Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION AND STEP THERAPY POLICY AND CRITERIA ORPTCONC057B.0225	**ANTINEOPLASTIC AGENTS** **GONADOTROPIN RELEASING HORMONE AGONISTS** See Table 1 for medications
Effective Date: 4/1/2025	**Review/Revised Date**: 08/97, 03/98, 08/98, 01/99, 03/00, 05/02, 12/02, 12/03, 12/04, 02/06, 06/07, 12/08, 12/09, 04/10, 06/11, 08/11, 02/12, 02/13, 02/14, 02/15, 04/15, 06/15, 01/16, 01/17,12/17, 09/18, 01/19, 03/19 , 05/19, 12/19, 08/20, 01/21, 05/21, 07/21, 01/22, 06/22, 12/22, 06/23, 12/23, 12/24 (MTW)
Original Effective Date: 10/97	**P&T Committee Meeting Date**: 01/99, 03/00, 12/02, 12/03, 12/04, 02/06, 06/07, 12/08, 12/09, 04/10, 08/11, 02/12, 02/13, 02/14, 06/14, 02/15, 04/15, 06/15, 02/16, 02/17, 12/17, 02/18, 09/18, 10/18, 02/19, 04/19, 06/19, 02/20, 08/20, 02/21, 06/21, 08/21, 02/22, 06/22, 02/23, 06/23, 02/24, 02/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:
Medicare Part B

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit. Medically necessary off-label uses may be approved according to the clinical criteria outlined in the policy.

REQUIRED MEDICAL INFORMATION:
For **initiation of therapy** with the requested agent (new starts), must meet the indication-specific criteria outlined below:

1. **For oncological indications,** gonadotropin releasing hormone agonists may be covered if the following criteria are met:
    a. Use is for an FDA approved indication or indication supported by National Comprehensive Cancer Network guidelines with recommendation 2A or higher
2. **For uterine leiomyomata (fibroids),** leuprolide acetate may be covered if one of the following criteria (a or b) are met:
    a. Request is for use prior to surgery to improve anemia caused by fibroids and the following criteria (i and ii) are met:
        i. Documented trial, failure, intolerance, or contraindication to at least 30 days of therapy with iron supplementation alone
        ii. Documentation that leuprolide acetate will be used in combination with iron supplementation
    b. Request is for use prior to surgery to reduce the size of fibroids and the following criteria are met:

i. Documentation that surgical removal of fibroids is planned within four months

3. **For endometriosis**, leuprolide acetate or goserelin acetate may be covered if the following criteria are met:
    a. Chart notes or provider attestation that other causes of gynecologic pain have been ruled out (such as irritable bowel syndrome, interstitial cystitis, urinary tract disorders)
    b. Documentation that patient has failed a three-month trial of hormonal contraceptives unless they are not tolerated, or contraindicated
4. **For endometrial thinning/dysfunctional uterine bleeding,** goserelin acetate may be covered if the following criteria are met:
    a. Documentation for use prior to endometrial ablation
5. **For central precocious puberty,** gonadotropin releasing hormone agonists may be covered if one of the following criteria (a or b) are met:
    a. Request is for a one-time dose for diagnostic purposes
    b. All the following criteria:
        i. Documentation of a history of early onset of secondary sexual characteristics (age eight years and under for females or nine years and under for males)
        ii. Confirmation of diagnosis by one of the following:
            - Pubertal response to a GnRH or GnRH analog (such as leuprolide) stimulation test [for example stimulated peak luteinizing hormone (LH) of approximately 4.0 to 6.0 IU/L and/or elevated ratio of LH/follicle-stimulating hormone at 0.66 or greater (reference range may vary depending on assay)]
            - Pubertal level of basal LH levels (0.2 IU/L or greater)
            - Bone age advanced one year beyond the chronological age
6. **For gender-affirming services,** gonadotropin releasing hormone agonists may be covered if the following criteria (a and b) are met:
    a. Prescribed by or in consultation with an endocrinologist
    b. Chart notes or provider attestation that puberty has progressed to a minimum of Tanner Stage 2
7. **For premenstrual symptoms,** gonadotropin releasing hormone agonists may be covered if all the following criteria are met:
    a. Attestation of severe symptoms
    b. Documented trial and failure or contraindication/intolerance to a selective serotonin reuptake inhibitor (SSRI) or a combined oral estrogen-progestin contraceptive
    c. Documentation that medication will be used in combination with “add-back” progesterone therapy (such as norethindrone)

For patients **established on the requested therapy** (within the previous year), must meet indication-specific criteria below:

