Pharmacy Drug Policy & Procedure

Policy Name:	Adzynma (ADAMTS13 Recombinant)	Policy#:	3232P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Adzynma (ADAMTS13 Recombinant)

Statement of the Policy

Health Alliance Medical Plans will approve the use of Adzynma (ADAMTS13 Recombinant) under the specialty medical benefit if the following criteria are met.

Criteria

1. Coverage Criteria

1.1 Diagnosis of severe congenital (hereditary) thrombotic thrombocytopenic purpura (cTTP) confirmed by both of the following:
- Genetic testing showing mutation in the ADAMTS13 gene
- ADAMTS13 enzyme activity testing showing <10% of normal ADAMTS13 activity in the absence of ADAMTS13 antibodies (patients currently receiving prophylactic therapy may exceed 10% ADAMTS13 enzyme activity level at screening)

1.2 Prescribed by or in consultation with a hematologist (blood doctor), oncologist (cancer doctor) or other specialist in blood disorders

1.3 For on-demand therapy: documentation that patient is experiencing a 50% or greater drop in platelet count or platelet count is <100,000/microliter

1.4 For prophylactic therapy: patient must have a history of at least one documented TTP event while receiving prophylactic plasma based therapy

1.5 Requests for coverage must be reviewed by both a pharmacist and medical director

2. Exclusion Criteria

2.1 Diagnosis of acquired or immune mediated thrombotic thrombocytopenic purpura (iTTP) or any other thrombocytopenic disorder

3. Approval Period

3.1 Initial: 12 months

3.2 Reauth: 12 months with documentation of positive clinical response such as improvement in acute and subacute TTP events, platelet counts, microangiopathic hemolytic anemia episodes, or clinical symptoms

CPT Codes	
HCPCS Codes	
J7171	Injection, adamts13, recombinant-krhn, 10 iu

References

1. Adzynma (ADAMTS13 Recombinant) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals USA Inc; November 2023.
2. Zheng XL, Vesely SK, Cataland SR, et al. ISTH guidelines for treatment of thrombotic thrombocytopenic purpura. J Thromb Haemost. 2020;18(10):2496-2502.
3. Scully M, Rayment R, Clark A, et al; BSH Committee. A British Society for Haematology guideline: diagnosis and management of thrombotic thrombocytopenic purpura and thrombotic microangiopathies. Br J Haematol. 2023;203(4):546-563

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