

Clinical Policy Title:	betaine
Policy Number:	RxA.087
Drug(s) Applied:	Cystadane®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
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 associated with 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 metabolic or genetic disease specialist;
3. Dose does not exceed 20 gm per day or 150 mg/kg/day, whichever is greater, in two divided doses.

Approval Duration

Commercial: 6 months

Medicaid: 6 months

II. Continued Therapy Approval

A. Homocystinuria (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 20 gm per day or 150 mg/kg/day, whichever is greater, in two divided doses.

Approval Duration

Commercial: 12 months

Medicaid: 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 October 3, 2022.
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 October 3, 2022.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
No changes	04/2020	
Policy was reviewed: <ol style="list-style-type: none"> 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. 	02/05/2021	03/09/2021
Policy was reviewed: <ol style="list-style-type: none"> 1) References were reviewed and updated. 	12/06/2021	01/17/2022
Policy was reviewed: <ol style="list-style-type: none"> 1. References were reviewed and updated. 	10/03/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023