Clinical Policy: Pentosan Polysulfate Sodium (Elmiron)

Reference Number: CP.PMN.276
Effective Date: 06.01.22
Last Review Date: 05.23
Line of Business: Commercial, 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 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 Centene Corporation® 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 both of the following (a and b):
   a. 300 mg per day;
   b. 3 capsules per day.

Approval duration: 6 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 300 mg per day;
   b. 3 capsules per day.

Approval duration: 12 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and 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.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. 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.

V. Dosage and Administration

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

VI. Product Availability

Capsule: 100 mg

VII. References

1. Elmiron Prescribing Information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2021. Available at: www.orthoelmiron.com. Accessed February 1, 2023.

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.
3. Clemens JQ, Erickson DR, Varela NP, Lai HH. Diagnosis and treatment of interstitial cystitis/bladder pain syndrome. *AUA*. 2022;208:34-42. doi.org/10.1097/JU.0000000000002756.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created per February SDC.	02.17.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.07.22	
2Q 2023 annual review: no significant changes; references reviewed and updated.	02.01.23	05.23

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.