Cablivi (caplacizumab-yhdp)

Coverage Criteria:

1. Patient is an adult diagnosed with acquired thrombotic thrombocytopenic purpura (aTTP) including the following:
   A. Thrombocytopenia with platelet count <100,000/microL (100x10E9/L), and,
   B. Includes microscopic evidence of red blood cell fragmentation (e.g., schistocytes),and,
2. Documentation of one of the following related to ADAMTS13:
   A. Severe ADAMTS13 deficiency (activity levels of less than 10%), or,
   B. ADAMTS deficiency (activity levels of >10% but <30%), with clinical rationale supporting the diagnosis of aTTP; or,
   C. ADAMTS13 has been ordered but lab results are not yet available; and,
3. Prescribed by a hematology/oncology specialist; and,
4. Prescribed in combination with plasma exchange and immunosuppressive therapy (such as high-dose glucocorticoids and/or rituximab; and
5. Cablivi will be discontinued if patient experiences more than 2 recurrences of aTTP while on Cablivi; and,
6. Thrombocytopenia due to another cause has been ruled out, including sepsis, infection with E. coli 0157, atypical hemolytic uremic syndrome, disseminated intravascular coagulation, or congenital thrombotic thrombocytopenic purpura; and,
7. Prescribed within the FDA approved regimen.

Renewal Criteria:

Reauthorization Criteria for extended self-administered treatment of an ongoing episode:

1. Prescribed by a hematology/oncology specialist; and,
2. Patient has been adherent to previous aTTP treatment protocol including Cablivi; and
3. Documentation of ADAMTS13 activity, and one of the following:
   A. Continued ADAMTS13 severe deficiency (activity levels of less than 10%), or,
   B. ADAMTS deficiency (activity levels of >10% but <30%), with clinical rationale supporting persistent disease with the continued need for Cablivi; and,
4. Prescribed in combination with plasma exchange and immunosuppressive therapy (such as high-dose glucocorticoids and/or rituximab; and,
5. Patient has not experienced more than 2 recurrences of aTTP while on Cablivi; and ,
6. Prescribed within the FDA approved regimen.

Reauthorization Criteria for subsequent isolated episodes:

Patients previously treated successfully with Cablivi, with a new isolated episode of aTTP will be reviewed against the same initial and re-authorization criteria as the first episode.

Isolated episode is defined as a new occurrence of aTTP following complete resolution of aTTP and discontinuation of Cablivi, with at least 30 days of clinical stability between episodes.

Other Criteria:

Professional administration will be approved for first dose administered intravenously. A medical benefit prior authorization is required for the initial single, intravenous dose.

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Effective Date: 7/1/2019

All subsequent doses should be self-administered subcutaneously by the patient and filled by a specialty pharmacy. A pharmacy benefit prior authorization is required for all doses after the initial intravenous dose.