

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

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. Individual presents with severe thrombocytopenia; **AND**
 - B. 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 \geq 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. Individual has confirmed signs of persistent underlying disease (e.g. ongoing suppressed ADAMTS13 activity levels) present after initial treatment course; **AND**

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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- III. 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 \geq 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).

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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 24, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.

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