UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3038-9
Program	Step Therapy
Medications	Procysbi® (cysteamine bitartrate)
P&T Approval Date	10/2014, 10/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020
Effective Date	12/1/2020; Oxford only: 12/1/2020

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try Cystagon® (cysteamine bitartrate) before providing coverage for Procysbi.

Procysbi is indicated for the management of nephropathic cystinosis in adults and pediatric patients 1 year of age and older.[1]

Cystagon is indicated for the management of nephropathic cystinosis in children and adults.[2]

Members currently on Procysbi therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria [a]:

A. Procysbi will be approved based on **one** of the following criteria:

1. History of failure, contraindication, or intolerance to Cystagon

-OR-

2. **Both** of the following:

   a. Patient is currently on Procysbi therapy

-AND-

   b. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Horizon sponsored TranscendRare program (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Procysbi*

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Horizon sponsored TranscendRare program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be granted for 60 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Notification may be in place.
- Supply limits may be in place.

4. References:

1. Procysbi [package insert]. Lake Forest, IL: Horizon Pharma USA, Inc.; February 2020.
2. Cystagon [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; January 2019.

Program	Step Therapy – Procysbi
Change Control	
10/2014	New program.
10/2015	Annual Review. Added additional sample pack language. Updated numbering format. Updated background, Procysbi now approved for children 2 years and older. Updated references. Added Maryland Continuation of Care.
7/2016	Added Indiana and West Virginia coverage information.
9/2016	Annual review. Updated background, clinical rules and references.
11/2016	Administrative change. Added California coverage information.
9/2017	Annual review. Updated sample language and references. Updated state mandate reference language.
9/2018	Annual review with no changes to coverage criteria. Updated background and reference.
9/2019	Annual review with no changes to coverage criteria. Updated reference.
9/2020	Annual review with no changes to coverage criteria. Updated reference.