Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Orilissa (elagolix)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial request: 6 months Continued use: 6 months Total approval duration should not exceed 24 months (2 years).

Medications	Quantity Limit
Orilissa (elagolix)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Orilissa (elagolix) may be approved if the following criteria are met:

I. Individual is female age 18 or over; **AND**
II. Individual has moderate or severe endometriosis-associated pain;

AND
III. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to two of the following medications or has a contraindication to all of the following medications (ACOG 2010):
   A. Nonsteroidal anti-inflammatory drugs (NSAIDs); **OR**
   B. Combined oral contraceptives (OCs); **OR**
   C. Oral or depot medroxyprogesterone (Provera, Depo-Provera); **OR**
   D. Oral norethindrone;

AND
IV. Individual is naïve to Orilissa (elagolix); **OR**
V. Individual is using low dose (150 mg once daily), has mild (Child-Pugh class A) or no hepatic impairment, and has utilized Orilissa (elagolix) for a combined total duration of less than 24 months in their lifetime; **OR**
VI. Individual is using high dose (200 mg twice daily) or has moderate hepatic impairment (Child-Pugh class B), and has utilized Orilissa (elagolix) for a combined total duration of less than 6 months in their lifetime.

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Requests for continued use of Orilissa (elagolix) may be approved if the following criteria are met:

I. Individual is using low dose (150 mg once daily) and does not have moderate hepatic impairment (Child-Pugh class B); **AND**
II. Individual has experienced a clinically significant improvement in endometriosis-associated pain.

Requests for Orilissa (elagolix) may **not** be approved for the following:

I. Individual has osteoporosis; **OR**
II. Individual has severe hepatic impairment (Child-Pugh class C); **OR**
III. Individual is requesting in concurrent therapy with hormonal contraceptives; **OR**
IV. Individual is requesting in concurrent therapy with contraindicated agents, such as but not limited to, cyclosporine or gemfibrozil.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
CRX-ALL-0260-18

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
CRX-ALL-0260-18