Mass General Brigham
Health Plan

Adzynma (ADAMTS13, recombinant-krhn)
Effective 10/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Adzynma (ADAMTS13, recombinant-krhn) is a human recombinant "A disintegrin and metalloproteinase with thrombospondin motifs 13" (rADAMTS13) indicated for prophylactic or on demand enzyme replacement therapy (ERT) in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP).

Coverage Guidelines
Authorization may be granted for members who are new to the plan within the last 90 days currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. Member has diagnosis of severe hereditary ADAMTS13 deficiency, defined as BOTH of the following:
    a. Molecular genetic testing
    b. ADAMTS13 activity < 10%, as measured by the fluorescent resonance transfer energy -von Willebrand factor73 (FRETS-VWF73) assay
2. The requested medication is prescribed by or in consultation with a hematologist, oncologist, or intensive care specialist

Continuation of Therapy
Reauthorization may be granted when the following criteria are met:

1. Documentation the member has experienced a positive response to therapy (e.g., improvement in TTP events, platelet counts, clinical symptoms, etc)

Limitations

1. Initial approvals will be granted for 6 months

2. Reauthorization approvals will be granted for 12 months

References

1. Adzynma [package insert], Lexington, MA: Takeda Pharmaceuticals, U.S.A, Inc.; November 2023.
2. Alwan F, Vendramin C, Liesner R, et al. Characterization and treatment of congenital thrombotic thrombocytopenic purpura *Blood*. 2019;133(15):1644-1651.
3. Asmis LM, Serra A, Krafft A, et al. Recombinant ADAMTS13 for hereditary thrombotic thrombocytopenic purpura. *NEJM*. 2022;387:2356-2361.
4. Scully M, Knöbl P, Kentouche K, et al. Recombinant ADAMTS-13: first-in-human pharmacokinetics and safety in congenital thrombotic thrombocytopenic purpura. *Blood*. 2017;130(19):2055-2063.
5. Scully M, Rayment R, Clark A, et al. A British Society for Haematology Guideline: Diagnosis and management of thrombotic thrombocytopenic purpura and thrombotic microangiopathies. *Br J Haematol*. 2023;203(4):546-563.
6. Zheng XL, Vesely SK, Cataland SK, et al. ISTH guidelines for treatment of thrombotic thrombocytopenic purpura. *J Thromb Haemost.* 2020;18(10):2496-2502.

Review History

08/14/2024 – Reviewed at August P&T. Effective 10/01/2024.