

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2026 P 3152-6
Program	Step Therapy
Medication	Elmiron® (pentosan polysulfate sodium)
P&T Approval Date	12/2020, 12/2021, 12/2022, 1/2024, 3/2025, 3/2026
Effective Date	6/1/2026

**1. Background:**

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

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a trial of amitriptyline before providing coverage for Elmiron.

**2. Coverage Criteria<sup>a</sup>:**

**A. Elmiron** will be approved based upon the following criterion:

1. History of failure, contraindication, or intolerance to amitriptyline.

**Authorization will be issued for 12 months.**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

**4. References:**

1. Elmiron [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; July 2024.
2. Diagnosis and Treatment of Interstitial Cystitis/Bladder Pain Syndrome: American Urological Associations (AUA) Guideline. 2022.
3. Management of interstitial cystitis/bladder pain syndrome. UpToDate, February 2025, reviewed Jan 2026. Accessed February 6, 2026.

Program	Step Therapy – Elmiron (pentosan polysulfate sodium)
<b>Change Control</b>	
12/2020	New program
12/2021	Annual review. Updated references.
12/2022	Annual review. Updated references.

1/2024	Annual review. Updated references.
3/2025	Annual review. Updated references.
3/2026	Annual review. Updated references.