STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAGOLIX

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

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient previously 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.
   DENIAL TEXT: See the initial 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 **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an obstetrician/gynecologist
   - The diagnosis is confirmed via surgical or direct visualization (e.g., pelvic ultrasound) or histopathological confirmation (e.g., laparoscopy or laparotomy) in the last 10 years
   - Orilissa will NOT be used concurrently with another GnRH-modulating agent (e.g., Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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

   If yes, **approve 150 mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #4.

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ELAGOLIX

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet ONE of the following?
   - The patient has normal liver function
   - The patient has mild hepatic impairment (Child-Pugh Class A)

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **150mg: #1 per day.**
   - **200mg: #2 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 (condition affecting the uterus)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
   D. Your diagnosis of endometriosis is confirmed by surgical or direct visualization (such as pelvic ultrasound [type of imaging]) or histopathological (tissue) confirmation (such as laparoscopy [type of surgery] or laparotomy [type of surgery]) in the last 10 years
   E. Orilissa will NOT be used at the same time with another GnRH-modulating agent (such as Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])
   F. 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)
   G. Requests will not be approved if you previously received ONE of the following:
      1. A 6-month course of Orilissa 200mg twice daily
      2. A 6-month course of Orilissa 150mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
      3. 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.

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ELAGOLIX

RENEWAL CRITERIA

1. Has the patient previously 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.
   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 **ALL** of the following criteria?
   - The patient has had improvement of pain related to endometriosis while on therapy
   - The patient has normal liver function OR mild hepatic impairment (Child-Pugh Class A)
   - Orilissa will NOT be used concurrently with another GnRH-modulating agent (e.g., Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])

   If yes, **approve 150mg for 18 months by GPID or GPI-14 with a quantity limit of #1 per day.**

   If no, do not approve.
   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 (condition affecting 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)
   D. Orilissa will NOT be used at the same time with another GnRH-modulating agent (such as Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])
   E. Requests will not be approved if you previously received ONE of the following:
      1. A 6-month course of Orilissa 200mg twice daily
      2. A 6-month course of Orilissa 150mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
      3. A 24-month course of Orilissa 150mg once daily and you have normal liver function or mild (liver) hepatic impairment (Child-Pugh Class A)

   (Renewal denial text continued on next page)

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ELAGOLIX

RENEWAL CRITERIA

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.; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/09/23

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