Prior Authorization Review Panel
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: Aetna Better Health	**Submission Date:** 8/1/2021
Policy Number:	**Effective Date:** 8/1/2021 **Revision Date:** 5/2021
Policy Name: Elmiron (Non-PDL)	
Type of Submission – Check all that apply: ☐ **New Policy** X **Annual Review – No Revisions** ☐ **Revised Policy**	
***All revisions to the policy must be highlighted using track changes throughout the document.** **Please provide any clarifying information for the policy below:** Thank you.	
Name of Authorized Individual (Please type or print): **Natalie Nkurunziza, Pharm.D.**	**Signature of Authorized Individual:** Natalie Nkurunziza, PharmD

Last Review: 5/2021
Last PARP Approval: 11/2020
Current PARP Approval: 9/2021

AETNA BETTER HEALTH®

Non-Formulary Prior Authorization guideline for Elmiron (Non-PDL)

Authorization guidelines:

A. Elmiron will pay at the point of sale (without requiring a prior authorization) for 6 months when the following criterion is met: Diagnosis of interstitial cystitis (ICD-10 N30.1*)
   OR
B. Prescriptions that do not pay at the point of sale require prior authorization and may be authorized for members who meet the following criteria: Diagnosis of bladder pain or discomfort associated with interstitial cystitis

Approval Duration

Initial Approval: 6 months

Renewal: 6 months

Criteria for renewal:

- Improvement in symptoms (for example: pelvic/bladder pain, urinary frequency/urgency)

Medically Necessary — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member's family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

References:

1. Elmiron® [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; Revised march 2021. https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/ELMIRON-pi.pdf. Accessed May 3, 2021.
2. Hanno PM, Burks DA, Clemens JQ. American Urological Association Guideline: Diagnosis and Treatment of Interstitial Cystitis/Bladder Pain Syndrome. September 2014. https://www.auanet.org/guidelines/interstitial-cystitis-(ic/bps)-guideline. Accessed March 5, 2020.