

Clinical Pharmacy Program Guidelines for Elmiron

Program	Prior Authorization
Medication	Elmiron (pentosan polysulfate sodium)
Issue Date	9/2010
Pharmacy and Therapeutics Approval Date	10/2017
Effective Date	11/2017

1. Background:

FDA Approved Indications

Interstitial Cystitis

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

If improvement has not occurred and if limiting adverse events are not present, Elmiron may be continued for another 3 months. The clinical value and risks of continued treatment in patients whose pain has not improved by 6 months is not known.

2. Coverage Criteria:

<p>A. <u>Authorization</u></p> <p>1. Patient has a documented diagnosis of bladder pain or discomfort associated with interstitial cystitis</p> <p>Authorization will be issued for 12 months.</p>
--

3. References:

1. Elmiron[®] [package insert]. Raritan, NJ: Ortho-McNeil-Janssen Pharmaceuticals Inc.; June 2010.

2. American College of Obstetricians and Gynecologists (ACOG). Chronic pelvic pain. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2004 Mar. 17 p. (ACOG practice bulletin; no. 51).
3. Jarrell JF, Vilos GA, Allaire C, et al. Consensus Guidelines for the Management of Chronic Pelvic Pain. *JOGC*. 2005; 164: 781-801.
4. Homma Y, Ueda T, Tomoe H, et al. Clinical guidelines for interstitial cystitis and hypersensitive bladder syndrome. *Int J Urol*. 2009; 16; 597-615.
5. Fall M, Baranowski AP, Elneil S, et al. EAU Guidelines on Chronic Pelvic Pain. *Eur Urol*. 2010; 57: 35-48.
6. Clinical Pharmacology Gold Standard. 2017.
7. Facts and Comparisons 4.0; 2017.
8. Micromedex Health Solutions. 2017.

Program	Prior Authorization- Elmiron (pentosan polysulfate sodium)
Change Control	
Date	Change
Sept 2010	New drug policy
Sept 2011	Annual Review
Sept 2012	Annual Review
Dec 2015	Annual Review
October 2016	Updated policy template. Changed initial authorization duration from 6 months to 3 months.
August 2017	Updated reauthorization criteria and reauthorization durations. Updated references.
September 2017	Updated authorization duration to 12 months. Removed reauthorization criteria to allow for Dx to Rx implementation