

**Cablivi (caplicizumab-yhdp)
Effective 01/01/2022**

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Cablivi is indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

Coverage Guidelines

Authorization may be granted for a total of 30 days for members who are currently receiving treatment with Cablivi excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. The member has a diagnosis is acquired thrombotic thrombocytopenic purpura (aTTP) after receiving plasma exchange in the inpatient setting
2. The requested medication will be given in combination with immunosuppressive therapy.
3. Member is \geq 18 years of age
4. Therapy is prescribed by or in consultation with a hematologist

Continuation of Therapy

Reauthorizations are limited to 28 days of therapy for continuation when all the following criteria is met:

- a. The member has either of the following documented signs of persistent underlying aTTP:
 - i. ADAMTS13 activity level less than 10% or
 - ii. All of the following:
 1. Microangiopathic hemolytic anemia (MAHA) documented by the presence of schistocytes on peripheral smear

2. Thrombocytopenia (platelet count below normal per laboratory reference range),
and
 - b. Elevated lactate dehydrogenase (LDH) level (LDH level above normal per laboratory reference range)
 - c. The requested medication will be given in combination with immunosuppressive therapy.
 - d. The member has not received a prior 28 day extension of therapy after the initial course of the requested medication for this course of treatment.
 - e. The member has not experienced more than 2 recurrences of aTTP while on the requested medication. (A recurrence is when the patient needs to reinitiate plasma exchange. A 28-day extension of therapy does not count as a recurrence.)

Limitations

1. Initial approvals are limited to 30 days of therapy
2. Reauthorizations are limited to 28 days of therapy

References

1. Cablivi [package insert]. Cambridge, MA: Genzyme Corporation; February 2019.
2. Scully M, Cataland SR, Peyvandi F; et al. Caplacizumab treatment for acquired thrombotic thrombocytopenic purpura. *N Engl J Med.* 2019;380(4):335-346.
3. Sadler JE. Pathophysiology of thrombotic thrombocytopenic purpura. *Blood.* 2017;130(10):1181-1188.
4. Scully M, Cataland S, Coppo P, et al. Consensus on the standardization of terminology in thrombotic thrombocytopenic purpura and related thrombotic microangiopathies. *J Thromb Haemost.* 2017; 15(2):312-322.
5. Scully M, Hunt BJ, Benjamin S, et al. Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies. *Br J Haematol.* 2012;158(3):323-335.
6. Westwood JP, Thomas M, Alwan F, et al. Rituximab prophylaxis to prevent thrombotic thrombocytopenic purpura relapse: outcome and evaluation of dosing regimens. *Blood Adv.* 2017; 1(15):1159-1166.

Review History

09/22/2021 – Reviewed at Sept P&T; no clinical changes; separated out MH vs. Comm/Exch. Effective 01/01/2022

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