

Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria ORIAHNN (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules)
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  $\geq 18$  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