

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Orilissa® Clinical Edit
<b>First Implementation Date:</b>	July 24, 2019
<b>Proposed Date:</b>	June 18, 2020
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of Orilissa® (elagolix)

**Why Issue Selected:** Orilissa® is an oral gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for management of moderate to severe pain associated with endometriosis in women 18 years of age and older. Orilissa inhibits endogenous GnRH signaling by binding to GnRH receptors in the pituitary gland resulting in dose-dependent suppression of luteinizing hormone and follicle-stimulating hormone. Subsequent suppression of estradiol levels then occurs. Endometriosis is a chronic disease that affects about 6% to 10% of women in the United States. Current treatment includes both pharmacological and surgical options. Some of the pharmacological options include NSAIDS, extended cycle combined oral contraceptives, progestin therapy, and GnRH agonists.

Program-Specific Information:	Date Range FFS 4-1-2019 to 3-31-2020				
	Drug	Claims	Spend	Cost per tab	Cost per month
	ORILISSA 150 MG TAB	253	\$207,752.30	\$31.12 NADAC	\$933.60 NADAC
	ORILISSA 200 MG TAB	63	\$53,236.51	\$15.71 NADAC	\$942.60 NADAC

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Orilissa® (elagolix)
- Age range: All appropriate MO HealthNet participants aged 18 years or older

## Approval Criteria

- Participant is 18 years of age or older **AND**
- Documented diagnosis of moderate to severe pain associated with endometriosis in the past year **AND**

- Documented trial of alternative therapy:
  - NSAIDS - trial defined as 30/180 days **AND**
  - Combined contraceptive therapy – trial defined as 180/270 days – **OR**
  - Progesterone/Progestin therapy:
    - Injectable contraceptive trial defined as 2 claims in 270 days **OR**
    - Medroxyprogesterone tablets trial defined as 30/90 days **OR**
    - Norethindrone acetate trial defined as 180/270 days
  - Clinical consultant review may be obtained if pain is severe or worsening after 2 months trial of alternative therapies
- For 200mg tablets only: documented diagnosis of dyspareunia
- Max allowable quantity and duration:
  - Moderate hepatic impairment (Child-Pugh B): 150mg/day for up to 6 months
  - Mild to no hepatic impairment (Child-Pugh A): 150mg/day for up to 24 months

## Denial Criteria

- Therapy will be denied if no approval criteria are met
- Participant is currently pregnant
- Documented diagnosis of osteoporosis in the past year
- Documented diagnosis of severe hepatic impairment (Child-Pugh C)
- For 200mg tablets only: documented diagnosis of moderate hepatic impairment (Child-Pugh B)
- Claim exceeds approved dosing limitations:
  - 150mg tablets: 1 tablet per day
  - 200mg tablets: 2 tablets per day

## Required Documentation

Laboratory Results:  
MedWatch Form:

<b>X</b>

Progress Notes:  
Other:

<b>X</b>

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)  
Rule Type: CE

## Default Approval Period

6 months

## References

- ORILISSA (elagolix) tablets, [package insert]. North Chicago, IL: AbbVie Inc.; August 2019.
- IPD Analytics. New Drug Approval: Orilissa (elagolix). July 2018.