Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

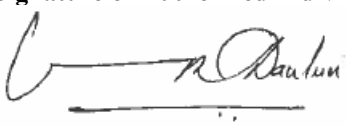
Plan: PA Health & Wellness	**Submission Date: 05/01/2022**
Policy Number: PA.CP.PMN.276	**Effective Date: 01/2022** **Revision Date: 04/2022**
Policy Name: Pentosan Polysulfate Sodium (Elmiron)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:** 

CLINICAL POLICY
Pentosan Polysulfate Sodium

Clinical Policy: Pentosan Polysulfate Sodium (Elmiron)

Reference Number: PA.CP.PMN.276
Effective Date: 05/2022
Last Review Date: 04/2022

Coding Implications
Revision Log

Description
Pentosan polysulfate sodium (Elmiron®) is a semi-synthetically produced heparin-like macromolecular carbohydrate derivative, which chemically and structurally resembles glycosaminoglycans.

FDA Approved Indication(s)
Elmiron is indicated 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.

It is the policy of health plans affiliated with PA Health and Wellness ® that Elmiron is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Interstitial Cystitis (must meet all)**:**

1. Diagnosis of interstitial cystitis with bladder pain or discomfort;
2. Age ≥ 16 years;
3. Failure of one of the following, unless clinically significant adverse effects are experienced or all are contraindicated: amitriptyline, cimetidine, hydroxyzine;
4. Dose does not exceed 300 mg (3 capsules) per day.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Therapy

A. Interstitial Cystitis (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 300 mg (3 capsules) per day.

Approval duration: 12 months

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

1. Currently receiving medication via PA Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
amitriptyline	25-100 mg PO per day*	100 mg/day
cimetidine	300-400 mg PO BID or 200 mg PO TID*	800 mg/day
hydroxyzine	10-75 mg PO per day*	75 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to the drug, structurally related compounds, or excipients
- Boxed warning(s): none reported

Appendix D: General Information

- Though the use of amitriptyline, cimetidine, and hydroxyzine is off-label for interstitial cystitis (while Elmiron does have an FDA approved indication), the American Urological Association guidelines on interstitial cystitis/bladder pain syndrome (published 2011, amended 2014) recommend all four as second-line treatment options without preference for any one product over the other (evidence strength: grades B, B, C, and B, respectively). The American Urological Association acknowledges that more data is available for Elmiron, but goes on to state that it is insufficient to recommend it over the other treatment options: "[Elmiron] is by far the most-studied oral medication in use for [interstitial cystitis/bladder pain syndrome]… there were seven randomized trials reporting on more than 500 patients from which to draw evidence... The body of evidence strength was categorized as Grade B because although the individual trials were of high quality, the findings from the trials were contradictory… Administration of oral [Elmiron], therefore, is designated an Option."
- Per Elmiron's prescribing information, the clinical value and risks of continued treatment in patients whose pain has not improved by 6 months is not known.

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Bladder pain or discomfort associated with interstitial cystitis	100 mg PO TID	300 mg/day

V. Product Availability

Capsule: 100 mg

VI. References

1. Elmiron Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2021. Available at: www.orthoelmiron.com. Accessed January 31, 2022.
2. Hanno PM, Burks DA, Clemens JQ, et al. American Urological Association (AUA) guideline: Diagnosis and treatment of interstitial cystitis/bladder pain syndrome. Published 2011. Amended 2014. Available at: https://www.auanet.org/guidelines/guidelines/interstitial-cystitis-(ic/bps)-guideline. Accessed January 31, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created per February SDC.	04/2022	