adamts13 recombinant-krhn (Adzynma)

Commercial 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 Health and Safety Code section 1367.21 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.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF ADZYNMA IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is initiating therapy with Adzynma (allowed for 1 month) or is being re-initiated on Adzynma after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Adzynma based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Adzynma based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

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 (ADAMTSI13 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