



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BETAINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BETAINE	CYSTADANE, BETAINE ANHYDROUS	12233		GPI-10 (3090452000)	

GUIDELINES FOR USE

- Does the patient have a diagnosis of homocystinuria (including cystathionine beta-synthase (CBS) deficiency, 5,10-methylenetetrahydrofolate reductase (MTHFR) deficiency, and cobalamin cofactor metabolism (cbl) defect)?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #20 grams per day.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BETAINE (Cystadane)** requires the following rule(s) be met for approval:

- You have homocystinuria (a type of genetic metabolic disorder), including cystathionine beta-synthase (CBS: a type of enzyme) deficiency, 5,10-methylenetetrahydrofolate reductase (MTHFR: a type of enzyme) deficiency, and cobalamin cofactor metabolism (cbl: vitamin B12 that is required for enzyme activity) defect

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cystadane.

REFERENCES

- Cystadane [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/23

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