PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Metabolic Disorders – Betaine Anhydrous Preferred Specialty Management Policy
- Cystadane® (betaine anhydrous powder – Recordati Rare Diseases, generic)

REVIEW DATE: 08/10/2022

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 Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The program directs the patient to try one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for the duration noted below. If the patient has not tried a Preferred Product, approval for a Preferred Product will be authorized.

Documentation: Documentation is required for use of betaine anhydrous powder as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

Automation: None.

Preferred Product: generic betaine anhydrous powder
Non-Preferred Product: Cystadane powder

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Cystadane	**1.** Approve for 1 year if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Metabolic Disorders – Betaine Anhydrous PA Policy* criteria; AND **B)** Patient meets BOTH of the following (i and ii): **i.** Patient has tried generic betaine anhydrous powder **[documentation required]**; AND **ii.** Patient cannot continue to use the Preferred Product due to a formulation difference in the inactive ingredient(s) [e.g., differences in the stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**.

REFERENCES

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