SmartPA Criteria Proposal

Drug/Drug Class:	Elagolix Clinical Edit
First Implementation Date:	July 24, 2019
Proposed Date:	June 17, 2021
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 elagolix agents

Why Issue Selected: Elagolix, an oral reversible gonadotropin-releasing hormone (GnRH) receptor antagonist, is available in 2 different brand name products, Orilissa® (elagolix) and Oriahnn® (elagolix/estradiol/norethindrone acetate). Elagolix 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, leading to decreased blood concentrations of the ovarian sex hormones estradiol and progesterone. Due to the risk of potentially irreversible bone loss, a baseline dual energy X-ray absorptiometry (DEXA) scan should be considered for all patients beginning elagolix therapy.

Orilissa, a single ingredient elagolix product, is indicated for the management of moderate to severe pain associated with endometriosis in women 18 years of age and older. 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.

Oriahnn, a combination product containing elagolix, estradiol, and norethindrone acetate, is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Uterine fibroids are benign neoplasms that grow along the uterine wall, occurring most commonly in women in their 30s and 40s. Clinically relevant symptoms, such as abnormal uterine bleeding, pelvic pressure, bowel dysfunction, urinary frequency and urgency, urinary retention, low back pain, constipation, dyspareunia and possibly even infertility, are experienced in 25% of women. However, it is estimated that upwards of 70% of women may have uterine fibroids without any noticeable symptoms. For patients over the age of 35, dilation and curettage (D&C) should be considered or other forms of uterine sampling prior to beginning therapy with Oriahnn. Oriahnn therapy should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

Due to possible adverse events and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of elagolix therapy.

Program-Specific Information:

Date Range FFS 4-1-2020 to 3-31-2021			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
ORIAHNN 300-1-0.5 MG CAP	5	$4,675.42	$935.08
ORILISSA 150 MG TAB	231	$203,538.60	$881.12
ORILISSA 200 MG TAB	45	$36,603.42	$813.41

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: Elagolix agents
- Age range: All appropriate MO HealthNet participants aged 18 years or older

Approval Criteria

- Participant is 18 years of age or older **AND**
- Prescribed by or in consultation with an obstetrician, gynecologist, or other specialist in the treated disease state **AND**
- For Orilissa:
  - 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
- For Oriahnn:
  - Documented diagnosis of menorrhagia associated with uterine leiomyomas **AND**
  - For initial therapy:
    - Baseline thrombophilia panel **AND**
    - Baseline dual-energy X-ray absorptiometry (DEXA) scan **AND**
    - Documented trial of alternative therapy:
      - NSAIDs – trial defined as 30/180 days **AND**
      - Combined contraceptive therapy – trial defined as 180/270 days
  - For continuation of therapy:
    - Participant demonstrates compliance to prescribed therapy (84/112 days) **AND**
    - Total duration of therapy does not exceed 24 months

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participant is currently pregnant
- Therapy with any other elagolix agent in the past 2 years
- Documented diagnosis of osteoporosis in the past year
- For Orilissa:
  - Documented diagnosis of severe hepatic impairment (Child-Pugh C) **OR**
  - For 200mg tablets: documented diagnosis of moderate hepatic impairment (Child-Pugh B)
- For Oriahnn: Documented diagnosis of any hepatic impairment
- Claim exceeds approved dosing limitations:
  - Oriahnn: 2 capsules per day
  - Orilissa 150mg tablets: 1 tablet per day
  - Orilissa 200mg tablets: 2 tablets per day

Required Documentation

Laboratory Results:	X	Progress Notes:	X
MedWatch Form:		Other:	X

Disposition of Edit

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

Default Approval Period

6 months

References

- ORIAHNN (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) [package insert]. North Chicago, IL: AbbVie Inc.; May 2020.
- ORILISSA (elagolix) tablets [package insert]. North Chicago, IL: AbbVie Inc.; February 2021.
- IPD Analytics. New Drug Review: Oriahnn (elagolix, estradiol, and norethindrone acetate). June 2020.
- IPD Analytics. New Drug Approval: Orilissa (elagolix). July 2018.
- IPD Analytics. Women's Health: Uterine Fibroids and Endometriosis. Accessed May 27, 2021.