STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAGOLIX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAGOLIX	ORILISSA	45108		GPI-10 (3009003010)	

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 given 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 preparation (e.g., combination hormonal contraceptive preparation, progestin-only therapy)

   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 or GPI-14 for the requested strength with the following quantity limits and approval durations:**
   - **Orilissa 150mg: #1 per day for 12 months.**
   - **Orilissa 200mg: #2 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 or GPI-14 for the following strength and quantity limit:**
   - **Orilissa 150mg: #1 per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for approval:
   A. You have moderate to severe pain associated with endometriosis (disorder where uterus tissue grows outside of the uterus)
   B. You are 18 years of age or older
   (Initial denial text continued on next page)

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ELAGOLIX

INITIAL CRITERIA (CONTINUED)

C. The requested medication is prescribed by or given in consultation with an obstetrician/gynecologist (doctor who specializes in women's health)
D. You had a previous trial of or contraindication to (a medical reason why you cannot use) a nonsteroidal anti-inflammatory drug (NSAID; such as ibuprofen, meloxicam, naproxen) **AND** a progestin-containing preparation (such as combination hormonal contraceptive preparation, progestin-only therapy)
E. Requests for Orilissa 200mg twice daily will only be approved if you have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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?
   - 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 or GPI-14 for the following strength and quantity limit:**
   - **Orilissa 150mg: #1 per day.**

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

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ELAGOLIX

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for renewal:

A. You have moderate to severe pain associated with endometriosis (disorder where uterus tissue grows outside of the uterus)
B. You have improvement of pain related to endometriosis while on therapy
C. You have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)

Requests will not be approved if you meet ONE of the following conditions:

A. You have received a 6-month course of Orilissa 200mg twice daily
B. You have received a 6-month course of Orilissa 150mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
C. You have received a 24-month course of Orilissa 150mg once daily and you have normal liver function or mild (liver) hepatic impairment (Child-Pugh Class A)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orilissa.

REFERENCES

- Orilissa [Prescribing Information]. North Chicago, IL: AbbVie Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/08/20
Created: 08/18
Client Approval: 10/20
P&T Approval: 04/18