

## adamts13 recombinant-krhn (Adzynma)

### Medical Benefit Drug Policy

#### Place of Service

Home infusion administration  
Infusion center administration  
Office administration  
Outpatient facility administration

### Drug Details

**USP Category:** GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT

**Mechanism of Action:** Bivariant human recombinant form of endogenous ADAMTS13

#### HCPCS:

J7171:Injection, adamts13, recombinant-krhn, 10 iu

#### How Supplied:

500 or 1500 international units (lyophilized powder in single-dose vials)

### Condition(s) listed in policy *(see coverage criteria for details)*

- Congenital Thrombotic Thrombocytopenic Purpura (cTTP)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

### Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

### Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

#### Congenital Thrombotic Thrombocytopenic Purpura (cTTP)

Meets medical necessity if all the following are met:

1. Presence of severe hereditary ADAMTS13 deficiency as confirmed by one of the following:
  - a. ADAMTS13 activity <10% as measured by the fluorescent resonance energy transfer-von Willebrand factor 73 (FRETs-VWF73) assay
  - b. Molecular genetic testing showing biallelic pathogenic variants in ADAMTS13

### Covered Doses:

Prophylactic therapy: 40 IU/kg given intravenously (IV) every other week or once a week  
On-demand therapy: 40 IU/kg given IV on day 1, 20 IU/kg given IV on day 2, 15 IU/kg given IV on day 3 and beyond until two days after the acute event is resolved

**Coverage Period:**

Prophylactic therapy:

Initial: 6 months

Reauthorization: Yearly if meets the below

1. Documentation of clinical benefit as evidenced by a reduction in acute TTP events (e.g., microangiopathic hemolytic anemia episodes, stroke/transient ischemic attacks, etc.)

On-demand therapy: Dependent on timeframe of acute event

**ICD-10:**

M31.10

**References**

1. Adzynma (ADAMTS13 recombinant-krhn) Prescribing Information. Takeda, Lexington, MA: 6/2024.
2. AHFS. Available by subscription at <http://www.lexi.com>
3. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>

**Review History**

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- No clinical change following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity  
Reviewed by P&T Committee*