JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS114
		Effective Date	01/16/2019
		Review Date	10/19/2022
	Subject **Oral GnRH receptor antagonists: Orilissa, Oriahnn, Myfembree**	*Revision Date*	10/19/2022
		Page	1 of 4

This document applies to the following Participating Organizations:

Priority Partners

Keywords: Myfembree, Oriahnn, Orilissa

Table of Contents		Page Number
I.	**POLICY**	**1**
II.	**POLICY CRITERIA**	**1**
	A. Orilissa	**1**
	B. Oriahnn	**1**
	C. Myfembree	**2**
III.	**AUTHORIZATION PERIOD/LIMITATIONS**	**2**
IV.	**RECOMMENDED DOSAGE**	**3**
V.	**EXCLUSIONS**	**3**
	A. Orilissa	**3**
	B. Oriahnn	**3**
	C. Myfembree	**3**
VI.	**REFERENCES**	**3**
VII.	**APPROVALS**	**4**

I. POLICY

Orilissa (elagolix), Oriahnn (elagolix-estradiol-norethindrone acetate) and Myfembree (relugolix-estradiol-norethindrone acetate) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Orilissa** may be approved for patients meeting the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing the following:
      a. Orilissa will be used for management of moderate to severe pain associated with endometriosis
      b. Patient has had trial and failure of at least two concurrent regimens consisting of a prescription strength nonsteroidal anti-inflammatory drug (NSAID) and either of the following:
         I. combination estrogen-progestin hormonal contraceptive
         II. progestin (such as norethindrone)
      c. **Additional requirement for patients with liver disease:
         I. Evidence of a Child-Pugh score of A or B
   3. Prescriber is a gynecologist

B. **Oriahnn** may be approved for patients meeting the following:

1. Patient is 18 years of age or older and premenopausal
2. Documentation has been submitted showing the following:
   a. Diagnosis of heavy menstrual bleeding associated with uterine fibroids
   b. Pelvic ultrasound documenting the presence of uterine fibroids
   c. Patient has had trial and failure of at least two contraceptives (such as estrogen-progestin, or progestin intrauterine device [IUD] products), as well as tranexamic acid
3. Prescriber is a gynecologist

C. **Myfembree** may be approved for patients meeting the following:
1. Heavy Menstrual Bleeding with Uterine Fibroids
   a. Patient is 18 years of age or older and premenopausal
   b. Documentation has been submitted showing the following:
      I. Diagnosis of heavy menstrual bleeding associated with uterine fibroids
      II. Pelvic ultrasound documenting the presence of uterine fibroids
      III. Patient has had trial and failure of at least two contraceptives (such as estrogen-progestin, or progestin intrauterine device [IUD] products), as well as tranexamic acid
   c. Prescriber is a gynecologist
2. Pain associated with Endometriosis
   a. Patient is 18 years of age or older and premenopausal
   b. Documentation has been submitted showing the following:
      a. Diagnosis of moderate to severe pain associated with endometriosis
      b. Patient has had trial and failure of at least two concurrent regimens consisting of a prescription strength nonsteroidal anti-inflammatory drug (NSAID) and either of the following:
         I. combination estrogen-progestin hormonal contraceptive
         II. progestin (such as norethindrone)
   c. Prescriber is a gynecologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approvals for Orilissa, Oriahnn, and Myfembree will be limited to 6 months of therapy
B. Drug-specific continuation of therapy:
1. Orilissa:
   a. In patients with a coexisting condition of dyspareunia, or moderate hepatic impairment (Child-Pugh Class B), a continuation of therapy beyond the initial 6-month approval will not be authorized.
   b. In patients without a coexisting condition of dyspareunia, or moderate hepatic impairment, approval for continuation of therapy can be extended in 6-month intervals up to a total treatment duration of 24-months with documentation showing a reduction of dysmenorrhea and non-menstrual pelvic pain.
2. Oriahnn:
   a. Approval for continuation of therapy can be extended in 6-month intervals up to a total treatment duration of 24-months with documentation showing a reduction in menstrual blood loss
3. Myfembree:
   a. Approveal for continuation of therapy can be extended in 6-month intervals up to a total treatment duration of 24- months with documentation showing one of the following:
      I. Reduction of dysmenorrhea and non-menstrual pelvic pain
      II. Reduction in menstrual blood loss

