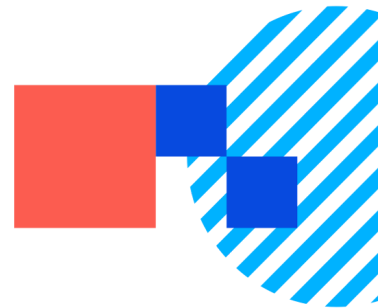




GnRH Prior Authorization

Drug(s) Applied:	Leuprolide acetate, Eligard (leuprolide acetate), Firmagon (degarelix acetate)
-------------------------	--

Criteria:

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

I. Initial Therapy Criteria

A. **Prostate cancer** as indicated by chart notes within past 180 days

1. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., oncology)

Approval Duration: 12 months

B. **Breast cancer** as indicated by chart notes within past 180 days

1. One of the following:

- a) Patient is a pre- or perimenopausal female with breast cancer **and**

- (1) One of the following:

- (a) Patient will use the requested agent for fertility preservation **or**

- (b) Patient will use the requested agent for ovarian suppression during endocrine therapy (e.g., anastrozole, letrozole, exemestane, fulvestrant, tamoxifen, etc.) **or**

- b) Patient is a male with hormone receptor positive advanced or metastatic breast cancer receiving endocrine therapy

Approval Duration: 12 months

C. **Ovarian cancer, fallopian tube cancer, or primary peritoneal cancer** as indicated by chart notes within past 180 days

1. Patient has persistent disease or disease recurrence

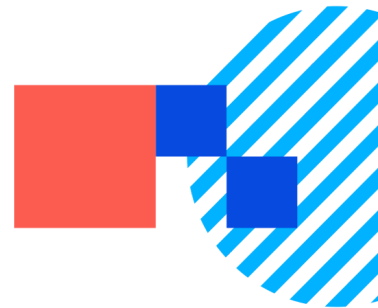
Approval Duration: 12 months

D. **Endometriosis** as indicated by chart notes within past 120 days

1. Patient is at least 18 years of age **and**

2. One of the following:

- a) Patient has tried and had an inadequate response to at least TWO oral or injectable depot contraceptives (e.g. Mirena, Liletta, norethindrone, or



depo-medroxyprogesterone) **or**

- b) Patient has an intolerance or FDA labeled contraindication to ALL oral or injectable depot contraceptives
- 3. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., gynecology)

Approval Duration: 6 months

E. Uterine fibroids as indicated by chart notes within past 120 days

- 1. Patient has anemia due to uterine leiomyomata **or**
- 2. Patient will use requested agent prior to uterine leiomyomata surgery **and**
- 3. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., gynecology)

Approval Duration: 3 months

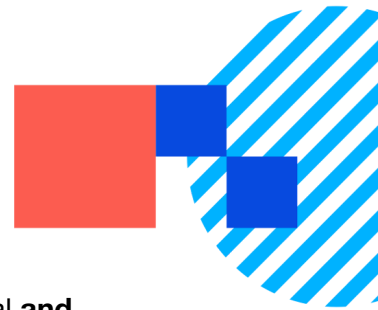
F. Central precocious puberty (CPP) as indicated by chart notes within past 120 days

- 1. Patient is at least 1 year of age and is a pediatric patient **and**
- 2. Diagnosis of CPP confirmed by GnRH stimulation test **and**
- 3. Bone age is 1 year above the chronological age **and**
- 4. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., endocrinology)

Approval Duration: 12 months

G. Gender dysphoria or GID as indicated by chart notes within past 120 days

- 1. Patient is an adolescent and ALL of the following:
 - a) Diagnosis is confirmed by mental health professional trained in child/adolescent developmental psychopathology
 - b) Sex hormone treatment
 - c) Patient does not have any contraindications to treatment
 - d) Patient has been counseled on the side effects of treatment
 - e) Patient is 16 years or older, if less than 16 years of age prescriber must provide support for treatment AND a minimum of two prescribers (e.g., psychiatrist, endocrinologist, primary care physician) have provided consent with a psychiatrist meeting one of the requirements
 - f) Patient, parent or caretaker has provided consent to treatment
 - g) Patient is able to start treatment. Coexisting psychological, medical or social problems have been addressed
 - h) If patient is continuing sex hormone treatment, patient is being monitored at least one time per year **or**
- 2. Patient is an adult and ALL of the following:



- a) Diagnosis is confirmed by mental health professional **and**
- b) Patient has sufficient mental capacity to give consent **and**
- c) Patient mental health issues are reasonably controlled **and**
- d) ONE of the following:
 - (1) Medical conditions that may be exacerbated by hormone treatment have been evaluated
 - (2) If patient is continuing sex hormone treatment, patient is being monitored at least one time per year **and**
- 3. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., endocrinology, psychiatry)

Approval Duration: 12 months

II. Continued Therapy Criteria

A. **Prostate cancer, breast cancer, ovarian cancer, fallopian tube cancer, or primary peritoneal cancer** as indicated by chart notes within past 12 months

- 1. Patient meets the initial therapy criteria above

Approval Duration: 12 months

B. **Endometriosis** as indicated by chart notes

- 1. See initial therapy criteria

Approval Duration: n/a

C. **Uterine fibroids** as indicated by chart notes

- 1. See initial therapy criteria

Approval Duration: n/a

D. **Central precocious puberty** as indicated by chart notes within past 12 months

- 1. Patient meets the initial therapy criteria above **and**
- 2. Documentation to support necessity of continued treatment and fusion of epiphyses has not occurred or chronological age is still beyond bone age

Approval Duration: 12 months

E. **Gender dysphoria** as indicated by chart notes within past 12 months

- 1. Patient meets the initial therapy criteria above **and**
- 2. Documented clinical benefit since starting the requested agent

Approval Duration: 12 months

Policy Owned by: Curative PBM team