Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules)

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

Medications	Quantity Limit
Oriahnn (elagolix, estradiol, and norethindrone acetate capsules, elagolix capsules)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Oriahnn (elagolix, estradiol, and norethindrone acetate capsules, elagolix capsules) may be approved if the following criteria are met:

I. Individual is premenopausal; **AND**
II. Individual has uterine leiomyomas (fibroids); **AND**
III. Individual is using for the management of heavy menstrual bleeding;
AND
IV. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to the following agents or has a contraindication (ACOG 2010):
    A. Hormonal contraceptives and/or progestin containing oral or depot (e.g. norethindrone);
AND
V. Individual is naïve to elagolix.

Requests for continued use of Oriahnn may be approved if the following criteria are met:

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

I. Individual has experienced a clinically significant improvement in fibroid-induced heavy menstrual bleeding defined as at least 50% reduction in menstrual blood loss from baseline to the final month (6 months).

Requests for Oriahnn (elagolix, estradiol, and norethindrone acetate capsules, elagolix capsules) may not be approved for the following:

I. Individual has osteoporosis; **OR**
II. Individual has a high risk of arterial, venous thrombotic, or thromboembolic disorder; **OR**
III. Individual is pregnant; **OR**
IV. Individual has a history of or current breast cancer or other hormonally-sensitive cancer; **OR**
V. Individual has severe hepatic impairment (Child-Pugh class C); **OR**
VI. Individual is requesting in concurrent therapy with hormonal contraceptives; **OR**
VII. Individual is requesting in concurrent therapy with contraindicated agents, such as but not limited to, strong OATP1B1 inhibitors (for example: cyclosporine or gemfibrozil).

Key References:

1. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin 114. Management of endometriosis. *Obstet Gynecol.* 2010;116:223-36.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. 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.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 3, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) for oral use [Package Insert]. North Chicago, IL: AbbVie Inc; May 2020.
7. Schlaff WD, Ackerman RT, Al-Hendy A et al. Elagolix for Heavy Menstrual Bleeding in Women with Uterine Fibroids. *New Engl J Med.* 2020; 382:328-40.

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