

Pharmacy Medical Necessity Guidelines: Elagolix Products: Orilissa and Oriahnn

Effective: July 20, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans <p>1. CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</p> <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan 		<p>Fax Numbers:</p> <p>RXUM: 617.673.0988</p>	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Endometriosis, the presence of endometrial tissue outside of the uterine cavity, affects up to 10 percent of reproductive-age woman causing pelvic pain, dysmenorrhea, dyspareunia, and decreased fertility.

Orilissa (elagolix) is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis.

Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) is a combination of elagolix, a gonadotropin-releasing hormone (GnRH) receptor antagonist, estradiol, an estrogen, and norethindrone acetate, a progestin, indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

Use of elagolix containing products should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

COVERAGE GUIDELINES

The plan may authorize coverage of Orilissa (elagolix) for Members, when the following criteria are met:

1. The member is at least 18 years of age
- AND**
2. The Member has a documented diagnosis of endometriosis by OB/GYN
- AND**
3. The Member has moderate to severe pain associated with endometriosis
- AND**
4. The Member has had an insufficient response or intolerance to generic alternatives in two of the following classes:
 - a. Nonsteroidal anti-inflammatory drugs (NSAIDs)
 - b. Hormonal contraceptives
 - c. Oral danazol
 - d. Oral or depot medroxyprogesterone
 - e. Oral norethindrone

The plan may authorize coverage of Oriahnn for Members when the following criteria are met:

1. Documentation that member is premenopausal
- AND**
2. Documented diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids)

AND

3. The Member has had an inadequate response or intolerance to **ALL** of the following:
 - a. A hormonal contraceptive method (e.g.: combined estrogen-progestin contraceptives, levonorgestrel-releasing intrauterine devices, or progestin-only contraceptives) **AND**
 - b. Generic tranexamic acid tablets

LIMITATIONS

1. Coverage authorization for Orilissa 200mg tablets is limited to 6 months. Coverage past 6 months will not be authorized.
2. Coverage authorization for Orilissa 150mg tablets and Oriahnn is limited to 24 months. Coverage past 24 months of therapy will not be authorized.
3. The following quantity limitations apply:

Orilissa (elagolix) 150 mg	up to 30 tablets per 30 days
Orilissa (elagolix) 200 mg	up to 60 tablets per 30 days
Oriahnn (elagolix, estradiol, and norethindrone acetate capsules;elagolix capsules)	4 blister packs per 28 days

CODES

None

REFERENCES

1. Am Fam Physician. 2013 Jan 15;87(2):107-13.
2. Orilissa (elagolix) [prescribing information]. North Chicago, IL: AbbVie Inc., 2020 May.
3. Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) [prescribing information]. North Chicago, IL: AbbVie Inc., 2020 May.

APPROVAL HISTORY

December 11, 2018: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- November 12, 2019: No changes.
- July 14, 2020: Added Oriahnn to the Medical Necessity Guidelines. Clarified that the total duration of approval for all elagolix containing products is limited to a maximum of 24 months total. Changed the title of the MNG to 'Elagolix Products: Orilissa® and Oriahnn'. Removed re-authorization criteria for Orilissa.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

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