

PHARMACY COVERAGE GUIDELINE

FENSOLVI® (leuprolide acetate) subcutaneous suspension **LUPRON DEPOT® (leuprolide acetate) intramuscular suspension** **LUPRON DEPOT PED® (leuprolide acetate) intramuscular suspension**

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
- The “Description” section describes the Service.
- The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
- The “Resources” section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require precertification is available at www.azblue.com/pharmacy. You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

Section A. Central Precocious Puberty:

FENSOLVI (leuprolide acetate) 45 mg SQ for 6-months use

LUPRON DEPOT-PED (leuprolide acetate) 7.5 mg, 11.25 mg, 15 mg IM for 1-month use

LUPRON DEPOT-PED (leuprolide acetate) 11.25 mg, 30 mg IM for 3-month use

- **Criteria for initial therapy:** Lupron Depot-PED (leuprolide acetate) or Fensolvi (leuprolide acetate) is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in the patient’s diagnosis or is in consultation with a Pediatric Endocrinologist

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2. Individual is **ONE** of the following:
 - a. **For Fensolvi:** 2 years of age or older
 - b. **For all others:** 1 years of age or older
3. A confirmed diagnosis of **central precocious puberty** by **ONE** of the following:
 - a. Bone age that has advanced at least 1 year beyond chronological age
 - b. GnRH stimulation test showing LH response is > 5 mIU/mL
 - c. Basal, unstimulated LH level is > 0.3 mIU/L (in the pubertal range)
 - d. Peak stimulated LH/FSH ratio is > 0.66
4. Individual has early onset of secondary sexual characteristics is **ONE** of the following
 - a. Female at < 8 years of age
 - b. Male < 9 years of age
5. There are **NO** FDA-label contraindications, such as:
 - a. Hypersensitivity to GnRH, GnRH agonist or any excipients
 - b. Pregnancy
6. Will **not** use partial syringes, combination of syringes, or other leuprolide depot forms to achieve a dose that is not an FDA-approved dose for the condition
7. **For Fensolvi only:** Provider must submit rationale for use over other leuprolide depot forms

Initial approval duration:

Fensolvi 45 mg for 6-month dosing: **12 months (total 2 injections)**

Lupron Depot-PED 7.5 mg, 11.25 mg, or 15 mg for 1-month dosing: **12 months (total 12 injections)**

Lupron Depot-PED 11.25 mg or 30 mg for 3-month dosing: **12 months (total 4 injections)**

- **Criteria for continuation of coverage (renewal request):** Lupron Depot-PED (leuprolide acetate) or Fensolvi (leuprolide acetate) is considered **medically necessary** and will be approved when **ALL** of the following criteria are met (**samples are not considered for continuation of therapy**):
1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Pediatric Endocrinologist
 2. Individual's condition has responded while on therapy with response defined as the **THREE** of the following:
 - a. LH level have been suppressed to pre-pubertal levels
 - b. Progression of secondary sex characteristics have been prevented
 - c. Growth rate has decreased and bone age to chronological age has decreased, but has not attained appropriate chronologic pubertal age yet
 - d. There is suppression of pituitary gonadotropins (FSH, LH) to pre-pubertal levels
 - e. There is suppression of peripheral sex steroids (testosterone and estradiol) to pre-pubertal levels
 3. Individual has been adherent with the medication

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4. Will **not** use partial syringes, combination of syringes, or other leuprolide depot forms to achieve a dose that is not an FDA-approved dose for the condition
5. Individual has not developed any contraindications that may exclude continued use such as:
Contraindications as listed in the criteria for initial therapy section

Renewal approval duration:

Fensolvi 45 mg for 6-month dosing: **12 months (total 2 injections)**

Lupron Depot-PED 7.5 mg, 11.25 mg, or 15 mg for 1-month dosing: **12 months (total 12 injections)**

Lupron Depot-PED 11.25 mg or 30 mg for 3-month dosing: **12 months (total 4 injections)**

AND there are evaluations for treatment discontinuation starting before age 11 years in girls and 12 years in boys, treatment will be discontinued with fusion of the epiphyses or achievement of appropriate chronologic pubertal age

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**
2. **Off-Label Use of Cancer Medications**

Section B. Endometriosis and Uterine Leiomyomata (fibroids):

LUPRON DEPOT (leuprolide acetate) IM 3.75 mg, for 1-month use

LUPRON DEPOT (leuprolide acetate) IM 11.25 mg for 3-month use

- **Criteria for initial therapy:** Lupron Depot (leuprolide acetate) is considered **medically necessary** and will be approved with the following criteria:
1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Gynecologist
 2. Individual is a woman 18 years of age or older
 3. A confirmed diagnosis of **ONE** of the following:
 - a. **Endometriosis-related pelvic pain, pelvic tenderness, dyspareunia, and dysmenorrhea**
 - b. **Uterine leiomyomata (fibroids)-induced anemia** for preoperative hematologic improvement
 4. Individual has failure, contraindication per FDA-label or intolerance to the following:
 - a. **For endometriosis: BOTH** of the following:
 - i. **ONE non-steroidal anti-inflammatory** agent such as ibuprofen, indomethacin, naproxen, meloxicam, and others
 - ii. **ONE** of the following: oral estrogen-progestin **contraceptive** or depot medroxyprogesterone or norethindrone acetate

