

PA Criteria	Criteria Details						
Covered Uses (FDA approved indication)	Adzynma is a human recombinant form of the A disintegrin and metalloproteinase with thrombospondin motifs 13 enzyme (rADAMTS13). The ADAMTS13 protein is involved with blood clotting. Adzynma replaces the missing or deficient ADAMTS13 enzyme in patients diagnosed with congenital thrombotic thrombocytopenic purpura (cTTP). TTP is a rare blood disorder that results in blood clots forming in small blood vessels throughout the body which can cause ischemic end organ damage.						
Exclusion Criteria	None.						
Required Medical Information	For initial and reauthorization requests: Medical records supporting the request must be provided, including the patient's current weight for dosing purposes. For initial requests: Must also have one genetic testing confirming the diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP); and two ADAMTS13 activity less than 10%.						
Other Criteria	For initial requests: The initial dosing frequency for prophylactic use must be every 2 weeks. The frequency may be adjusted to once weekly based on prior prophylactic dosing regimen or clinical response and supporting documentation is required. For reauthorization requests: Must demonstrate a beneficial response to therapy (e.g., decrease in acute and subacute TTP events, improvement in platelet count from baseline, decrease in microangiopathic hemolytic anemia episodes).						
Age Restriction	None.						
Prescriber Restrictions	Must be prescribed by, or in consultation with, a specialist for the disease state.						
Coverage Duration	Initial: 12 months. Reauthorization: 12 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.						
Other Criteria/Information	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. <table border="1" data-bbox="496 1346 1511 1491"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J7171</td> <td>Adzynma (ADAMTS13, recombinant-krhn)</td> <td>Billing Unit 10 IU 500 IU SDV, 1500 IU SDV</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J7171	Adzynma (ADAMTS13, recombinant-krhn)	Billing Unit 10 IU 500 IU SDV, 1500 IU SDV
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	5/15/2025	Pharmacy & Therapeutics (P&T) Committee	5/15/2025