This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0193-18
**APPROVAL CRITERIA**

I. **Breast Cancer – Goserelin acetate or leuprolide acetate (Lupron Depot 3.75 mg)**

Goserelin acetate or leuprolide acetate (Lupron Depot 3.75 mg) **may be approved** for the treatment of men and pre- or peri-menopausal women with hormone receptor positive breast cancer.

Goserelin acetate or leuprolide acetate **may NOT be approved** for the treatment of breast cancer when the criteria above are not met.

II. **Ovarian Cancer (including fallopian tube cancer and primary peritoneal cancer) – Leuprolide acetate (Lupron Depot 3.75 mg, Lupron Depot-3 Month 11.25 mg)**

Leuprolide acetate (Lupron Depot 3.75 mg, Lupron Depot-3 Month 11.25 mg) **may be approved** for ovarian cancer when **any** of the following are met:

---

*FHK- Florida Healthy Kids*
This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0193-18
Degarelix, goserelin acetate, histrelin acetate (Vantas), leuprolide acetate, or triptorelin pamoate may **NOT be approved for** treatment of prostate cancer when the criteria above are not met.

IV. **Central Precocious Puberty- Leuprolide acetate (Lupron Depot-Ped), nafarelin acetate, histrelin acetate subcutaneous implant (Supprelin LA), Triptodur (triptorelin pamoate intramuscular extended release)**

Leuprolide acetate (Lupron Depot-Ped), nafarelin acetate, histrelin acetate subcutaneous implant (Supprelin LA), and Troptodur* (triptorelin IM) **may be approved** for the treatment of children known to have central precocious puberty (defined as the beginning of secondary sexual characteristics before age 8 in girls and 9 in boys).

*Triptodur (triptorelin pamoate) is indicated for intramuscular injection every 6 months for pediatric persons 2 years of age or older with central precocious puberty. Leuprolide acetate (Lupron Depot-Ped), nafarelin acetate, histrelin acetate subcutaneous implant (Supprelin LA) and Triptodur (triptorelin) **may NOT be approved** for the treatment of central precocious puberty when the criteria above are not met.

V. **Gynecology Uses- Goserelin acetate, leuprolide acetate, leuprolide acetate for depot suspension and norethindrone (Lupaneta Pack), or nafarelin acetate**

A. Goserelin acetate, leuprolide acetate, or nafarelin acetate **may be approved** when **any** of the following indications are met:

1. Chronic pelvic pain (noncyclical pain lasting 6 or more months that localizes to the anatomic pelvis, anterior abdominal wall at or below the umbilicus, the lumbosacral back, or the buttocks, and is of sufficient severity to cause functional disability or lead to medical care [ACOG, 2004])-not to continue beyond 3 months if there is no symptomatic relief; **OR**
2. To induce amenorrhea in women in certain populations, including menstruating women diagnosed with severe thrombocytopenia or aplastic anemia

B. Goserelin acetate **may be approved** for **any** of the following additional indications:

1. Endometriosis (duration of treatment limited to 6 months); **OR**
2. Dysfunctional uterine bleeding; **OR**
3. Endometrial thinning prior to endometrial ablation for dysfunctional uterine bleeding (3.6 mg implant only)
Market Applicability

| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | MD | NJ | NV | NY | TN | TX | WA |
|--------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|
| Applicable | X | X | NA | NA | X | NA | X | X | X | X | NA | NA | NA | NA |

*FHK- Florida Healthy Kids

C. Leuprolide acetate may be approved for any of the following additional indications:
   1. Initial treatment of endometriosis (duration of treatment limited to 6 months); OR
   2. Retreatment of endometriosis (duration of treatment limited to 6 months); OR
   3. Preoperative treatment as adjunct to surgical treatment of uterine fibroids (leiomyoma uteri). May be used to reduce size of fibroids to allow for a vaginal procedure; OR
   4. Prior to surgical treatment (myomectomy or hysterectomy) in individuals with documented anemia

D. Leuprolide acetate for depot suspension and norethindrone acetate tablets (Lupaneta Pack) may be approved for any of the following indications:
   1. Initial treatment of endometriosis (duration limited to 6 months); OR
   2. Retreatment of endometriosis (duration of treatment limited to 6 months).

E. Nafarelin acetate may be approved for the following additional indication:
   1. Endometriosis (duration of treatment limited to 6 months).

Goserelin acetate, leuprolide acetate, leuprolide acetate for depot suspension and norethindrone acetate tablets, or nafarelin acetate may NOT be approved for gynecological uses when the criteria above are not met.

VI. Ovarian Preservation for Fertility during Chemotherapy

   A. GnRH analogs may be approved for preservation of fertility in pre-menopausal women that will receive chemotherapy with curative intent.

GnRH analogs may NOT be approved for preservation of fertility when the criteria above are not met.

VII. Gender Dysphoria/Incongruence in Adolescents

   A. GnRH analogs may be approved for adolescents (greater than or equal to 10 years of age and less than 18 years of age) with gender dysphoria when all of the following criteria are met:
      1. Fulfills the DSM V criteria for gender dysphoria; and
      2. Has experienced puberty to at least Tanner stage 2; and
This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0193-18
This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0193-18
This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0193-18