

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	X	NA	NA	NA

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Gonadotropin Releasing Hormone Analogs (GnRH)

CG-DRUG-60
CG-DRUG-61

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Varies upon diagnosis

Medications	Quantity Limit	Line of Business
Eligard (leuprolide acetate) 7.5mg	1 per 4 weeks	All MCD
Eligard (leuprolide acetate) 22.5mg	1 per 12 weeks	All MCD
Eligard (leuprolide acetate) 30mg	1 per 16 weeks	All MCD
Eligard (leuprolide acetate) 45mg	1 per 24 weeks	All MCD
Firmagon (degarelix) 80mg	1 injection (80 mg) per 28 days	VA MCD and AGP MCD Only
Firmagon (degarelix) 120mg	2 injections (240 mg) per year	VA MCD and AGP MCD Only
Lupaneta Pack (leuprolide acetate and norethindrone acetate)	N/A	VA MCD and AGP MCD Only
Leuprolide acetate (immediate release)	N/A	All MCD
Lupron Depot (1 month) (leuprolide acetate) 3.75mg	1 per 4 weeks	VA MCD and AGP MCD Only
Lupron Depot (1 month) (leuprolide acetate) 7.5 mg	1 per 4 weeks	VA MCD and AGP MCD Only
Lupron Depot (3 months) (leuprolide acetate) 11.25mg and 22.5mg	1 kit per 12 weeks	VA MCD and AGP MCD Only
Lupron Depot (4 month) (leuprolide acetate) 30mg	1 per 16 weeks	VA MCD and AGP MCD Only
Lupron Depot (6 month) (leuprolide acetate) 45mg	1 per 24 weeks	VA MCD and AGP MCD Only
Lupron Depot Ped (leuprolide acetate) 7.5mg	1 per 4 weeks	VA MCD and AGP MCD Only
Lupron Depot Ped (leuprolide acetate) 11.25mg	N/A	VA MCD and AGP MCD Only
Lupron Depot Ped (leuprolide acetate) 15mg	N/A	VA MCD and AGP MCD Only

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Lupron Depot Ped (3 month) (leuprolide acetate) 11.25mg and 30mg	N/A	VA MCD and AGP MCD Only
Supprelin LA (histrelin acetate) 50mg	1 implant per year	VA MCD and AGP MCD Only
Synarel Nasal Spray (nafarelin acetate) 2mg/mL (60 sprays/bottle)	5 bottles per 30 days	All MCD
Trelstar (triptorelin pamoate) 22.5mg	1 per 24 weeks	VA MCD and AGP MCD Only
Trelstar Depot (triptorelin pamoate) 3.75mg	1 per 4 weeks	VA MCD and AGP MCD Only
Trelstar LA (triptorelin pamoate) 11.25mg	1 per 12 weeks	VA MCD and AGP MCD Only
Triptodur (triptorelin pamoate extended release) 22.5mg kit	1 kit per 24 weeks	VA MCD and AGP MCD Only
Vantas Implant (histrelin acetate)	N/A	VA MCD and AGP MCD Only
Zoladex (1 month) (goserelin acetate) 3.6mg implant	1 per 4 weeks	VA MCD and AGP MCD Only
Zoladex (3 month) (goserelin acetate) 10.8mg implant	1 per 12 weeks	VA MCD and AGP MCD Only

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:

PAGE 2 of 8 01/01/2018

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CRX-ALL-0193-18

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- A. Hormonal therapy for clinical relapse in individuals with stage II-IV granulosa cell tumors; **OR**
- B. Hormonal therapy for treatment of epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer as a single agent for persistent disease or recurrence.

Leuprolide acetate **may NOT be approved** for ovarian cancer when the criteria above are not met.

III. **Prostate Cancer- Degarelix; goserelin acetate; histrelin acetate (Vantas); leuprolide acetate (Eligard 7.5 mg [1 Month], 22.5 mg [3 Month], 30 mg [4 month], 45 mg [6 Month]); Lupron Depot 7.5 mg [1 Month], 22.5 mg [3 Month], 30 mg [4 Month], 45 mg [6 Month]), or triptorelin pamoate**

- A. Degarelix; goserelin acetate; histrelin acetate (Vantas); leuprolide acetate, **or** (Eligard 7.5 mg [1 Month], 22.5 mg [3 Month], 30 mg [4 Month], 45 mg [6 Month]; Lupron Depot 7.5 mg [1 Month], 22.5 mg [3 Month], 30 mg [4 Month], 45 mg [6 Month]); triptorelin pamoate **may be approved** for the treatment of prostate cancer when **any** of the following indications are met:
 1. Used as androgen deprivation therapy as a single agent or in combination with an antiandrogen; **OR**
 2. Used for clinically localized disease* with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, 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**
 3. Used for progressive castration-naïve disease; **OR**
 4. Used for castration-recurrent disease; **OR**
 5. 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.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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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 Triptodur* (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)

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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- 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**

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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**
6. Demonstrates knowledge and understanding of the expected outcomes of GnRH analog treatment.

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

VIII. Salivary Gland Tumors – Leuprolide acetate (Eligard 7.5 mg [1 Month], 22.5 mg [3 Month]; Lupron Depot 7.5 mg [1 Month], 22.5 mg [3 Month])

- A. Leuprolide acetate (Eligard 7.5 mg [1 Month], 22.5 mg [3 Month]; Lupron Depot 7.5 mg [1 Month], 22.5 mg [3 Month]) **may be approved** for the treatment of salivary gland tumors when all of the following criteria are met:
1. Used for androgen receptor positive recurrent disease with distant metastases; **AND**
 2. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0-3.

Leuprolide acetate **may NOT be approved** for the treatment of salivary gland tumors when the criteria above are not met.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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2. Degarelix Acetate. In: DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Last Modified: February 20, 2018. Available at: <http://www.micromedexsolutions.com>. Accessed on April 4, 2018.
3. Degarelix Acetate Monograph. Lexicomp® Online, American Hospital Formulary Service® (AHFS®) Online, Hudson, Ohio. Lexi-Comp., Inc. Last revised October 16, 2017. Accessed on April 4, 2018.
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 - Goserelin acetate
 - Histrelin acetate
 - Leuprolide acetate
 - Leuprolide acetate for depot suspension
 - Triptorelin pamoate
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 - Head and Neck Cancers (V.1.2018). Revised February 15, 2018
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 - Prostate Cancer (V.2.2018). Revised March 8, 2018.

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