curative

GnRH Prior Authorization Drug List A

Drug(s) Applied:	**Leuprolide acetate, Eligard** (leuprolide acetate)**, Firmagon** (degarelix acetate), **Lupron Depot** (leuprolide acetate), **Orgovyx** (relugolix), **Vabrinty** (leuprolide 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. For Lupron Depot, Orgovyx, and Vabrinty, ONE of the following:
   a. Patient has tried and had an inadequate response to Eligard and Firmagon **or**
   b. Patient has an intolerance or FDA labeled contraindication to Eligard and Firmagon **and**
2. 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. For Lupron Depot and Vabrinty, ONE of the following:
   a) Patient has tried and had an inadequate response to Eligard **or**
   b) Patient has an intolerance or FDA labeled contraindication to Eligard **and**
2. 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. For Lupron Depot and Vabrinty, ONE of the following:
      a) Patient has tried and had an inadequate response to Eligard **or**
      b) Patient has an intolerance or FDA labeled contraindication to Eligard **and**
   2. 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. For Lupron Depot and Vabrinty ONE of the following:
      a) Patient has tried and had an inadequate response to Eligard **or**
      b) Patient has an intolerance or FDA labeled contraindication to Eligard **and**
   3. 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 **and**
   4. 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. For Lupron Depot and Vabrinty, ONE of the following:
      a) Patient has tried and had an inadequate response to Eligard or
      b) Patient has an intolerance or FDA labeled contraindication to Eligard **and**
   2. Patient has anemia due to uterine leiomyomata **or**
   3. Patient will use requested agent prior to uterine leiomyomata surgery **and**
   4. 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) For Lupron Depot or Vabrinty, ONE of the following:
        (1) Patient has tried and had an inadequate response to Eligard **or**
        (2) Patient has an intolerance or FDA labeled contraindication to Eligard **and**
    b) Diagnosis is confirmed by mental health professional **and**
    c) Patient has sufficient mental capacity to give consent **and**
    d) Patient mental health issues are reasonably controlled **and**
    e) 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