Cablivi (caplacizumab-yhdp)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Cablivi (caplacizumab-yhdp)

APPROVAL CRITERIA

Requests for Cablivi (caplacizumab-yhdp) may be approved if the following criteria are met:

I. Individual is 18 years of age; **AND**
II. Individual has a diagnosis or suspected diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP), confirmed by the following:
    A. Documentation is provided that individual presents with severe thrombocytopenia (platelet count <100 x 10^9/L) (ISTH 2020); **AND**
    B. Documentation is provided that individual presents with microangiopathic hemolytic anemia (MAHA) confirmed by red blood cell fragmentation (e.g. schistocytes) on peripheral blood smear; **AND**
    C. Individual is testing for ADAMTS13 activity levels has been completed or in progress;

AND

III. Individual is using in combination with plasma exchange and immunosuppressive therapy for the duration of the daily plasma exchange period; **OR**
IV. Individual is using after completion of plasma exchange for 30 days and has not had more than 2 recurrences/exacerbations of aTTP while on Cablivi therapy (recurrence/exacerbation is defined as thrombocytopenia after initial recovery of platelet count (platelet count ≥ 150,000) that requires re-initiation of daily plasma exchange).

Requests for continuation of Cablivi (caplacizumab-yhdp) subcutaneous use may be approved if the following criteria are met:

I. Individual has received Cablivi initial treatment course (in combination with plasma exchange/immunosuppressive therapy, and for 30 days beyond the last plasma exchange); **AND**
II. Documentation is provided that individual has confirmed signs of persistent underlying disease (e.g. ongoing suppressed ADAMTS13 activity levels) present after initial treatment course; **AND**
III. Documentation is provided that individual has not had more than 2 recurrences/exacerbations of aTTP while on caplacizumab-yhdp therapy (recurrence/exacerbation is defined as thrombocytopenia after initial recovery of platelet

count (platelet count ≥ 150,000) that requires re-initiation of daily plasma exchange); **AND**

IV. Individual is using for a maximum of 28 total additional days (given consecutively).

Cablivi (caplacizumab-yhdp) may not be approved when the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: April 16, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Zheng XL, Vesely SK, Cataland SR, et. al. ISTH Guidelines for the Diagnosis of Thrombotic Thrombocytopenic Purpura. International Society on Thrombosis and Haemostasis. 2020. J Thromb Haemost. 2020;18:2486–2495. Available at https://www.isth.org/page/TTPGuidelines. Accessed on April 19, 2021.
5. Zheng XL, Vesely SK, Cataland SR, et. al. ISTH Guidelines for Treatment of Thrombotic Thrombocytopenic Purpura. International Society on Thrombosis and Haemostasis. 2020. J Thromb Haemost. 2020;18:2496–2502. Available at https://www.isth.org/page/TTPGuidelines. Accessed on April 19, 2021.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.