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- b. **For uterine leiomyomata (fibroids):** 1-month trial of iron supplementation **and** if approved, iron supplementation will be continued
5. There are **NO** FDA-label contraindications, such as:
 - a. Hypersensitivity to GnRH, GnRH agonist or any excipients
 - b. Pregnancy
 - c. Undiagnosed abnormal vaginal bleeding
6. Will **not** use partial syringes, combination of syringes, or other leuprolide depot forms to achieve a dose that is not an FDA-approved dose for the condition

Initial approval duration:

For endometriosis is 6 months using **ONE** of the following:

- Lupron Depot 3.75 mg for 1-month dosing: total 6 injections, with or without add-back therapy
- Lupron Depot 11.25 mg for 3-month dosing: total 2 injections, with or without add-back therapy

For uterine leiomyomata (fibroids) is for 3 months only using **ONE** of the following

- Lupron Depot 3.75 mg for 1-month dosing: total 3 injections only
- Lupron Depot 11.25 mg for 3-month dosing: total 1 injection only

- **Criteria for continuation of coverage (renewal request):** Lupron Depot (leuprolide acetate) is considered ***medically necessary*** and will be approved with the following criteria (**samples are not considered for continuation of therapy**):
1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Gynecologist
 2. Individual's **endometriosis** has worsened while on therapy or symptoms have recurred defined as: Recurrence of symptoms of endometriosis after initial course of therapy with return of pelvic pain, dysmenorrhea, dyspareunia, pelvic tenderness, or pelvic induration
 3. For **endometriosis**, must be used with norethindrone acetate 5 mg daily or a combination oral estrogen-progestin contraceptive add-back therapy
 4. Bone mineral density has been measured prior to retreatment
 5. Individual has been adherent with the medication
 6. Will **not** use partial syringes, combination of syringes, or other leuprolide depot forms to achieve a dose that is not an FDA-approved dosed for the condition
 7. Individual has not developed any contraindications that may exclude continued use such as: Contraindications as listed in the criteria for initial therapy section

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Renewal approval duration:

For endometriosis is 6 months using **ONE** of the following:

Lupron Depot 3.75 mg for 1-month dosing: total of 6 injections only

Lupron Depot 11.25 mg for 3-month dosing: total of 2 injections only

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**
2. **Off-Label Use of Cancer Medications**

Description:

Benefit Type:

Pharmacy Benefit:

Lupron Depot

Lupron Depot-PED

Medical Benefit:

Fensolvi

Coding:

HCPCS: J1950 (Lupron Depot, Lupron Depot-PED); **J1951** (Fensolvi); **J9217** (Lupron Depot, Eligard)

Leuprolide is a synthetic analog of endogenous gonadotropin-releasing hormone (GnRH), or gonadorelin. GnRH regulates the anterior pituitary gland synthesis and secretion of follicle-stimulating hormone (FSH) and luteinizing hormone (LH). In response to GnRH, FSH and LH synthesis initially increases, causing a short-term increase in circulating levels of sex hormones. With continuous use for one to three weeks, the pituitary gland down-regulates and desensitizes GnRH receptors, reducing FSH and LH secretion.

The end result of continuous GnRH use is markedly reduced testosterone levels in males and estrogen levels in females. In men, testosterone levels increase briefly during the first week after the initial dose, then falls to castration levels after two to four weeks of therapy. Correspondingly, in women, estradiol levels transiently increase and then falls to postmenopausal levels by three weeks after initiating therapy. The physiologic functions and tissues that are dependent on gonadal steroids for their maintenance become inactive. Normal pituitary and gonadal function usually returns within three months of discontinuing GnRH agonist therapy.

Precocious Puberty:

Precocious puberty is the onset of pubertal development at an age that is earlier than the average age. It is traditionally defined as onset of secondary sexual characteristics before the age of 8 years in girls and 9 years in boys. Precocious puberty is classified on the underlying pathologic process.

