



Oriahnn Prior Authorization

Drug(s) Applied:	Oriahnn (elagolix/estradiol/norethindrone)
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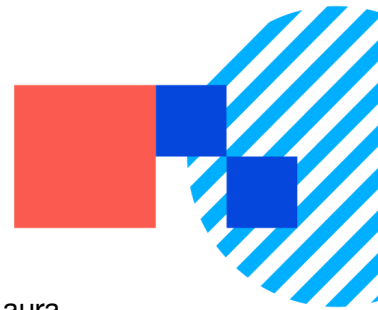
Criteria:

Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria

A. Uterine Fibroids as indicated by chart notes within past 90 days

1. Patient is ≥ 18 years old **and**
2. Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **and**
3. Diagnosis of uterine fibroids was confirmed via imaging (e.g. ultrasound) **and**
4. Patient has not had a hysterectomy **and**
5. Patient is premenopausal **and**
6. ONE of the following:
 - a) Patient has had an inadequate response (3-month trial) to ALL of the following:
 - (1) at least two hormonal contraceptives including one that is a combined estrogen and progestin and one that is progestin-only **and**
 - (2) levonorgestrel-releasing intrauterine systems (IUD) **and**
 - (3) Tranexamic acid **and**
 - (4) Leuprolide, **or**
 - b) Patient has an intolerance or FDA labeled contraindication to ALL agents listed above **and**
7. Patient will NOT be using the requested agent in combination with another GnRH agent **and**
8. Patient has not previously received a continuous regimen of 24 months or longer of therapy with Oriahnn or Myfembree **and**
9. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to the requested drug including:
 - a) Active pregnancy
 - b) Osteoporosis
 - c) Hepatic impairment/disease
 - d) Over 35 years old and active tobacco use or headaches with focal



neurological symptoms or migraine headaches with aura

- e) Uncontrolled hypertension
 - f) History of vascular disease (ex: cerebrovascular disease, coronary artery disease, peripheral vascular disease)
 - g) Thrombogenic valvular or thrombogenic rhythm diseases of the heart (ex: atrial fibrillation)
 - h) Inherited or acquired hypercoagulopathies
 - i) History of thrombotic or thromboembolic disorder including pulmonary embolism, deep vein thrombosis, stroke, or myocardial infarction
 - j) History of breast cancer
 - k) Contraindicated medications (ex: cyclosporine, gemfibrozil) **and**
10. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., Obstetrician-Gynecologist) or is a prescriber who specializes in treatment of women's health.

Approval Duration: up to 6 months; lifetime maximum of 24 months

II. Continued Therapy Criteria

A. **Uterine Fibroids** as indicated by chart notes within past 6 months

- 1. Patient meets the initial therapy criteria above **and**
- 2. Documented clinical benefit since starting the requested agent (i.e., reduction in menstrual blood loss volume) **and**
- 3. Prescriber has confirmed the patient's bone health allows for continued therapy with the requested agent **and**
- 4. Patient has not received a continuous regimen of 24 months or longer of therapy with Oriahnn or Myfembree

Approval Duration: up to 6 months; lifetime maximum of 24 months

Policy Owned by: Curative PBM team