1. **For oncological indications:**
    a. Documentation of successful clinical response to therapy
2. **For uterine leiomyomata (fibroids):**
    a. Documentation that the patient has not received more than three months of therapy for current course of treatment. Initial criteria must be met for a new course of treatment.
3. **For endometriosis:**
    a. For leuprolide acetate:
        i. Documentation that it will be used in combination with "add-back" progesterone therapy (such as norethindrone) to help prevent bone mineral density loss
        ii. Documentation that the patient has not received more than 12 months of therapy
    b. For goserelin acetate: Documentation that the patient has not received more than six months of therapy
4. **For endometrial thinning/dysfunctional uterine bleeding:**
    a. Documentation that the patient has not had more than two months of therapy for current course of treatment. Initial criteria must be met for a new course of treatment.
5. **For central precocious puberty:**
    a. Documentation of clinical response to treatment such as pubertal slowing or decline, height velocity, bone age, LH, or estradiol and testosterone level, and
    b. Documentation that hormonal and clinical parameters are being monitored periodically during treatment to ensure adequate hormone suppression
6. **For gender-affirming services:** Documentation of successful clinical response to therapy
7. **For premenstrual symptoms**: Documentation of successful clinical response to therapy

EXCLUSION CRITERIA:
Treatment of male infertility

AGE RESTRICTIONS: N/A

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:

- **Oncological Indications:** Authorization will be approved until no longer eligible with the plan, subject to formulary and/or benefit changes.
- **Uterine leiomyomata (fibroids):** Initial authorization will be approved for three months. No reauthorization.
- **Endometriosis:** For Lupron®- authorization/reauthorization will be approved for up to six months (total of 12 months). For Zoladex® - initial authorization for up to six months and no reauthorization.
- **Endometrial thinning/dysfunctional uterine bleeding:** Initial authorization will be approved for two months. No reauthorization.
- **Central precocious puberty:** Authorization/reauthorization will be approved for one year
- **Gender-affirming services:** Authorization/reauthorization will be approved for one year
- Premenstrual symptoms: Authorization/reauthorization will be approved for six months

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For off-label use criteria please see the Chemotherapy Treatment Utilization Criteria; Coverage for Non-FDA Approved Indications ORPTCOPS105.

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:

Leuprolide acetate, an LH-RH agonist, is a synthetic analog of naturally occurring gonadotropin-releasing hormone (GnRH). GnRH regulates follicle-stimulating hormone (FSH) and luteinizing hormone (LH) synthesis and secretion by the pituitary gland. The synthetic leuprolide possesses greater potency than the natural GnRH hormone. With continued leuprolide administration for more than one to three weeks, the pituitary gland downregulates and desensitizes GnRH receptors, reducing FSH and LH secretion. In humans, administration of leuprolide acetate results in an initial increase in circulating levels of FSH and LH, leading to a transient

increase in concentrations of gonadal steroids (testosterone and dihydrotestosterone in males, and estrone and estradiol in premenopausal females). However, continuous administration of leuprolide acetate results in decreased levels of LH and FSH. In males, leuprolide reduces serum testosterone to castrate levels within two to four weeks after initiation of treatment and requires continuation of therapy as maintenance. Normal pituitary and gonadal function typically return after approximately three months of discontinuation of leuprolide however testosterone production may not return to baseline in some cases.

Triptorelin, nafarelin, and histrelin are also LH-RH analogs that reversibly inhibit gonadotropin secretion. Initial temporary increase in LH, FSH, testosterone, and estradiol is followed by a sustained reduction in LH and FSH which in turn lowers testicular and ovarian steroidogenesis.

FDA APPROVED INDICATIONS: [1-2]

Camcevi® (leuprolide mesylate)

- Must be administered by a healthcare provider
- Treatment of advanced prostate cancer
    - 42 mg SQ every six months

Eligard® (leuprolide acetate)

- Must be administered by a healthcare professional
- Treatment of advanced prostate cancer
    - 7.5 mg subcutaneously (SC) every month
    - 22.5 mg SC every three months
    - 30 mg SC every four months
    - 45 mg SC every six months

Fensolvi® (leuprolide acetate)

- Must be administered by a healthcare professional
- Central Precocious Puberty (two years and older)
    - 45 mg SC every six months

Lupron® (leuprolide acetate)

