Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 325.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Adzynma (ADAMTS13, recombinant-krhn)

I. Policy:
Adzynma (ADAMTS13, recombinant-krhn)

II. Purpose/Objective:
To provide a policy of coverage regarding Adzynma (ADAMTS13, recombinant-krhn)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Adzynma (ADAMTS13, recombinant-krhn) is a recombinant form of the endogenous ADAMTS13. ADAMTS13 is a plasma zinc metalloprotease that regulates the activity of von Willebrand factor (VWF) by cleaving large and ultralarge VWF multimers to smaller units and thereby reducing the platelet binding properties of VWF and its propensity to form microthrombi.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Adzynma (ADAMTS13, recombinant-krhn) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Medical record documentation that Adzynma is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis congenital thrombotic thrombocytopenia purpura (TTP) and both of the following:
    - Documentation of confirmed molecular genetic testing **AND**
    - Documentation of ADATS13 activity less than 10% of normal activity as measured by the fluorescent resonance energy transfer-von Willebrand factor 73 (FRETS-VWF73) assay

AND

- If being used for prophylactic treatment: Medical record documentation that member is currently receiving prophylactic therapy OR medical record documentation of at least one thrombotic thrombocytopenia purpura (TTP) event

AUTHORIZATION DURATION: Initial approval will be for **6 months** or less if the reviewing provider feels it is medically necessary. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically necessary. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of a positive clinical response as defined by one of the following:
    - Documentation of a reduction in or improvement in acute and subacute thrombotic thrombocytopenia purpura (TTP) events **OR**
    - Documentation of an improvement in clinical symptoms of congenital thrombotic thrombocytopenia purpura (TTP) **OR**
    - If used for on-demand Adzynma treatment, documentation of improved platelet level to greater than or equal to 150,000/µL or platelet count within 25% of baseline (prior to the acute event)

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Adzynma [Prescribing Information]. Lexington MA. Takeda Pharmaceutical Company Limited. November 2023.
2. Scully M, Antun A, Cataland SR, et al. Recombinant ADAMTS13 in Congenital Thrombotic Thrombocytopenic Purpura. New England Journal of Medicine. 2024;390:1584-1596 [cited 2024 Jul 26]. Available from: https://www.nejm.org/doi/10.1056/NEJMoa2314793?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 5/21/24

Revised:

Reviewed:

MA UM Committee approval: 8/30/24