

Effective date: 02/01/2021
Review: 11/20, 05/21, 04/22, 03/23, 3/24, 4/25, 4/26
Scope: Medicaid

Cystagon (cysteamine bitartrate)

POLICY

I. Criteria for approval:

An authorization of 6 months may be granted for the treatment of cystinosis when all the following criteria are met:

- A. Member has a diagnosis of nephropathic cystinosis
- B. Diagnosis is confirmed by one of the following:
 - a. Increased leukocyte cystine concentration (normal concentration: <0.2 nmol half-cystine/g protein)
 - b. Genetic testing for pathologic variant(s) of Cystinosin, lysosomal cystine transporter gene mutation
- C. Prescribed by or in consultation with a specialist with experience in treating nephropathic cystinosis, such as an endocrinologist, nephrologist, or urologist.
- D. Medication effectiveness will be monitored (by WBC cysteine levels or plasma cysteamine concentration)
- E. Will not be used in combination with Procysbi (cysteamine bitartrate)
- F. Dose does not exceed 1.95 g/m² per day

II. Continuation of therapy:

Authorization of 12 months may be granted for all members (including new members) who meet the following:

- A. Member is responding positively to therapy as evidenced by improvement, stabilization, or slowing of disease progression in the leukocyte cystine concentration since starting treatment.

III. REFERENCES

1. Cystagon [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; August 2021.