- Must be administered by a healthcare professional, except for the 3.75 mg and 1 mg/0.2 mL strengths
- Long term therapy (greater than six months) with leuprolide can reduce bone mineral density. This effect is partially reversible, although bone mineral density may remain below pretreatment values for up to one year after discontinuing leuprolide therapy.
- Treatment of advanced prostate cancer
    - Leuprolide acetate injection 1 mg/0.2 ml SQ daily
    - Lupron® Depot 7.5 mg intramuscularly (IM) monthly

  - Lupron® Depot 22.5 mg IM every three months
  - Lupron® Depot 30 mg IM every four months
  - Lupron® Depot 45 mg IM every six months
- Endometriosis
  - Lupron® Depot 3.75 mg IM monthly (up to six months)
  - Lupron® Depot 11.25 mg IM every three months (up to six months)
  - If symptoms recur, retreatment may be reconsidered for no more than six months but only with the addition of norethindrone acetate add-back therapy
- Uterine Leiomyomata (Fibroids)
  - Lupron® Depot 3.75 mg IM monthly (up to three months)
  - Lupron® Depot 11.25 mg IM as a single injection
- Central Precocious Puberty
  - Lupron Depot-Ped® (1-month formulation) IM monthly (weight-based dosing)
    - 25 kg and less: 7.5 mg
    - 25 to 37.5 kg: 11.25 mg
    - 37.5 kg and greater: 15 mg
  - Lupron Depot-Ped® (3-month formulation) IM 11.25 mg or 30 mg every three months
  - Lupron Depot-Ped® (3-month formulation) IM 45 mg every six months

Triptodur® (triptorelin)

- Must be administered by a healthcare provider
- Central Precocious Puberty for patients aged two years or older
  - Triptodur® 22.5 mg IM injection every 24 weeks

Trelstar® (triptorelin pamoate kit)

- Must be administer under the supervision of a physician
- Treatment of advanced prostate cancer
  - Trelstar® 3.75 mg IM injection every four weeks
  - Trelstar® 11.25 mg IM injection every twelve weeks
  - Trelstar® 22.5 mg IM injection every twenty-four weeks

Supprelin LA® (histrelin acetate implant)

- Must be administer under the supervision of a physician
- Central Precocious Puberty
  - Supprelin LA 50 mg implant inserted SQ every 12 months

Zoladex® (goserelin implant)

- Must be administered under the supervision of a physician
- Palliative treatment of advanced prostate cancer
  - Zoladex® 3.6 mg SQ every 28 days
  - Zoladex® 10.8 mg SQ every 12 weeks

- Prostate cancer, in combination with flutamide for locally confined stage B2-C disease
    - Zoladex® 3.6 mg SQ followed in 28 days by 10.8 mg, started eight weeks prior to radiotherapy in combination with flutamide
    - Four injections of Zoladex® 3.6 mg at 28-day intervals, two injections prior to and two injections during radiotherapy
- Palliative treatment of advanced breast cancer in pre- and peri-menopausal women
    - Zoladex® 3.6 mg SQ every 28 days for long-term therapy
- Endometriosis
    - Zoladex® 3.6 mg SQ every 28 days for up to six months
- Hypoplasia of endometrium
    - Zoladex® 3.6 mg SQ four weeks prior to endometrial ablation surgery
    - Two Zoladex® 3.6 mg SQ given four weeks apart with endometrial ablation surgery performed within 2-4 weeks of the second injection

Treatment of male infertility is not a covered indication.

POSITION STATEMENT:
Gonadotropin releasing hormone agonists are approved by the Food and Drug Administration (FDA) for several indications including treatment of prostate cancer, breast cancer, uterine fibroids, endometriosis, hypoplasia of endometrium, and central precocious puberty in children.

Uterine fibroids or leiomyomata:
- Lupron Depot® 3.75 mg IM monthly and 3-Month 11.25 mg as single injection are administered concomitantly with iron therapy to assist in preoperative management of anemia caused by fibroids. Some patients may respond to a one-month trial of iron therapy alone. Leuprolide may be added if the response to iron therapy is not adequate.
- Treatment with leuprolide can also reduce both uterine and fibroid volume. The recommended duration of therapy with Lupron Depot® for this indication is three months (or a single injection of Lupron Depot® 3-month 11.25 mg). This therapy has only been studied in women 18 years of age and older.
- Add-back therapy with norethindrone is not indicated for leiomyomas but may be considered to maintain amenorrhea and reduce uterine volume, as well as prevention of vasomotor symptoms.
- According to a Cochrane review in 2017, there is low quality of evidence to support the use of preoperative GnRH analogs reduced blood loss, operation time, and complication rates during hysterectomy.

