DRUG DETERMINATION POLICY

Title: DDP-44 Orilissa Use for Endometriosis

Effective Date: 06/03/2020

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. These criteria were developed and implemented to ensure appropriate use of preferred medications prior to Orilissa.

3.0 Clinical Determination Guidelines:

A. Age: at least 18 years.

B. Diagnosis and severity (meet both below):

   1. Pre-menopausal.

   2. Moderate to severe pain associated with endometriosis within the last two years.

C. Other therapies (both below):

   1. Analgesics (four months): contraindication to, failed or experienced significant adverse effects from two analgesics (e.g., ibuprofen, meloxicam, naproxen).

   2. Hormones (four months): contraindication to, failed or experienced significant adverse effects to one hormone therapy (one below):

      a. Hormonal contraceptives.

b. Progesterones (e.g., norethindrone).

D. Contraindications (one below):

1. Osteroporosis.

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).

E. Dosage regimen: Orilissa (elagolix):

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

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

F. Approval:

1. Initial: six months.

2. Reapproval:

a. Endometriosis: one year up total duration of two years.

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

4.0 Coding:

None.

5.0 References, Citations & Resources:

1. Lexicomp Online® Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Orilissa acesssed February 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 3.

7.0 Revision History:

Original Effective Date: 06/03/2020

Next Review Date: 06/03/2021

Revision Date	Reason for Revision

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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 criteria	• None