MEDICAL MUTUAL®

Drug Policy

Policy:	Orilissa (elagolix)	Annual Review Date: 06/20/2024 Last Revised Date: 06/20/2024

OVERVIEW

Orilissa is a gonadotropin-releasing hormone (GnRH) receptor antagonist. Orilissa is indicated for the management of moderate to severe pain associated with endometriosis. Endometriosis is considered a chronic disease. Endometriosis treatments include medical and surgical options. Primary treatment for mild to moderate endometriosis is contraceptives and nonsteroidal anti-inflammatory drugs (NSAIDS). Those with severe symptom or recurrent symptoms may try a GnRH agonist (such as leuprolide). Surgery may be considered for those who do not respond to prescription treatment. Clinical studies for Orilissa evaluated the reduction of endometriosis-associated pain in women over six months of treatment. It should be noted that Orilissa lowers estrogen levels which may lead to bone mineral density loss. Discontinue Orilissa if BMD Z- score is lower than –2.0.

POLICY STATEMENT

This policy involves the use of Orilissa. Prior authorization is recommended for pharmacy benefit coverage of Orilissa. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Orilissa as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Orilissa be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Orilissa is recommended in those who meet the following criteria:

1. **Endometriosis – initial therapy**
   - A. Patient is ≥ 18yrs old; AND
   - B. Patient has moderate to severe pain; AND
   - C. Prescribed by or in consultation with an obstetrician, gynecologist, or reproductive endocrinologist; AND
   - D. Patient does not have any of the following contraindications: osteoporosis, undiagnosed vaginal bleeding, severe hepatic impairment, concomitant use of a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor such as cyclosporine or gemfibrozil; AND

E. Patient is not pregnant; AND
F. Provider will monitor for decreases in bone density and elevation in lipids; AND
G. Patient has failed or is intolerant to at least a 3-month trial of: nonsteroidal anti-inflammatory drugs (NSAIDs); AND
H. Patient has tried ONE of the following, unless contraindicated (i, ii, or iii):
    i. A contraceptive (e.g., combination oral contraceptives, levonorgestrel-releasing intrauterine systems [e.g., Mirena, Liletta]); OR
    ii. An oral progesterone (e.g., norethindrone tablets); OR
    iii. A depo-medroxyprogesterone injection; AND
I. Patient will not use 200 mg twice daily for more than 6 months.

2. Endometriosis – continuation of therapy

A. Patient is ≥ 18yrs old; AND
B. Patient has moderate to severe pain; AND
B. Prescribed by or in consultation with an obstetrician, gynecologist, or reproductive endocrinologist; AND
C. Provider will continue monitor for decreases in bone mineral density if clinically appropriate; AND
D. Patient is experiencing a beneficial response to therapy with a decrease in pain and less analgesic medication usage per provider; AND
E. The patient has used Orilissa for a total treatment duration of less than 24 months.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months
B) *Extended Approval:* 6 months (MAXIMUM total approval of 24 months)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Orilissa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company

also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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