Original Effective Date: 08/2020
Current Effective Date: 09/15/2024
Last P&T Approval/Version: 07/31/2024
Next Review Due By: 07/2025
Policy Number: C19481-A

Cablivi (caplacizumab-yhdp)

PRODUCTS AFFECTED

Cablivi (caplacizumab-yhdp)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Acquired/Immune-mediated thrombotic thrombocytopenic purpura (aTTP/iTTP)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ACQUIRED/IMMUNE-MEDIATED THROMBOTIC THROMBOCYTOPENIC PURPURA:
1. Documented diagnosis of acquired/immune-mediated thrombotic thrombocytopenic purpura (aTTP/iTTP)
   AND
2. Documentation that Cablivi IV was initiated in the inpatient setting in combination with plasma exchange therapy. Submit date of plasma exchange therapy. [DOCUMENTATION

REQUIRED]
AND

3. Documentation that the member is currently receiving at least one immunosuppressive therapy (e.g., systemic corticosteroids at immunosuppressive doses [See Appendix], rituximab [or a rituximab product], cyclosporine, cyclophosphamide, mycophenolate mofetil, hydroxychloroquine, bortezomib)

CONTINUATION OF THERAPY:
NA

DURATION OF APPROVAL:
Initial authorization: Approve for one course of treatment (up to 60 days following the last plasma exchange session), Continuation of therapy: NA
NOTE: 60-day approval allows for administration of Cablivi for 30 days following the last daily plasma exchange and for a 28-day extension in members with persistent underlying disease after the initial treatment course.

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a hematologist. [If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
Day 1 of treatment with plasma exchange: Two doses of Cablivi (11 mg intravenous [IV] bolus and 11 mg subcutaneous [SC] dose)
Treatment during daily plasma exchange: 11 mg SC injection once daily
Treatment after the plasma exchange period: 11 mg SC injection once daily for 30 days beyond the last plasma exchange

Maximum Quantity Limits – 58 days of 11 mg SC injection once daily after the plasma exchange period
NOTE: 60-day approval allows for administration of Cablivi for 30 days following the last daily plasma exchange and for a 28-day extension in members with persistent underlying disease after the initial treatment course.

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous, Subcutaneous

DRUG CLASS:
Anti-von Willebrand Factor Agents

FDA-APPROVED USES:
Indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Systemic corticosteroid immunosuppressive doses include:
≥ 14 days therapy with doses ≥ 80 mg per day of prednisone.
Equivalent doses include:

- ≥ 400mg/day cortisone
- 320mg/day hydrocortisone
- 80mg/day prednisolone
- 64mg/day methylprednisolone
- 12mg/day dexamethasone

The HERCULES trial required that corticosteroid treatment should be initiated/continued with (methyl)prednisolone or (methyl)prednisone regimen of at least 1 mg/kg/day intravenous or oral during the daily plasma exchange period and continued for the 1st week after end of daily plasma exchange.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Acquired thrombotic thrombocytopenic purpura (aTTP) is a rare disease characterized by microangiopathic hemolytic anemia and thrombocytopenia. aTTP is caused by autoantibodies directed against ADAMTS13. Reduced ADAMTS13 activity leads to accumulation of ultra-large vWF multimers in the blood, which bind to platelets and lead to excessive platelet clumping in the microvasculature, resulting in multi-organ failure and death. Cablivi is a nanobody that targets the ultra-large vWF and inhibits the interaction between vWF and platelets, thereby preventing platelet adhesion.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Cablivi (caplacizumab-yhdp) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Cablivi (caplacizumab-yhdp) include: patients with a previous severe hypersensitivity reaction to caplacizumab-yhdp or to any of its excipients. Hypersensitivity reactions have included urticaria. Avoid concomitant use of antiplatelet agents or anticoagulants.

OTHER SPECIAL CONSIDERATIONS:
Serious and fatal bleeding can occur. Risk of bleeding is increased in patients with underlying coagulopathies or on concomitant antiplatelet agents, anticoagulants. If clinically significant bleeding occurs, interrupt treatment. Withhold Cablivi 7 days prior to elective surgery, dental procedures, or other invasive interventions.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J3590	Unclassified biologics

AVAILABLE DOSAGE FORMS:
Cablivi KIT 11 MG single-dose vial

REFERENCES

1. Cablivi® for injection [prescribing information]. Cambridge, MA: Genzyme Corporation; April 2023.
2. Duggan S. Caplacizumab: first global approval. Drugs. 2018;78:1639-1642.
3. Coppo P, Cuker A, George JN. Thrombotic thrombocytopenic purpura: toward targeted therapy and precision medicine. Res Pract Thromb Haemost. 2019;3:26-37.
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5. Scully M, Cataland SR, Peyvandi F, et al. Caplacizumab treatment for acquired thrombotic thrombocytopenic purpura. N Engl J Med. 2019;380:335-346.
6. Scully M, Hunt BJ, Benjamin S, et al. Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies. Br JHaematol. 2012;158:323- 335.
7. Zheng, X. L., Vesely, S. K., Cataland, S. R., Coppo, P., Geldziler, B., Iorio, A., … Peyvandi, F. (2020). ISTH guidelines for treatment of thrombotic thrombocytopenic purpura. Journal of Thrombosis and Haemostasis, 18(10), 2496–2502. doi:10.1111/jth.15010
8. Scully, M., Rayment, R., Clark, A., Westwood, J., Cranfield, T., Gooding, R., … Lester, W. (2023). A British Society for Haematology Guideline: Diagnosis and management of thrombotic thrombocytopenic purpura and thrombotic microangiopathies. British Journal of Haematology, 203(4). https://doi.org/10.1111/bjh.19026

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Required Medical Information Duration of Approval Quantity Drug Class Contraindications/Exclusions/ Discontinuation Available Dosage Forms References	Q3 2024
REVISION- Notable revisions: Required Medical Information Place of Administration Appendix References	Q3 2023
REVISION- Notable revisions: Required Medical Information Prescriber Requirements Other Special Considerations Coding/Billing Information References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file