



Procysbi Prior Authorization Program Summary

POLICY REVIEW CYCLE

Effective Date
12-15-2025

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

| Target Brand Agent(s) | Target Generic Agent(s) | Strength | Targeted MSC | Available MSC | Final Age Limit | Preferred Status |
|-----------------------|---|----------------|---------------|---------------|-----------------|------------------|
| 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 | Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods |
| Procysbi | cysteamine bitartrate delayed release granules packet | 300 MG ; 75 MG | Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual |

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|----------------------------|------------------------------|----------|----------------------------|
| | | | 2026 ; Topaz ; Whole Foods |

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

| Module | Clinical Criteria for Approval |
|--------|--|
| | <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of nephropathic cystinosis OR B. The patient has another FDA labeled indication for the requested agent and route of administration OR C. The patient has an indication that is supported in compendia for the requested agent and route of administration AND 2. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication OR B. There is support for using the requested agent for the patient's age for the requested indication AND 3. ONE of the following: <ol style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] OR C. The patient has tried and had an inadequate response to Cystagon (immediate release cysteamine) [chart notes are required] OR D. Cystagon (immediate release cysteamine) was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR E. The patient has an intolerance or hypersensitivity to Cystagon (immediate release cysteamine) that is not expected to occur with the requested agent [chart notes are required] OR F. The patient has an FDA labeled contraindication to Cystagon (immediate release cysteamine) that is not expected to occur with the requested agent [chart notes are required] OR G. Cystagon (immediate release cysteamine) is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes are required] OR H. Cystagon (immediate release cysteamine) is not in the best interest of the patient based on medical necessity [chart notes are required] OR I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as Cystagon (immediate release cysteamine) and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] AND 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Compendia Allowed: AHFS or DrugDex 1, 2a, or 2b level of evidence</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months All other plans: 12 months</p> |

| Module | Clinical Criteria for Approval |
|--------|---|
| | <p>The requested agent will also be approved when ALL the following are met:</p> <ol style="list-style-type: none"> 1. The member resides in Ohio AND 2. The plan is Fully Insured or HIM Shop (SG) AND 3. The patient does NOT have any FDA labeled contraindications to the requested agent AND 4. ONE of the following: <ol style="list-style-type: none"> A. The patient has another FDA labeled indication for the requested agent and route of administration OR B. The patient has another indication that is supported in compendia for the requested agent and route of administration OR C. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months All other plans: 12 months</p> |