, OR USE IN PROMOTION.



# Patient Discharged from Hospital with Treatment at Home

- When a patient is home receiving daily CABLIVI treatments, they are following the treatment regimen prescribed to them by the HCP in the hospital
- CABLIVI treatment at home is an important stage for the patient to complete their CABLIVI treatment regimen
- ABMs have no role in these stages unless requested by appropriate action owner

