

Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 10, 2020

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

LENGTH OF AUTHORIZATION: SIX MONTHS

REVIEW CRITERIA:

- Patient is ≥ 18 years of age; **AND**
- Patient has a confirmed diagnosis of uterine leiomyomas (fibroids) with heavy menstrual bleeding; **AND**
- Prescribed or in consultation with a specialist in gynecology or reproductive health; AND
- Patient is premenopausal; AND
- Patient has failed (or has contraindication to) adequate trial of the following therapy:
 - Combination hormonal contraceptives, and/or progestin containing oral or depot (e.g. norethindrone)

DOSING AND ADMINISTRATION:

- Morning: One capsule (elagolix 300 mg, estradiol 1mg, norethindrone acetate 0.5mg)
- Evening: One capsule (elagolix 300mg)
- Treatment should be limited to 24 months due to the risk of continued bone loss, which may not be reversible