Endometriosis:

- There are several agents and procedures used to treat patient symptoms however none of them result in a cure or long-term management for most patients. The management of endometriosis is dependent on patient specific factors such as type and severity of symptoms, current or future reproductive goals, and patient demographics.
- First line treatment considerations include non-steroidal anti-inflammatory drugs (NSAIDS), combined oral contraceptives, and progestins. Second line treatment considerations include GnRH agonists, progestin intrauterine devices (IUDs), and aromatase inhibitors. Lupron Depot® 3.75 mg and 3-Month 11.25 mg IM injections, Synarel® nasal solution, and Zoladex® subcutaneous implant are indicated for the management of endometriosis.
- Concurrent use of progestin, such as norethindrone acetate 5mg, or combined hormone therapy (estrogen and progestin), is also indicated for management of endometriosis as add-back therapy to reduce severity of hypoestrogenic effects of gonadotropin-releasing hormone (GnRH) agonists and to manage pelvic pain.
- Hypoestrogenic effects include loss of bone density, hot flushes, vaginal dryness, headaches, and mood changes. GnRH agonist monotherapy beyond six months is not recommended due to hypoestrogenic effects, therefore duration of initial treatment or retreatment should be limited to six months.
- Retreatment with a GnRH agonist (Lupron Depot®) including add-back therapy is recommended. If patients cannot take concomitant norethindrone for retreatment, then retreatment is not recommended. Retreatment with Synarel® and Zoladex® (after initial treatment of six months) is not recommended due to lack of safety data of use beyond six months.

Palliative Treatment of Prostate Cancer:

- Leuprolide, goserelin, and triptorelin are treatment options to consider as part of androgen deprivation therapy (ADT) in prostate cancer. They can be used alone or in combination with antiandrogen therapy. Other options for ADT include LHRH antagonists or orchiectomy. Lupron Depot®, Camcevi®, Eligard®, Trelstar®, and Zoladex® are approved for use in prostate cancer.

Central Precocious Puberty (CPP):

- Females less than eight years of age and males less than nine years of age that have an onset of secondary sexual characteristics (e.g., maturation of pubic hair, maturation of breasts in females, maturation of testes and penis in males) should be evaluated for CPP. [3,10,13,15] Children with CPP also have significant advancement of bone age and/or accelerated linear growth for their age.

- Prior to initiation of leuprolide, triptorelin, nafarelin, or histrelin therapy, the diagnosis should be confirmed by measuring basal and/or GnRH-analog-stimulated luteinizing hormone (LH) levels.
    - Typically, prepubertal basal LH level is less than 0.3 IU/L when measured using an ultrasensitive methodology, such as immunochemiluminescence that has a lower limit of detection of 0.1 IU/L.
    - For GnRH analog stimulation test, it is suggested that a peak stimulated LH level greater than approximately 4.0 to 6.0 IU/L after GnRH analog administration is indicative of CPP. In contrast, children who are prepubertal will have minimal increase from baseline.
    - Due to variable assay and sensitivity limits, precise cutoffs of basal and GnRH analog stimulated LH levels are difficult to establish and results should be interpreted based on specific assay performed.
    - A peak stimulated LH:FSH (follicle-stimulating hormone) ratio greater than 0.66 indicates puberty in females. Peak LH:FSH ratio is often used to distinguish progressive CPP (LH:FSH greater than 0.66) from nonprogressive CPP in both males and females.
    - Measurement of basal or stimulated sex steroids (testosterone and estradiol) can also be helpful in evaluating patient for CPP, although sex steroid levels alone is insufficient to confirm diagnosis of CPP. It is not recommended to utilize random estradiol levels in CPP evaluation since it may be unmeasurable even in advanced puberty stage.
- Baseline evaluation should also include height and weight measurements, sex steroid levels, and other diagnostic tests to rule out tumors.
- The manufacturer recommends consideration of discontinuation before the age of 11 in females and 12 in males.

Gender Dysphoria:

- GnRH analogs have been shown to be effective in suppressing pubertal hormones.
- According to the Endocrine Society and World Professional Association for Transgender Health guidelines, adolescents who fulfill eligibility and readiness criteria for gender reassignment should initially undergo treatment to suppress pubertal development. The guideline suggests that clinicians counsel patients regarding options for fertility preservation prior to initiating GnRH treatment.
    - The suppression of pubertal hormones should begin when girls and boys first exhibit physical changes of puberty (confirmed by pubertal levels of estradiol and testosterone, respectively), but no earlier than Tanner stages 2 to 3.
    - Tanner stages, also known as Sexual Maturity Rating (SMR), is a staging system for evaluation of pubertal development in children and adolescents

by using description of secondary sexual characteristics which includes pubic hair changes, breast changes in females, and genital changes in males.

