# Adzynma® (ADAMTS13, recombinant-krhn)

Effective Date: 7/1/24
Medical Care Management Committee Approval: 4/25/24

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## Coverage Policy

This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures, medications and therapy. This Guideline does not address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This policy applies to the following Adzynma® (ADAMTS13, recombinant-krhn) product:

| HCPCS Code | Description |
|---|---|
| J3490 | Unclassified drugs |
| J3590 | Unclassified biologics |

## Initial Coverage Criteria

Adzynma® (ADAMTS13, recombinant-krhn) will be considered medically necessary for members meeting ALL of the following criteria:

1. Diagnosis of congenital thrombotic thrombocytopenia purpura (cTTP); AND
2. Adzynma is prescribed by or in consultation with a hematologist; AND
3. Member has ADAMTS13 mutation confirmed by molecular genetic testing AND serum assay showing less than 10% of normal ADAMTS13 enzyme activity; AND
4. Adzynma will be used as monotherapy for congenital thrombotic thrombocytopenia purpura (cTTP)

## Criteria for Continuation of Coverage

1. No evidence of intolerable adverse effects from Adzynma
2. Documentation of positive response to therapy
3. Adzynma will continue to be used as monotherapy for chronic thrombotic thrombocytopenia (cTPP)

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive.

| HCPCS Code | Description |
|---|---|
| J3490 | Unclassified drugs |
| J3590 | Unclassified biologics |

| Diagnosis Code | Description |
|---|---|
| D69.42 | Congenital and hereditary thrombocytopenia purpura |

## Policy Revision History

| Status | Effective Date | Description |
|---|---|---|
| Baseline | 7/1/24 | Initial version of Adzynma Review Guideline |