Clinical Policy: Pentosan Polysulfate Sodium (Elmiron)

Reference Number: IN.CP.PHAR.35
Effective Date: 01.01.2022
Last Review Date: 12.21
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Pentosan Polysulfate Sodium (Elmiron™) is a Urinary Analgesics and Anesthetic agent.

FDA Approved Indication(s)

Elmiron is indicated for the treatment for the relief of bladder pain or discomfort associated with interstitial cystitis

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

1. Must meet one of the following (a or b):
   a. Diagnosis of bladder pain or discomfort associated with interstitial cystitis (documentation of diagnosis via labs, medical records, or additional special studies required)If genetic studies are negative (i.e., no mutation identified), positive muscle biopsy (e.g., absence of dystrophin protein);
   b. Diagnosis of hemorrhagic cystitis in patients who previously received pelvic irradiation or chemotherapy with cyclophosphamide (documentation of diagnosis via labs, medical records, or additional special studies required
2. Dosage: Not to exceed 3 caps per day or 300mg per day

Approval duration: 3 months

A. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Must meet all for the following**:**

1. History of the requested agent within the past 90 days
2. Documentation of symptom improvement (i.e., pain relief)

Approval duration:

Medicaid – 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created for IN Medicaid Moratorium	12.2021	01.2022