ELAGOLIX

Generic	Brand	HICL	GCN	Exception/Other
ELAGOLIX	ORILISSA	45108		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication is prescribed by or in consultation with an obstetrician/gynecologist
   - The patient had a previous trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) **AND** a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have normal liver function or mild hepatic impairment (Child-Pugh Class A)?

   If yes, **approve by GPID for the requested strength with the following quantity limits and approval durations:**
   - **Orilissa 150mg (GPID 45026): #1 tablet per day for 12 months.**
   - **Orilissa 200mg (GPID 45028): #2 tablets per day for 6 months.**

   If no, continue to #3.

3. Does the patient have moderate hepatic impairment (Child-Pugh Class B)?

   If yes, **approve for 6 months by GPID for the following strength and quantity limit:**
   - **Orilissa 150mg (GPID 45026): #1 tablet per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **ELAGOLIX (Orilissa)** requires a diagnosis of moderate to severe pain associated with endometriosis. Additionally, the following criteria must be met:

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with an obstetrician/gynecologist
- The patient had a previous trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) **AND** a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation)

Requests for Orilissa 200mg twice daily will only be approved in patients with normal liver function or mild hepatic impairment (Child-Pugh Class A).

RENEWAL CRITERIA

1. Has the patient received **ONE** of the following regimens?
   - A 6-month course of Orilissa 200mg twice daily
   - A 6-month course of Orilissa 150mg once daily and the patient has moderate hepatic impairment (Child-Pugh Class B)
   - A 24-month course of Orilissa 150mg once daily and the patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

   If yes, do not approve.
   RENEWAL DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis and meet the following criteria?
   - Physician attestation of improvement of pain related to endometriosis while on therapy
   - The patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

   If yes, **approve for 12 months by GPID for the following strength and quantity limit:**
   - **Orilissa 150mg (GPID 45026): #1 tablet per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RENWEAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **ELAGOLIX (Orilissa)** requires a diagnosis of moderate to severe pain associated with endometriosis for renewal. The following criteria must also be met:

- Physician attestation of improvement of pain related to endometriosis while on therapy
- The patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

Requests will not be approved if the patient meets one of the following conditions:

- The patient has received a 6-month course of Orilissa 200mg twice daily
- The patient has received a 6-month course of Orilissa 150mg once daily and the patient has moderate hepatic impairment (Child-Pugh Class B)
- The patient has received a 24-month course of Orilissa 150mg once daily and the patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

RATIONALE

Ensure appropriate utilization and safety criteria are used for the management of requests for Orilissa (elagolix).

FDA-APPROVED INDICATION

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

DOSING AND ADMINISTRATION

Pregnancy should be excluded before starting Orilissa (elagolix), or Orilissa (elagolix) can be initiated within 7 days from the onset of menses. The lowest effective dose should be used, taking into account the severity of symptoms and treatment objectives. Treatment duration should be limited due to the potential for decreases in bone mineral density that may not be completely reversible.

Orilissa (elagolix) is dosed according to the following table:

Hepatic Function	Dosing Regimen	Maximum Treatment Duration
Normal hepatic function *or* mild hepatic impairment (Child-Pugh Class A)	150 mg once daily	24 months
	200 mg twice daily*	6 months
Moderate hepatic impairment (Child-Pugh Class B)	150 mg once daily	6 months
Severe hepatic impairment (Child-Pugh Class C)	Contraindicated	
*Regimen to be considered for those with coexisting dyspareunia		

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REFERENCES

- Orilissa [Prescribing Information]. North Chicago, IL: AbbVie Inc.; July 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/24/18
Created: 08/18
Client Approval: 08/18
P&T Approval: 04/18