IV. RECOMMENDED DOSAGE

A. Orilissa Dosing:
   1. Patients without dyspareunia or moderate hepatic impairment: 150mg once daily for a maximum of 24 months
   2. Patients with coexisting dyspareunia: 200mg twice daily for a maximum of 6 months
   3. Patients with coexisting moderate hepatic impairment: 150mg once daily for a maximum of 6 months. Use of 200mg twice daily is NOT recommended.

B. Oriahnn Dosing:
   1. One capsule (elagolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg) in the morning and one capsule (elagolix 300 mg) in the evening for a maximum of 24 months.

C. Myfembree Dosing:
   1. One capsule (fixed-dose combination of relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) once daily for a maximum of 24 months.

V. EXCLUSIONS

A. **Orilissa** will not be approved for patients with any of the following:
   1. Severe hepatic impairment (Child-Pugh C)
   2. Pregnancy
   3. Osteoporosis
   4. Concurrent use of strong OATP 1B1 Inhibitors
   5. Hypersensitivity reactions to Orilissa or any of its inactive ingredients

B. **Oriahnn** and **Myfembree** will not be approved for patients with any of the following:
   1. Hepatic impairment or disease
   2. Pregnancy
   3. Osteoporosis
   4. High risk of arterial, venous thrombotic, or thromboembolic disorder (e.g. history of vascular disease, deep vein thrombosis or pulmonary embolism, over the age of 35 and current smoker, hypercoagulopathies, etc.)
   5. History or current diagnosis of breast cancer, or other hormonally-sensitive malignancies
   6. Undiagnosed abnormal uterine bleeding
   7. Concurrent use of strong OATP 1B1 Inhibitors
   8. Hypersensitivity reaction to any of their ingredients

C. Orilissa, Oriahnn and Myfembree will not be approved for any indications or uses that are FDA-approved or guideline-supported

D. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

VI. REFERENCES

1. Orilissa. [Prescribing Information]. North Chicago, IL: AbbVie Inc; February 2021
2. Oriahnn [Prescribing Information]. North Chicago, IL: AbbVie Inc; August 2021
3. Myfembree [Prescribing Information]. Brisbane, CA: Myovant Sciences Inc.; September 2022
4. Marjoribanks J, Proctor M, Farquhar C, Derks RS. Nonsteroidal anti-inflammatory drugs for dysmenorrhoea. Cochrane Database Syst Rev 2010; :CD001751.
5. Zorbas KA, Economopoulos KP, Vlahos NF. Continuous versus cyclic oral contraceptives for the treatment of endometriosis: a systematic review. Arch Gynecol Obstet 2015; 292:37.

6. Bedaiwy MA, Allaire C, Yong P, Alfaraj S. Medical Management of Endometriosis in Patients with Chronic Pelvic Pain. Semin Reprod Med 2017; 35:38.
7. Armstrong, C.ACOG Updates Guideline on Diagnosis and Treatment of Endometriosis. Am Fam Physician. 2011 Jan 1;83(1):84-85.
8. Kalaitzopoulos DR, et al.Treatment of endometriosis: a review with comparison of 8 guidelines. BMC Womens Health.. 2021 Nov 29;21(1):397.
9. Members of the Endometriosis Guideline Core Group, Becker CM, et al. ESHRE guideline: Endometriosis. Hum Reprod Open. 2022 Feb 26;2022(2):hoac009.

VII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
01/16/2019	Policy creation
01/23/2020	Minor clarification of criteria related to diagnosis
04/21/2021	Added criteria for Oriahnn
12/08/2021	Updated Exclusions section regarding physician samples
04/20/2022	Orilissa criteria update
10/19/2022	Added criteria for Myfembree

Review date: 1/16/2019, 04/21/2021, 04/20/2022, 10/19/2022

Revision date: 1/23/2020, 04/21/2021, 12/08/2021, 04/20/2022, 10/19/2022