Elagolix Prior Authorization with Quantity Limit

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Myfembree® (relugolix, estradiol hemihydrate, norethindrone acetate) Tablet	Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal patients Management of moderate to severe pain associated with endometriosis in premenopausal patients Limitations of Use: Use of Myfembree should be limited to 24 months due to the risk of continued bone loss which may not be reversible.		3
Oriahnn® (elagolix, estradiol, norethindrone acetate) Capsule	management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal patients. Limitations of Use: Use of Oriahnn should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.		2
Orilissa® (elagolix) Tablet	Management of moderate to severe pain associated with endometriosis Limitations of Use: Limit the duration of use based on the dose and coexisting condition (refer to labeling for additional details).		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

TARGET AGENT(S)

Oriahnn™ (elagolix, estradiol, norethindrone acetate)

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Myfembree	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) and BOTH of the following: 1. The patient's diagnosis of uterine fibroids was confirmed via imaging (e.g., ultrasound) **AND** 2. The patient has NOT had a hysterectomy **OR** B. The patient has a diagnosis of moderate to severe pain associated with endometriosis **AND** 2. The patient is premenopausal (e.g., less than 12 months since last menstrual period) **AND**

	3. The prescriber has confirmed the patient's bone health allows for initiating therapy with the requested agent **AND** 4. ONE of the following: A. The patient has tried and had an inadequate response to at least ONE hormonal contraceptive used in the treatment of the requested indication **OR** B. The patient has an intolerance or hypersensitivity to at least ONE hormonal contraceptive used in the treatment of the requested indication **OR** C. The patient has an FDA labeled contraindication to ALL hormonal contraceptive therapy (i.e., oral, topical patches, implants, injections, IUD) **AND** 5. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. ONE of the following: A. The patient is initiating therapy with the requested agent **OR** B. The patient is not initiating therapy with the requested agent and BOTH of the following: 1. The prescriber has provided information indicating the number of months the patient has been on therapy **AND** 2. The total duration of treatment with the requested agent has NOT exceeded 24 months per lifetime **Length of Approval:** Up to 6 months, with a lifetime maximum of 24 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient is premenopausal (e.g., less than 12 months since last menstrual period) **AND** 3. The patient has had clinical benefit with the requested agent **AND** 4. The prescriber has assessed the patient's bone health AND confirmed the patient's bone health allows for continued therapy with the requested agent **AND** 5. The patient has NOT had a fragility fracture since starting therapy with the requested agent **AND** 6. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 8. BOTH of the following: A. The prescriber has provided information indicating the number of months the patient has been on therapy **AND** B. The total duration of treatment with the requested agent has NOT exceeded 24 months per lifetime **Length of Approval:** Up to 6 months, with a lifetime maximum of 24 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Oriahnn	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met:

1. The patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND**
2. The patient's diagnosis of uterine fibroids was confirmed via imaging (e.g., ultrasound) **AND**
3. The patient has NOT had a hysterectomy **AND**

2. The patient is premenopausal (e.g., less than 12 months since last menstrual period) **AND**
3. The prescriber has confirmed the patient's bone health allows for initiating therapy with the requested agent **AND**
4. ONE of the following:
   A. The patient has tried and had an inadequate response to at least ONE hormonal contraceptive used in the treatment of the requested indication **OR**
   B. The patient has an intolerance or hypersensitivity to at least ONE hormonal contraceptive used in the treatment of the requested indication **OR**
   C. The patient has an FDA labeled contraindication to ALL hormonal contraceptive therapy (i.e., oral, topical patches, implants, injections, IUD) **AND**
5. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
7. ONE of the following:
   A. The patient is initiating therapy with the requested agent **OR**
   B. The patient is not initiating therapy with the requested agent and BOTH of the following:
      1. The prescriber has provided information indicating the number of months the patient has been on therapy **AND**
      2. The total duration of treatment with the requested agent has NOT exceeded 24 months per lifetime

Length of Approval: Up to 6 months, with a lifetime maximum of 24 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Renewal Evaluation

Target Agent (s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**
2. The patient is premenopausal (e.g., less than 12 months since last menstrual period) **AND**
3. The patient has had clinical benefit with the requested agent **AND**
4. The prescriber has assessed the patient's bone health AND confirmed the patient's bone health allows for continued therapy with the requested agent **AND**
5. The patient has NOT had a fragility fracture since starting therapy with the requested agent **AND**
6. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication **AND**
7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
8. BOTH of the following:
   A. The prescriber has provided information indicating the number of months the patient has been on therapy **AND**
   B. The total duration of treatment with the requested agent has NOT exceeded 24 months per lifetime

Length of Approval: Up to 6 months, with a lifetime maximum of 24 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.