Medical Policy:

Cablivi® (caplacizumab-yhdp) intravenous infusion or subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.222	March 3, 2025	April 1, 2019

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Cablivi, a von Willebrand factor (vWF)-directed antibody fragment, is indicated for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP) in adults, in combination with plasma exchange and immunosuppressive therapy. Two doses of Cablivi are given on the first day of plasma exchange, followed by one dose of Cablivi per day during plasma exchange; treatment is continued for 30 days after the last plasma exchange session. If, after the initial treatment course, there are signs of persistent underlying disease such as suppressed ADAMTS13 (A Disintegrin And Metalloproteinase with ThromboSpondin-1 motif, member 13) levels, Cablivi therapy may be extended for a maximum of 28 days. Cablivi should be discontinued if the patient experiences more than two recurrences of aTTP while on Cablivi. Cablivi increases the risk of bleeding; the risk of bleeding is further increased in patients with underlying coagulopathies (e.g., hemophilia, other coagulation factor deficiencies) and in patients receiving Cablivi concomitantly with drugs that affect hemostasis and coagulation.

Length of Authorization

Approve for one course of treatment (up to 60 days following the last plasma exchange session)

Dosing Limits [Medical Benefit]

Approve the following dosing regimens:

A. Day 1 of treatment with plasma exchange: Two doses of Cablivi (11 mg intravenous [IV] bolus prior to plasma exchange followed by an 11 mg subcutaneous [SC] dose after completion of plasma exchange); **AND**
B. 11 mg SC injection up to once daily; **AND**
C. Do not exceed 60 doses following the last plasma exchange session.

Guideline

1. **Acquired Thrombotic Thrombocytopenic Purpura.** Approve for one course of treatment (up to 60 days following the last plasma exchange session) if the patient meets ALL of the following criteria (A, B, C, D, and E):
   A. Patient ≥ 18 years of age; **AND**
   B. Cablivi was initiated in the inpatient setting, in combination with plasma exchange therapy; **AND**
   C. Patient is currently receiving at least one immunosuppressive therapy; **AND**
      Note: Examples include systemic corticosteroids, rituximab (or a rituximab product), cyclosporine, cyclophosphamide, mycophenolate mofetil, hydroxychloroquine, bortezomib.
   D. If the patient has previously received Cablivi, he/she has not had more than two recurrences of acquired thrombotic thrombocytopenic purpura while on Cablivi; **AND**
   E. The medication is prescribed by or in consultation with a hematologist.

Applicable Procedure Codes

Code	Description
C9047	Injection, caplacizumab-yhdp, 1 mg

Applicable NDCs

Code	Description
58468-0225-01	Cablivi 11mg Kit
58468-0227-01	Cablivi 11 mg

ICD-10 Diagnoses

Code	Description
M31.1	Thrombotic microangiopathy
M31.10	Thrombotic microangiopathy, unspecified
M31.11	Hematopoietic stem cell transplantation-associated thrombotic microangiopathy
M31.19	Other thrombotic microangiopathy

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/3/2025	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	3/25/2024	Annual Review: Added NDC 58468-0227-01, Added M31.10, M31.11 and M31.19

EmblemHealth & ConnectiCare	04/04/2023	Transfer from CCUM Template to CoBranded Medical Template Retired MG.MM.PH.185
EmblemHealth & ConnectiCare	02/22/2023	Annual Revision: No criteria changes
EmblemHealth & ConnectiCare	2/09/2022	Acquired Thrombotic Thrombocytopenic Purpura: Clarified the dosing schedule for Day 1 of treatment with plasma exchange – one dose of Cablivi prior to plasma exchange followed by one dose after completion of plasma exchange.

References

1. Cablivi® for injection [prescribing information]. Cambridge, MA: Genzyme; February 2022.