| AETNA BETTER HEALTH®<br>Coverage Policy/Guideline | | | |
|---|---|---|---|
| Name: | Adzynma (ADAMTS13, recombinant-krhn) | Page: | 1 of 2 |
| Effective Date: | 3/26/2024 | Last Review Date: | 01/26/2024 |
| Applies to: | ☒Illinois<br>☒Maryland<br>☐Michigan | ☐Florida<br>☒Florida Kids<br>☒ Virginia | ☒New Jersey<br>☒Pennsylvania Kids<br>☒Kentucky PRMD |

## Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Adzynma under the patient's prescription drug benefit.

## Description:

FDA-Approved Indication

Adzynma is indicated for prophylactic or on demand enzyme replacement therapy (ERT) in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP).

All other indications are considered experimental/investigational and not medically necessary.

## Applicable Drug List:

Adzynma

## Policy/Guideline:

**Documentation**

**Submission of the following information is necessary to initiate the prior authorization review:**

A. Initial requests:
   ADAMTS13 enzyme assay and ADAMTS13 genetic testing results supporting the diagnosis.
B. Continuation of therapy requests:
   Medical records (e.g., chart notes, lab reports) documenting a response to therapy (e.g., reduction or maintenance of number of thrombotic thrombocytopenic purpura [TTP] events, increase in platelet count, decrease in lactate dehydrogenase [LDH] level).

**Criteria for Initial Approval**

**Congenital thrombotic thrombocytopenic purpura (cTTP)**

**Authorization may be granted for the treatment of congenital thrombotic thrombocytopenic purpura (cTTP) when BOTH of the following criteria are met:**

A. The diagnosis of cTTP has been confirmed by genetic testing with biallelic mutations in the ADAMTS13 gene.
B. Member has an ADAMTS13 activity level of less than 10% at the time of diagnosis.

**Continuation of Therapy**

**Authorization may be granted for continued treatment when the following criteria are met:**

A. Member is responding to therapy (e.g., reduction or maintenance of number of thrombotic thrombocytopenic purpura [TTP] events, increase in platelet count, decrease in lactate dehydrogenase [LDH] level).

## Approval Duration and Quantity Restrictions:

**Initial Approval:** 6 Months
**Renewal Approval:** 12 Months

**Quantity Level Limit:** Reference Formulary for drug specific quantity level limits

## References:

1. Adzynma [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; November 2023.
2. Asmis LM, Serra A, Krafft A, et al. Recombinant ADAMTS13 for Hereditary Thrombotic Thrombocytopenic Purpura. N Engl J Med 2022; 387: 2356-2361.