Effective date: 02/01/2021
Review:11/20, 05/21, 04/22, 03/23, 3/24 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/m^2 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.