CareSource

PHARMACY POLICY STATEMENT **North Carolina Marketplace**	
DRUG NAME	Cablivi (caplacizumab-yhdp)
BILLING CODE	Must use valid NDC, or J3590
BENEFIT TYPE	Medical or pharmacy
SITE OF SERVICE ALLOWED	Home/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT—30 vials/30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Cablivi (caplacizumab-yhdp) is a **non-preferred** product and will only be considered for coverage under the **medical** or **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ACQUIRED THROMBOTIC THROMBOCYTOPENIC PURPURA (aTTP)

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a hematologist; AND
3. Member has known or highly likely diagnosis of severe aTTP with ALL of the following:
   a) Lab results showing platelet count less than 100,000[4,5];
   b) Microangiopathic hemolytic anemia (MAHA) confirmed by presence of schistocytes on blood smear;
   c) Documentation of a PLASMIC score between 5 and 7 (intermediate to high risk)[6];
   d) Testing shows an ADAMTS13 activity level less than 10%, OR test has been ordered and results are pending; AND
4. Cablivi was initiated inpatient with plasma exchange and will be continued in combination with immunosuppressive therapy (i.e. glucocorticoids, rituximab) as indicated.
   Note: Rituximab requires prior authorization.
5. **Dosage allowed:** 11mg once daily[1]

If member meets all the requirements listed above, the medication will be approved for 30 days.

For **reauthorization**:

1. Platelet count normalized (at least 150,000) for at least 2 days during treatment; AND
2. ADAMTS13 activity remains less than 20%; AND
3. Member has not experienced more than 2 recurrences (need to restart plasma exchange) of aTTP during treatment (within the same episode or acute event).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 28 days.

CareSource considers Cablivi (caplacizumab-yhdp) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
07/15/2020	New policy for Cablivi created.
11/17/2021	Annual review, no changes

References:

1. Cablivi [package insert]. Cambridge, MA: Genzyme Corporation; 2019.
2. George JN, Cuker A.Acquired TTP: Initial treatment. *UpToDate*. http://www.uptodate.com. Updated September 30, 2019. Accessed July 15, 2020.
3. ISTH Guideline for the Diagnosis and Management of Thrombotic Thrombocytopenic Purpura. https://cdn.ymaws.com/www.isth.org/resource/resmgr/guidance_and_guidelines/ttp_guideline/isth_ttp_guideline_september.pdf. Accessed 7/15/2020.
4. Scully M, Cataland SR, Peyvandi F, et al. Caplacizumab Treatment for Acquired Thrombotic Thrombocytopenic Purpura. *N Engl J Med*. 2019;380(4):335-346. doi:10.1056/NEJMoa1806311
5. Peyvandi F, Scully M, Kremer Hovinga JA, et al. Caplacizumab for Acquired Thrombotic Thrombocytopenic Purpura. *N Engl J Med*. 2016;374(6):511-522. doi:10.1056/NEJMoa1505533
6. Coppo P, Cuker A, George JN. Thrombotic thrombocytopenic purpura: Toward targeted therapy and precision medicine. *Res Pract Thromb Haemost*. 2018;3(1):26-37. Published 2018 Nov 16. doi:10.1002/rth2.12160
7. Assessment report (Cablivi dossier). European Medicines Agency. https://www.ema.europa.eu/en/documents/assessment-report/cablivi-epar-public-assessment-report_en.pdf. Published 2018. Accessed August 20, 2020.

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