Orilissa
Prior Authorization with Quantity Limit
Program Summary

This program applies to Blue Partner, Commercial, GenPlus, NetResults A series, SourceRx, and Health Insurance Marketplace.

FDA APPROVED INDICATIONS AND DOSAGE[1]

<table>
<tr><th>Agent</th><th>Indication</th><th>Dosage & Administration</th></tr>
<tr><td>Orilissa™
(elagolix)

Tablet</td><td>Management of moderate to severe pain associated with endometriosis</td><td>
• Exclude pregnancy before starting Orilissa or start Orilissa within 7 days from the onset of menses.
• Limit the duration of use because of bone loss:
<table>
<tr><th>Dosing Regimen</th><th>Maximum Treatment Duration</th><th>Coexisting Condition</th></tr>
<tr><td>Initiate treatment with Orilissa 150 mg once daily</td><td>24 months</td><td>None</td></tr>
<tr><td>Consider initiating treatment with Orilissa 200 mg twice daily</td><td>6 months</td><td>Dyspareunia</td></tr>
<tr><td>Initiate treatment with Orilissa 150 mg once daily. Use of 200 mg twice daily is not recommended.</td><td>6 months</td><td>Moderate hepatic impairment (Child-Pugh Class B)</td></tr>
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CLINICAL RATIONALE

Endometriosis is an estrogen-dependent, benign, inflammatory disease that affects women during their premenarcheal, reproductive, and postmenopausal hormonal stages. While endometriosis is a common and nonmalignant process, ectopic endometrial tissue and resultant inflammation can cause dysmenorrhea, dyspareunia, chronic pain, and infertility. Symptoms can range from minimal to severely debilitating. While definitive diagnosis of endometriosis requires tissue biopsy and histologic confirmation, the combination of symptoms, signs, and imaging findings can be used to make a presumptive, nonsurgical diagnosis of endometriosis.[2]

The first line option for the treatment of mild and moderate pain associated with endometriosis is non-steroidal anti-inflammatory drug (NSAID) and continuous hormonal contraceptives (estrogen/progestin, or progestin only) as this therapy has low risk with few side effects and provides symptom relief for many women. As there is no data supporting superiority of one therapy over another, the use of gonadotropin-releasing hormone (GnRH) for initial therapy may be reasonable. For those who have severe pain, or continue to experience symptoms on NSAID and continuous hormone therapy, a GnRH may be included in therapy or laparoscopy can be conducted for diagnosis and treatment. If symptoms continue despite the addition of GnRH, aromatase inhibitors may be tried. While danazol is effective at treating endometriosis-related pain, it is not commonly used because of

androgenic side effects. Women who do not respond to medical treatment may move on to laparoscopy for diagnosis and treatment.[3]

Safety
Orilissa has no black box warnings.[1]

Orilissa has the following contraindications:[1]
- Pregnancy
- Known osteoporosis
- Severe hepatic impairment
- Strong organic anion transporting polypeptide (OATP) 1B1 inhibitors

REFERENCES

1. Orilissa prescribing information. AbbVie Inc. July 2018.
2. Endometriosis: pathogenesis, clinical, features, and diagnosis. UptoDate. Current through 7/2018. Last updated 7/26/18.
3. Endometriosis: treatment of pelvic pain. UptoDate. Current through 7/2018. Last updated 7/18/2018.

Orilissa Prior Authorization with Quantity Limit

OBJECTIVE
The intent of the Orilissa prior authorization with quantity limit program is to encourage appropriate selection of patients for treatment according to product labeling and/or clinical studies and/or guidelines. The program will not be approved for those who have any FDA labeled contraindication to the requested agent. The program will approve for doses within the set limit. Doses above the set limit will be approved if the requested quantity is below the FDA limit and cannot be dose optimized or when the quantity is above the FDA limit and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis. Requests will be reviewed when patient specific documentation is provided.

TARGET AGENT(S)
Orilissa™ (elagolix)

PROGRAM PRIOR AUTHORIZATION AND QUANTITY LIMITS

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day)
Orilissa (elagolix)			
150 mg tablet	30090030100320	M, N, O, Y	1 tablet
200 mg tablet	30090030100330	M, N, O, Y	2 tablets

PRIOR AUTHORIZATION AND QUANTITY LIMIT CRITERIA FOR APPROVAL
Target Agent will be approved when ALL of the following are met:
Evaluation

1. The patient has a diagnosis of moderate to severe pain associated with endometriosis
   AND
2. ONE of the following:
   a. The patient has tried and had an inadequate response to therapy with hormonal contraceptives
      OR
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to hormonal contraceptives
   AND
3. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
4. The prescriber has submitted information on how long the patient has already been on therapy with the requested agent
   AND
5. ONE of the following:
   a. The patient has coexisting dyspareunia AND has not received 6 or more months of therapy with the requested agent
      OR
   b. The patient has coexisting moderate hepatic impairment (Child-Pugh Class B) AND has not received 6 or more months of therapy with the requested agent
      OR
   c. The patient does not have coexisting dyspareunia or moderate hepatic impairment (Child-Pugh Class B), AND has not received 24 or more months of therapy with the requested agent
   AND
6. ONE of the following:
   a. The requested quantity (dose) is NOT greater than the program quantity limit
      OR

b. ALL of the following:
    i. The requested quantity (dose) is greater than the program quantity limit
    AND
    ii. The requested quantity (dose) is less than the maximum FDA labeled dose (for the requested indication)
    AND
    iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

Length of Approval: Based on coexisting condition:

- Dyspareunia **OR** moderate hepatic impairment (Child-Pugh Class B) – up to a total of 6 months (inclusive of previous duration of therapy)
- No coexisting condition - up to a total of 24 months (inclusive of previous duration of therapy)