Procysbi (cysteamine bitartrate) Prior Authorization Program Summary

POLICY REVIEW CYCLE

Effective Date	Date of Origin
3/1/2023	

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Procysbi® (cysteamine bitartrate delayed release) Oral capsule, oral granules	Treatment of nephropathic cystinosis in adults and pediatric patients 1 year and older		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

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Efficacy(1)	A multicenter, open-label, randomized clinical trial was completed comparing Procysbi to immediate-release cysteamine bitartrate (Cystagon). All patients were required to be on a stable dose of immediate-release cysteamine bitartrate prior to randomization.

	The study demonstrated that Procysbi administered every 12 hours was non-inferior to immediate-release cysteamine bitartrate dosed every 6 hours.
Safety(1)	Procysbi is contraindicated in patients with a serious hypersensitivity reaction, including anaphylaxis, to penicillamine or cysteamine.

REFERENCES

Number	Reference
1	Procysbi prescribing information. Horizon Pharma USA, Inc. February 2022.
2	Elmonem MA, Veys KR, Soliman NA, van Dyck M, van den Heuvel LP, Levtchenko E. (2016) Cystinosis: A review. Orphanet J Rare Dis 11:47. DOI: 10.1186/s13023-016-0426-y

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Preferred Status	Effective Date
Procysbi	cysteamine bitartrate cap delayed release	25 MG ; 75 MG	M ; N ; O ; Y	N		
Procysbi	cysteamine bitartrate delayed release granules packet	300 MG ; 75 MG	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Procysbi	cysteamine bitartrate cap delayed release	25 MG ; 75 MG	Commercial ; HIM ; ResultsRx
Procysbi	cysteamine bitartrate delayed release granules packet	300 MG ; 75 MG	Commercial ; HIM ; ResultsRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has an FDA approved indication for the requested agent **AND** 2. ONE of the following: A. The patient's age is within FDA labeling for the requested indication **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to Cystagon (immediate release cysteamine) **OR** B. The patient has an intolerance or hypersensitivity to Cystagon that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to Cystagon that is not expected to occur with the requested agent **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

