MEDICAL MUTUAL®

Drug Policy

Policy: **Impacted Drugs:**	**Cystadane (betaine anhydrous) powder for oral solution** **Betaine anhydrous powder for oral solution**	**Annual Review Date:** **09/21/2023** **Last Revised Date:** **09/21/2023**

OVERVIEW

Betaine anhydrous powder (Cystadane, generic), a methylating agent, is indicated for the treatment of **homocystinuria** to decrease elevated homocysteine blood concentrations in pediatric and adult patients.[1]

POLICY STATEMENT

This policy involves the use of Cystadane. Prior authorization is recommended for pharmacy benefit coverage of Cystadane. Approval is recommended for those who meet the conditions of coverage in the Criteria and Initial/Extended Approval for the diagnosis provided. Conditions Not Recommended for Approval are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

RECOMMENDED AUTHORIZATION CRITERIA

For all indications: If brand Cystadane is prescribed, the patient must have tried generic betaine anhydrous AND the brand product is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand product and the bioequivalent generic product which, per the prescribing provider, would result in a significant allergy or serious adverse reaction [documentation required]; AND

1. **Homocystinuria.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   - **A)** Patient has a confirmed diagnosis based on genetic testing demonstrating one of the following (i, ii, or iii):
     - **i.** Cystathionine beta-synthase deficiency; OR
     - **ii.** 5,10-methylenetetrahydrofolate reductase deficiency; OR
     - **iii.** Cobalamin cofactor metabolism defect; AND
   - **B)** Patient has tried or is concurrently receiving vitamin B6 (pyridoxine), vitamin B12 (cobalamin), or folate supplementation; AND
   - **C)** The medication is prescribed by or in consultation with a geneticist, metabolic disease specialist, or a physician who specializes in the management of homocystinuria.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Cystadane® powder [prescribing information]. Lebanon, NJ: Recordati Rare Diseases; November 2018.