

ALASKA MEDICAID
Prior Authorization Criteria

**Orilissa™ 150mg, 200mg
tablets (elagolix)**

FDA INDICATIONS AND USAGE¹

Orilissa is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of severe pain associated with endometriosis.

APPROVAL CRITERIA^{1,2}

1. Patient has the diagnosis of endometriosis **AND**;
2. Patient is 18-49 years of age **AND**;
3. Patient is not pregnant **AND**;
4. Patient has no known osteoporosis **AND**;
5. Patient does not have severe hepatic impairment **AND**;
6. Patient is not taking a strong organic anion transporting polypeptide 1B1 inhibitor (i.e. cyclosporine) **AND**;
7. Patient has had an adequate trial of an oral combination contraceptive for at least 3 months **AND**;
8. Patient has had a trial of either a long acting progestin-only contraceptive or GnRH agonist.

DENIAL CRITERIA^{1,2}

1. Patient does not have the diagnosis of endometriosis **OR**;
2. Patient is not between 18-49 years of age **OR**;
3. Patient is pregnant **OR**;
4. Patient has known osteoporosis **OR**;
5. Patient has severe hepatic impairment **OR**;
6. Patient is taking a strong organic anion transporting polypeptide 1B1 inhibitor **OR**;
7. Patient has not had an adequate trial of an oral combination contraceptive for at least 3 months **OR**;
8. Patient has not trialed either a long acting progestin-only contraceptive or a GnRH agonist.

CAUTIONS¹

- Orilissa may be associated with potentially irreversible bone loss.
- It may reduce the ability to recognize pregnancy.
- It may increase suicidal ideation and mood disorders.
- It may increase liver transaminases and should be monitored.
- It has the potential to decrease efficacy of estrogen containing contraceptives.

DURATION OF APPROVAL¹

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- Initial Approval: up to 6 months for both strengths
- Reauthorization Approval: up to 12 months for 150mg dose only

QUANTITY LIMITS

- 30 – 150mg tablets per month
- 60 – 200mg tablets per month

REFERENCES / FOOTNOTES:

1. Orilissa™ (elagolix) [prescribing information]. North Chicago, IL: AbbVie Inc.; July 2018. Available at: https://www.rxabbvie.com/pdf/orilissa_pi.pdf. Accessed September 2018.
2. Schragger S, Falleroni J, Edgoose J. Evaluation and Treatment of Endometriosis. American Family Physician. 2013 Jan 15;87(2):107-113.