SmartPA Criteria

Drug/Drug Class:	Orilissa™ (elagolix) Clinical Edit
First Implementation Date:	July 24, 2019
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 of Orilissa™ (elagolix) oral tablets.

Why was this 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:

Drug	Cost per Claim
Orilissa™	*$844.87/mo WAC*

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 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
- Documented diagnosis of moderate to severe pain associated with endometriosis

- 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
- For 200mg tablets only:
    - Participant has 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 pregnant
- Participantt has documented diagnosis of osteoporosis
- Participant has documented diagnosis of severe hepatic impairment (Child-Pugh C)
- For 200mg tablets only:
    - Documented diagnosis of moderate hepatic impairment (Child-Pugh B)

References

1) Orilissa [package insert]. North Chicago, IL: AbbVie Inc; 2018.
2) Orilissa product information
3) 1998-2018 Mayo Foundation for Medical Education and Research (MFMER).