Clinical Policy Title:	betaine
Policy Number:	RxA.087
Drug(s) Applied:	Cystadane®
Original Policy Date:	02/07/2020
Last Review Date:	4/1/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Homocystinuria (must meet all):

1. Diagnosis of homocystinuria confirmed by one of the following (a, b, or c):
   a. Cystathionine beta-synthase (CBS) deficiency;
   b. 5,10-methylenetetrahydrofolate reductase (MTHFR) deficiency;
   c. Cobalamin cofactor metabolism (cbl) defect;

2. Prescribed by or in consultation with a metabolic or genetic disease specialist;

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Homocystinuria (must meet all):

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Morris AAM, Kozich V, Santra S, et al. Guidelines for the diagnosis and management of cystathionine beta-synthase deficiency. J Inherit Metab Dis 2017; 40:49-74. Available at: https://pubmed.ncbi.nlm.nih.gov/27778219/. Accessed March 28, 2024.
2. Huemer M, Diodato D, Schwahn B, et al. Guidelines for diagnosis and management of the cobalamin-related remethylation disorders cblC, cblD, cblE, cblF, cblG, and MTHFR deficiency. J Inherit Metab Dis 2017; 40:21-48. Available at: https://pubmed.ncbi.nlm.nih.gov/27905001/. Accessed March 28, 2024

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
No changes	04/2020	
Policy was reviewed:	02/05/2021	03/09/2021

1) Continuation therapy criteria II.A.1. rephrased to “Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy 2) Initial therapy and continued therapy approval duration updated & HIM deleted 3) References were updated 4) Updated the approval coverage duration for continuation of therapy to 12 months.		
Policy was reviewed: 1) References were reviewed and updated.	12/06/2021	01/17/2022
Policy was reviewed: 1) References were reviewed and updated.	10/03/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1) Removed dosing criteria. 2) Removed reauthorization requirement for positive response to therapy. 3) Updated the initial approval coverage duration to 12 months. 4) References were reviewed and updated.	3/28/2024	4/1/2024