DRUG DETERMINATION POLICY

Title: DDP-44 Gonadatropin-Releasing Hormone Receptor Antagonists

Effective Date: 03/09/2021

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Orilissa is an agent used to treat moderate to severe pain associated with endometriosis and Oriahnn is an agent used to treat heavy menstral bleeding. These criteria were developed and implemented to ensure appropriate use of preferred medications prior to these agents.

3.0 Clinical Determination Guidelines:

A. Age: at least 18 years.

B. Diagnosis and severity [meet both below]:

   1. Pre-menopausal.

   2. Diagnosis.

      a. Orilissa (elagolix): moderate to severe pain associated with endometriosis within the last two years.

      b. Oriahnn (elagolix, estradiol, norethindrone): heavy menstral bleeding associated with uterine leiomyomas (fibroids).

C. Other therapies: contraindication, inadequate response or significant adverse effects to two analgesics for one month each and one hormone therapy for four months [must meet both listed below]:

1. Analgesics: ibuprofen, meloxicam, naproxen.

2. Hormones: hormonal contraceptives, progesterones (e.g., norethindrone).

D. Dosage regimen:

1. Orilissa (elagolix):

a. Endometrosis: 150mg daily for a maximum treatment duration of two years.

b. Endometriosis with dyspareunia: 200mg two times daily for maximum treatment duration of six months.

2. Oriahnn (elagolix, estradiol, norethindrone): elagolix 300mg/estradiol 1mg/norethindrone 0.5mg evey morning and elagolix 300mg every evening for maximum treatment duration of two years.

E. Approval:

1. Initial: six months.

2. Reapproval:

a. Endometriosis or heavy menstral bleeding: one year up total duration of two years.

b. Endometriosis with dyspareunia: not indicated (total duration six months).

F. Exclusions [any listed below]:

1. Osteoporosis.

2. Severe hepatic impairment (Child-Pugh Class C).

3. Pregnancy.

4. Use of strong organic anion transporting polypeptide (OATP)-1B1 inhibitor (e.g., cyclosporine, gemfibrozil).

5. High risk of arterial, venous thromboembolic disorders.

4.0 Coding:

None.

5.0 References, Citations, Resources & Associated Documents:

1. Lexicomp Online® Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Orilissa, Oriahnn acesssed December 2020.
2. UpToDate: Endometriosis - Treatment of Pelvic pain accessed February 2020, https://www.uptodate.com/contents/endometriosis-treatment-of-pelvic-pain?search=endometriosis%20treatment&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.
3. Long-Term Outcomes of Elagolix in Women With Endometriosis: Results From Two Extension Studies. Obstet Gynecol 2018; 132:147.

6.0 Appendices:

See page 4.

7.0 Revision History:

Original Effective Date: 03/09/2021

Next Review Date: 01/27/2022

Revision Date	Reason for Revision
12/20	Annual review, added drug Oriahnn diagnosis, dosage and monitoring/patient safety, simplifed criteria instructions, approved by P&T 2/24/21

Appendix I - Monitoring and patient safety

Drug	Adverse Reactions	Monitoring & Contraindications	REMS
Orilissa elagolix	• Central nervous system: headache (17-20%) • Dermatological: night sweats (46%) • Endocrine and metabolic: amenorrhea (4-57%), hot flash (46%) • Gastrointestinal: nausea (16%) • Neuromuscular and skeletal: decrease bone mineral density (21%)	• Pregnancy • Labs: liver function tests, bone mineral density (after 12 months) • Mental status • Contraindications listed in exclusions	• None
Oriahnn elagolix, estradiol, norethindrone	• Endocrine and metabolic: hot flash (22%)	• Pregnancy • Labs: liver function tests, bone mineral density (after 12 months), hgb, lipid profile • Mental status • Cardiovascular: signs and symptoms of thromboembolic disorders • Contraindications listed in exclusions	• Medication Guide