

Pharmacy Policy Bulletin

Title: Pentosan polysulfate (Elmiron®)

Policy #: Rx.01.183

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for pentosan polysulfate (Elmiron®) as provided under the member's prescription drug benefit.

Description:

Interstitial cystitis/bladder pain syndrome (IC/BPS) is defined as an unpleasant sensation (pain, pressure, discomfort) perceived to be related to the urinary bladder, associated with lower urinary tract symptoms of more than six weeks duration in the absence of infection or other identifiable causes. The prevalence of IC/BPS in the United States is estimated to be 83,000 men and 1.2 million women. Treatment should start with conservative therapies and progress to more aggressive therapies if symptom control is not adequate. Medications, including amitriptyline, cimetidine, hydroxyzine and pentosan polysulfate are all considered second line treatments.

The mechanism of action of pentosan polysulfate sodium in IC/BPS is unknown. The compound is similar to low molecular weight heparin, and has anticoagulant and fibrinolytic effects. It is thought to prevent solutes in the urine from irritating the bladder wall by binding to the mucosal membrane and acting as a buffer. Pentosan polysulfate sodium is indicated for the relief of bladder pain or discomfort associated with interstitial cystitis.

Policy:

INITIAL CRITERIA: Pentosan polysulfate sodium (Elmiron®) is approved when ALL of the following are met:

1. Diagnosis of interstitial cystitis/ bladder pain syndrome and BOTH of the following:
 - a. Pain, pressure, or discomfort associated with lower urinary tract symptoms for 6 weeks or longer; and
 - b. Absence of infection or other identifiable cause; and
2. Inadequate response to conservative therapy (e.g. bladder training, pelvic floor rehab, biofeedback, etc.); and
3. Member is 16 years of age or older; and
4. Inadequate response or inability to tolerate ONE of the following:
 - a. Amitriptyline; or
 - b. Cimetidine; or
 - c. Hydroxyzine

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Pentosan polysulfate sodium (Elmiron®) is re-approved when there is documentation of positive clinical response to therapy.

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

None

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Hanno PM, Burks DA, Clemens JQ, et al. Diagnosis and treatment of interstitial cystitis/ bladder pain syndrome. American Urological Association. Available at: <https://www.auanet.org/common/pdf/education/clinical-guidance/IC-Bladder-Pain-Syndrome-Revised.pdf>. Accessed January 04, 2023.

Elmiron® (pentosan polysulfate sodium) [prescribing information]. Titusville, NJ, Janssen Pharmaceuticals, Inc.; March 2021. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=f0ba651e-3d8a-11df-8fbe-119855d89593&type=display>. Accessed January 04, 2023.

Rovner ES. Interstitial cystitis. Available at: <http://emedicine.medscape.com/article/2055505-overview>. Accessed January 04, 2023.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Elmiron®	Pentosan polysulfate sodium

Cross References:

Off-Label Use Rx.01.33

Policy Version Number:	8.00
P&T Approval Date:	December 08, 2022
Policy Effective Date:	April 01, 2023
Next Required Review Date:	December 08, 2023

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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