AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: (Select applicable drug below)

❑ **Procysbi®** (cysteamine bitartrate) **delayed-release capsules and packets**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Intial Authorization: 6 months

❑ Member is ≥1 year of age and has a confirmed diagnosis of nephropathic cystinosis

AND

❑ Prescriber is an endocrinologist, nephrologist, urologist or other specialist in the treatment of nephropathic cystinosis

AND

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- ❑ Diagnosis confirmed by the presence of increased cystine concentration in leukocytes OR by genetic testing confirming biallelic pathogenic variants of the CTNS gene consistent with nephropathic cystinosis (submit labs or genetic test results confirming the member's diagnosis)

AND

- ❑ Member's white blood cell (WBC) cystine level is >2 nmol ½ cystine/mg protein at baseline (must submit labs documenting cystine concentration)

AND

- ❑ Member's serum creatinine is <3.0 mg/dL(must submit current serum creatinine lab levels)

AND

- ❑ Member has had trial and clinically significant intolerance to Cystagon therapy (chart notes must be submitted to document intolerance. *Note: the plan does not consider frequency of dosing and/or lack of compliance to dosing regimens an indication of medical necessity)

AND

- ❑ Chart notes documenting member's current height and weight must be submitted

AND

- ❑ Member is able to take Procysbi on an empty stomach (30 minutes before eating or 2.5 hours after eating)

AND

- ❑ Member's dose will not exceed the maximum FDA-approved dose of 1.95 g/m2 per day

Reauthorization Approval: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ All of the initial authorization continues to be met

AND

- ❑ Member has maintained a white blood cell (WBC) cystine level < 1 nmol ½ cystine/mg protein (must submit current lab results documenting levels)

AND

- ❑ Chart notes documenting member's current height and weight must be submitted

AND

- ❑ Member has not experienced any significant medication-related adverse reactions such as gastrointestinal symptoms (GI bleeding, nausea, vomiting, anorexia, or abdominal pain), severe skin rashes, or CNS symptoms (eg, seizures, lethargy, somnolence, depression, encephalopathy)

AND

- ❑ Member's serum creatinine is <3.0 mg/dL and has not increased from baseline (must submit current serum creatinine lab levels)

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Medication being provided by Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pha rmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: 4/20/2020
REVISED/UPDATED: ~~6/12/2020;10/11/2021;~~ **10/30/2023**