Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Endocrine Agents**

Effective: March 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

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) tablet is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis. Limit the duration of use based on the dose and coexisting condition (i.e., use of Orilissa 150mg once daily should be limited for up to 24 months, and 200mg twice daily for up to 6 months).

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 Oriahnn should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

Myfembree (relugolix, estradiol hemihydrate, and norethindrone acetate) tablet is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Also indicated for management of moderate to severe pain associated with endometriosis in premenopausal women. Use of relugolix containing products should be limited to 24 months.

Synarel (nafarelin acetate) nasal solution is a GnRH agonist indicated for the treatment of central precocious puberty (CPP) and indicated for management of endometriosis, including pain relief and reduction of endometriotic lesions.

Clinical Guideline Coverage Criteria

Orilissa or Myfembree for the diagnosis of pain associated with endometriosis

The plan may authorize coverage of **Orilissa or Myfembree** for patients when the following criteria are met:

1. The patient is at least 18 years of age or older

AND

2. The patient has moderate to severe pain associated with endometriosis

AND

3. The patient has had an insufficient response or intolerance to both of the following:
    a. Oral nonsteroidal anti-inflammatory drugs (NSAIDs)

    AND

    b. Hormonal contraceptive

Oriahnn or Myfembree for the diagnosis of heavy menstrual bleeding

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

1. Documentation the patient is 18 years of age and older and is premenopausal

AND

2. Documented diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids)

AND

3. The patient has had an inadequate response or intolerance to a hormonal contraceptive

Synarel (nafarelin acetate)

The plan may authorize coverage of **Synarel (nafarelin acetate)** for patients, when the following criteria are met:

For Endometriosis:

1. The patient is at least 18 years of age and older

AND

2. The patient has a documented diagnosis of endometriosis by OB/GYN

AND

3. The patient 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

For Central Precocious Puberty (CPP):

1. The patient is ≤ 12 years of age

AND

2. The patient has a documented diagnosis of central precocious puberty (CPP)

Dysphoria/gender incongruence in Adolescents:

1. Documented diagnosis of dysphoria / gender incongruence

AND

2. Documentation the patient is less than 18 years of age or older

AND

3. Documentation the patient has experienced puberty development to at least Tanner stage 2

Gender Reassignment in Adults:

1. Documented diagnosis of dysphoria / gender incongruence

AND

2. Documentation the patient is at least 18 years of age or older

AND

3. Documentation the patient will receive the requested agent concomitantly with cross sex hormones (testosterone or estrogen and spironolactone)

Limitations

1. Coverage authorization for Orilissa 200mg tablets is limited to 6 months. Coverage of Orilissa 200mg tablets past 6 months will not be authorized.
2. Coverage authorization for Orilissa 150mg tablets is limited to 24 months. Coverage of Orilissa 150mg tablets past 24 months will not be authorized. Combined total duration of coverage for all strengths of Orilissa is limited to 24 months.
3. Coverage authorization for Myfembree and Oriahnn is limited to 24 months. Coverage past 24 months of therapy will not be authorized.
4. Coverage authorization for Synarel for the diagnosis of endometriosis will be limited to six months. Coverage of Synarel past six months for the diagnosis of endometriosis will not be authorized. Coverage authorization for Synarel for the diagnosis of Central Precocious Puberty will be through age 18.

Codes

None

References

1. Am Fam Physician. 2013 Jan 15;87(2):107-13.
2. Orilissa (elagolix) [prescribing information]. North Chicago, IL: AbbVie Inc., June 2023.
3. Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) [prescribing information]. North Chicago, IL: AbbVie Inc., June 2023.
4. Myfembree (relugolix, estradiol hemihydrate, and norethindrone acetate tablet, film coated) [prescribing information]. Marlbourough, MA: Sumitomo Pharma America, Inc. August 2025.
5. Synarel (nafarelin acetate) [prescribing information]. New York, NY: Pfizer Labs Inc., November 2025.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- March 14, 2023: Added criteria for Myfembree for the diagnosis of moderate to severe pain associated with endometriosis in premenopausal women, mirroring existing criteria for Orilissa.
- September 12, 2023: Effective December 1, 2023, updated the limitations section that the duration of coverage for Orilissa 200mg tablets is limited to 6 months and 150mg tablets is limited to 24 months and that the combined total duration of coverage for all strengths of Orilissa is limited to 24 months. An administrative edit was made in the overview section to clarify the duration of coverage for Orilissa and Oriahnn.
- April 9, 2024: Effective July 1, 2024, updated the limitations section that coverage of Synarel past 6 months for the diagnosis of endometriosis will not be authorized.
- January 14, 2025: Effective February 1, 2025, updated language to indicate hormonal contraceptives within the criteria for Orilissa and Myfembree for endometriosis and criteria for Oriahnn and Myfembree for heavy menstrual bleeding associated with uterine leiomyomas (fibroids).
- February 10, 2026: No changes.
- February 2026: Administrative update to remove CareLink from Medical Necessity Guideline template.

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.