ATRIO HEALTH PLANS

Adzynma

Adzynma (ADAMTS13 recomb-krhn) J7171

Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ Patient has a diagnosis of severe congenital thrombotic thrombocytopenic purpura (cTTP); AND
☐ Patient is using for on-demand treatment; AND
☐ Documentation is provided that individual has the following (A and B) (NCT03393975, NCT04683003):
  ☐ Molecular genetic testing showing mutation in the ADAMTS13 gene; AND
  ☐ ADAMTS13 activity testing showing less than 10% of normal ADAMTS13 activity; AND
☐ Documentation is provided that individual is experiencing a 50% or greater drop in platelet count or platelet count is less than 100,000/microliter; AND
☐ Lactate dehydrogenase elevation (LDH) is more than 2 times baseline or more than 2 times upper limit of normal (ULN) as defined by laboratory values;

OR

☐ Patient has a diagnosis of severe congenital thrombotic thrombocytopenic purpura (cTTP); AND
☐ Patient is using for prophylactic treatment; AND

☐ Documentation is provided that individual has the following (A and B):
- ☐ Molecular genetic testing showing mutation in the ADAMTS13 gene; AND
- ☐ ADAMTS13 activity testing showing less than 10% of normal ADAMTS13 activity; AND

☐ Documentation is provided that individual presents with platelet count greater than 100,000/ microliter; AND

☐ Patient presents with lactate dehydrogenase (LDH) less than 2 times the upper limit of normal (ULN) as defined by laboratory values.

Requests for Adzynma (ADAMTS13, recombinant-krhn) may not be approved for the following:
- Patient is diagnosed with acquired idiopathic or secondary forms of thrombotic thrombocytopenic purpura

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**

If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Documentation is provided that individual is using on-demand treatment and platelet counts increase to at least 150,000/microliter or increases to 25% from baseline platelet counts; OR

☐ Documentation is provided that individual is using for prophylactic treatment and individual has decreased number of TTP events.

☐ If not, please provide clinical rationale for continuing this medication:

_____
_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Adzynma PA

Drug Name(s):

ADZYNMA **ADAMTS13, RECOMBINANT-KRHN**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Initial approval will be for 6 months. Continuation may be approved for up to 12 months.

FDA Indications:

Adzynma

- Thrombotic thrombocytopenic purpura, Congenital; Treatment and Prophylaxis

Off-Label Uses:

- N/A

Age Restrictions:

N/A

Other Clinical Considerations:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?navitem=headerLogout#