Clinical Policy: Elagolix (Orilissa)

Reference Number: PA.CP.PHAR.136
Effective Date: 10.17.18
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Revision Log

Description
Elagolix (Orilissa™) is a gonadotropin-releasing hormone (GnRH) receptor antagonist.

FDA Approved Indication(s)
Orilissa is indicated for the management of moderate to severe pain associated with endometriosis.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Orilissa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Endometriosis Pain (must meet all):

1. Diagnosis of pain due to endometriosis;
2. Prescribed by or in consultation with a gynecologist;
3. Failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced (a or b):
   a. A non-steroidal anti-inflammatory drug *(see Appendix B for examples)*;
   b. A progestin-containing oral or depot injectable contraceptive agent *(see Appendix B for examples)*;
4. For requests for 200 mg BID: member does not have osteoporosis;
5. Dose does not exceed 400 mg per day.

Approval duration: 6 months for 200 mg twice daily; 12 months for 150 mg once daily

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Endometriosis Pain (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy as evidenced by improvement in dysmenorrhea, dyspareunia, pelvic pain/induration/tenderness, or size of endometrial lesions;
3. If request is for a dose increase, new dose does not exceed 400 mg per day.

Approval duration: up to 6 months for 200 mg twice daily; up to 12 months for 150 mg once daily
Total duration of therapy should not exceed 6 months for 200 mg twice daily or 24 months for 150 mg once daily.

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
GnRH: gonadotropin-releasing hormone
OATP: organic anion transporting polypeptide

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
NSAIDs: ibuprofen, naproxen, fenoprofen, ketoprofen, mefenamic acid, meclofenamate, indomethacin, tolmetin, diclofenac, etodolac, diflunisal, meloxicam, piroxicam	Varies – refer to specific prescribing information	Varies – refer to specific prescribing information
Progestin-containing oral contraceptives: norethindrone, ethinyl estradiol + (desogestrel, ethynodiol diacetate, drospirenone, etonogestrel, levonorgestrel,	1 tablet PO QD	1 tablet/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
norelgestromin, norethindrone, norgestimate, or norgestrel); estradiol valerate + dienogest; mestranol + norethindrone		
Depot injection progestin contraceptives: medroxyprogesterone acetate (Depo-Provera®, Depo-SubQ Provera 104®)	IM: 150 mg every 13 weeks SC: 104 mg every 12 to 14 weeks	IM: 150 mg/3 months SC: 104 mg/3 months

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Pregnancy
  - Known osteoporosis
  - Severe hepatic impairment
  - Concomitant use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine and gemfibrozil)
- Boxed warning(s): None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Endometriosis pain	150 mg PO QD or 200 mg PO BID	150 mg/day x 24 months or 400 mg/day x 6 months

VI. Product Availability

Tablets: 150 mg, 200 mg

VII. References

1. Orilissa Prescribing Information. North Chicago, IL: AbbVie Inc.; July 2018. Available at: http://www.orilissa.com. Accessed August 8, 2018.
2. American College of Obstetricians and Gynecologists. Practice bulletin: clinical management guidelines for obstetrician-gynecologist: management of endometriosis. Am J Obstet Gynecol 2010; 116(1):223-236.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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