- Off-label dosing for gender dysphoria, transgender females (male-to-female) according to Endocrine Society guidelines:
    - Leuprolide acetate (Lupron®, Eligard®) 3.75 mg IM (depot only) or SC once monthly or 11.25 mg IM every three months in combination with other hormonal therapies
    - Goserelin acetate (Zoladex®) 3.8 mg SC every four weeks in combination with estradiol valerate 10 mg IM every 10 days

Endometrial thinning/dysfunctional uterine bleeding: GnRH agonists, such as Lupron® 3.75 mg IM monthly, can be used for endometrial preparation for hormonal suppression prior to endometrial ablation. Endometrial ablation is a procedure to treat abnormal uterine bleeding and, depending on the ablation technique, it is most effective when performed with relatively thin endometrium which can be achieved with hormonal therapy, including GnRH. Pretreatment should be initiated 30 to 60 days prior to procedure.

Severe, refractory premenstrual symptoms[20]:

- For the management of premenstrual symptoms, the American College of Obstetricians and Gynecologists (ACOG) guideline for the Management of Premenstrual Disorders recommends lifestyle and behavioral interventions as well as medical management using selective serotonin reuptake inhibitors (SSRIs) or hormonal agents for some patients. Choice of therapy depends on timing, type, and severity of a patient's symptoms. SSRIs are recommended as first-line based on the available efficacy and safety data in this population. There are three SSRIs approved by the FDA to treat premenstrual dysphoric disorder (sertraline, paroxetine, and fluoxetine). Venlafaxine may also improve symptoms. For hormonal medical management, treatment options include combined oral contraceptives (COCs), gonadotropin-releasing hormone (GnRH) agonists, progestin-only methods, and non-contraceptive continuous estrogen formulations, however it is noted that COCs and GnRH agonists have the best evidence to support this use. ACOG suggests the use of GnRH agonists with adjunctive combined hormonal add-back therapy only for adult patients who have severe physical and affective premenstrual symptoms that have not responded to other treatments due to the risks for adverse effects, including vasomotor symptoms and decreased bone density.

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Table 1. Gonadotropin-Releasing Hormone Agonists

Generic Name	Brand Name	Dosage	HCPCS Code	Benefit
leuprolide mesylate syringe for SC administration	**Camcevi®**	• 42 mg	J1952	Part B
leuprolide acetate injection (IM or SC)	**Generic leuprolide acetate for depot suspension**	• 22.5 mg	J1954	Part B
	Eligard®	• 7.5 mg • 22.5 mg • 30 mg • 45 mg	J9217	Part B
	Fensolvi®	• 45 mg	J1951	Part B
	Lupron Depot-Ped®	• 7.5 mg • 11.25 mg • 15 mg	J1950	Part B

		• 30 mg • 45 mg)		
	Lupron Depot®	• 3.75 mg	J1950	Part B or Part D when self-administered
	Lupron Depot®	• 7.5 mg • 11.25 • 22.5 mg • 30 mg • 45 mg	J9217	Part B
	Lupron®	• 1 mg/0.2 ml solution • 14 mg/2.8 ml kit	J9218	Part D *on CMS SADs exclusion list
histrelin SC implant	**Supprelin LA®**	• 50 mg	J9226	Part B
triptorelin pamoate vial for IM injection	**Trelstar®**	• 3.75 mg • 11.25 mg • 22.5 mg	J3315	Part B
	Triptodur®	• 22.5 mg	J3316	Part B
goserelin SC implant	**Zoladex®**	• 3.6 mg • 10.8 mg	J9202	Part B

Table 2. ICD-10 codes covered without Prior Authorization
HCPCS codes will not require Prior Authorization when billed with any of the following diagnosis codes:

ICD-10 Code	Description	Drugs	HCPCS Code
C61	Malignant neoplasm of prostate	Camcevi	J1952
		Eligard and Lupron Depot • 7.5 mg • 22.5 mg • 30 mg • 45 mg	J9217
		Lupron Depot 3.75 mg	J1950
		Leuprolide acetate 1 mg/0.2 ml	J9218

		Leuprolide acetate depot 22.5 mg	J1954
		Trelstar • 3.75 mg • 11.25 mg • 22.5 mg	J3315
		Zoladex • 3.6 mg • 10.8 mg	J9202