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.

WEB-PEC-0573-17
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III. Prostate Cancer- Degarelix, goserelin acetate, histrelin acetate (Vantas), leuprolide acetate, or triptorelin pamoate

A. Degarelix, goserelin acetate, histrelin acetate (Vantas), leuprolide acetate, or triptorelin pamoate may be approved for the treatment of prostate cancer when any of the following indications are met:

1. Clinically localized disease* with intermediate (T2b to T2c cancer, Gleason score of 7, or prostate specific antigen (PSA) value of 10-20 ng/ml) or higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery; OR
2. Following radical prostatectomy as adjuvant therapy when lymph node metastases are present; OR
3. Locally advanced disease*; OR
4. Other advanced*, recurrent, or metastatic disease*.

*Definitions –
- Clinically localized prostate cancer: Cancer presumed to be confined within the prostate based on pre-treatment findings such as physical exam, imaging, and biopsy findings.
- Locally advanced disease (prostate cancer): Cancer that has spread from where it started to nearby tissue or lymph nodes.
- Metastatic: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.
- Advanced prostate cancer: Disease that has spread beyond the prostate to surrounding tissues or distant organs.

May NOT be approved:
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, or histrelin acetate subcutaneous implant (Supprelin LA)

Leuprolide acetate (Lupron Depot-Ped), nafarelin acetate, or histrelin acetate subcutaneous implant (Supprelin LA) 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).

May NOT be approved:
Leuprolide acetate (Lupron Depot-Ped), nafarelin acetate, or histrelin acetate subcutaneous implant (Supprelin LA) 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

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.
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)

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).

**May NOT be approved**
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

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

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

VI. Gender Dysphoria 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
   3. Has (early) pubertal changes that have resulted in an increase of their gender dysphoria; and
   4. Does not suffer from a psychiatric comorbidity that interferes with the diagnostic work-up or treatment; and
   5. Has psychological and social support during treatment; and

**May NOT be approved:**
GnRH analogs may NOT be approved for adolescents with gender dysphoria when the criteria above are not met.

### State Specific Mandates

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<tr>
<th>State name</th>
<th>Date effective</th>
<th>Mandate details (including specific bill if applicable)</th>
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**Key References:**


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