SmartPA Criteria Proposal

Drug/Drug Class:	Orilissa® Clinical Edit
First Implementation Date:	July 24, 2019
Proposed Date:	June 18, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **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 crieria 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:	X	Progress Notes:	X
MedWatch Form:		Other:	

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.