



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 26, 2024

## Adzynma™ (ADAMTS 13, recombinant-krhn)

### **LENGTH OF AUTHORIZATION:**

Initial Therapy: On Demand enzyme replacement therapy (ERT) - Up to 2 months

Prophylactic enzyme replacement therapy (ERT) - 6 months

Continuation of Therapy: Prophylactic enzyme replacement therapy (ERT) - 6 months

### **REVIEW CRITERIA:**

- Patient must be  $\geq 2$  years of age; **AND**
- Patient must have a documented diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) confirmed by the following:
  - Molecular genetic testing showing mutation in the ADAMTS13 gene; **AND**
  - ADAMTS 13 activity testing showing less than 10% of normal activity.
- Drug must be prescribed for Prophylactic **OR** On Demand ERT, and the following requirements (per diagnosis) must apply (*official labs required*):
  - **For Prophylactic ERT:**
    - Platelet count  $> 100,000/\mu\text{L}$ ; **AND**
    - Lactate dehydrogenase (LDH)  $> 2$  times the upper limit of normal (ULN) as defined by laboratory values.
  - **For On Demand ERT**, the patient must present with the following:
    - $\geq 50\%$  drop in platelet count or platelet count  $< 100,000/\mu\text{L}$ ; **AND**
    - LDH  $< 2$  times the ULN as defined by laboratory values.

### **CONTINUATION OF THERAPY:**

- Patient met initial review criteria; **AND**
- Documentation of improved clinical response (e.g., decrease in incidence of acute/subacute TTP events and TTP manifestations, a decreased incidence of supplemental therapy administration); **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

### **DOSING AND ADMINISTRATION:**

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as a lyophilized powder in single-dose vials containing nominally 500 or 1500 international units.