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Central precocious puberty (CPP, also known as gonadotropin-dependent precocious puberty or true precocious puberty) is due to early maturation of the hypothalamic-pituitary-gonadal axis. Children with CPP have accelerated linear growth for age, advanced bone age, and pubertal levels of LH and FSH. CPP can be treated with a GnRH agonist, to downregulate the pituitary response to endogenous GnRH, to produce a pre-pubertal hormonal state, and to stop the progression of secondary sexual development, accelerated growth, and bone age advancement

Peripheral precocity (also known as peripheral precocious puberty or gonadotropin-independent precocious puberty) is caused by excess secretion of sex hormones (estrogens or androgens) from the gonads or adrenal glands, exogenous sources of sex steroids, or ectopic production of gonadotropin from a germ cell tumor. FSH and LH levels are suppressed (in the pre-pubertal range) and do not increase substantially with GnRH stimulation. The approach to treatment for peripheral precocity depends on the cause. GnRH agonist therapy is ineffective

Benign or non-progressive pubertal variants include isolated breast development in girls (premature thelarche), or isolated androgen-mediated sexual characteristics (such as pubic and/or axillary hair, acne, and apocrine odor) in boys or girls that result from early activation of the hypothalamic pituitary adrenal axis as confirmed by mildly elevated levels of dehydroepiandrosterone sulfate (DHEAS) for age (premature adrenarche). Early development of secondary sexual characteristics does not signal underlying pathology and is not followed by progressive development. Serum LH and estradiol concentrations are typically in the pre-pubertal range.

Basal LH, FSH, and either estradiol and/or testosterone concentrations are used to differentiate between CPP and peripheral precocity.

Basal serum LH can identify activation of the hypothalamic-pituitary-gonadal axis. Measurement of basal LH concentration (ideally in the morning), using sensitive assays with a lower limit of detection of ≤ 0.1 mIU/L. LH concentrations in the pre-pubertal range (< 0.2 mIU/L) are consistent with either peripheral precocity or a benign pubertal variant. LH concentrations $> 0.2-0.3$ mIU/L (depending on the assay used) can identify progressive CPP with high sensitivity and specificity. Serum LH after GnRH agonist stimulation value of 3.3-5 mIU/mL defines the upper limit of normal for stimulated LH values in pre-pubertal children, concentrations above this normal range suggest CPP. Basal FSH concentrations are often higher in children with CPP compared with benign pubertal variants, but there is substantial overlap.

High serum estradiol concentrations are associated with suppression of gonadotropins and are generally indicative of peripheral precocity. Elevated serum testosterone concentrations may be due to testicular testosterone production in boys, or of adrenal testosterone production or exogenous exposure in both sexes. Very high concentrations, with associated suppression of gonadotropins, are generally indicative of peripheral precocity

Endometriosis:

Endometriosis is defined as endometrial glands and stroma that occur outside the uterine cavity. The lesions are usually located in the pelvis but can occur at other sites including the bowel, diaphragm, and pleural cavity. Endometriosis is an estrogen-dependent, benign, inflammatory disease that can affect a women during their premenarcheal, reproductive, and postmenopausal hormonal stages. Ectopic endometrial tissue and inflammation cause dysmenorrhea, dyspareunia, chronic pelvic pain, pelvic tenderness, pelvic induration, infertility and/or an ovarian mass. Less common symptoms include bowel and bladder dysfunction (e.g., dyschezia and dysuria),

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abnormal uterine bleeding, low back pain, or chronic fatigue. For some, the disease is asymptomatic and is an incidental finding at the time of surgery or imaging done for other indications.

Uterine leiomyomas (fibroids):

Uterine leiomyomas (also known as fibroids or myomas) are the most common benign pelvic tumor in women. The tumors develop from the smooth muscle cells of the myometrium. They develop in reproductive aged women and usually present with symptoms of abnormal uterine bleeding and/or pelvic pain/pressure. Uterine fibroids may affect fertility and lead to adverse pregnancy outcomes. In most cases, they are asymptomatic or mildly symptomatic and can usually be followed without intervention.

Anecdotal data suggest medical therapy provides adequate symptom relief in women who have bleeding as the dominant or only symptom. GnRH agonists are the most effective medical therapy for uterine fibroids but long term use is complicated by bone loss. GnRH decrease uterine and fibroid volume, allowing for relief of abdominal bloating, pelvic pain and pressure. Excessive vaginal bleeding (menorrhagia and menometrorrhagia) is decreased resulting in improved hematologic parameters. GnRH agonists are primarily used as preoperative therapy with iron supplementation to reduce the volume of blood loss and improve anemia caused by uterine fibroids. Bone loss may be minimized by giving so-called “add-back” therapy with norethindrone.

Definitions:

Clinical characteristics of forms of early pubertal development:

	Central precocious puberty (CPP)	Peripheral precocity	Non-progressive precocious puberty
Physical examination: Advancement through pubertal stages (Tanner stage)	Progression to next pubertal stage in 3-6 months	Progression	No progression in Tanner staging during 3-6 months of observation
Growth velocity	Accelerated (> 6 cm per year) *	Accelerated *	Normal for bone age
Bone age	Advanced for height age	Advanced for height age	Normal to mildly advanced
Serum estradiol concentration (girls) †	Pre-pubertal to pubertal	Increased in ovarian causes of peripheral precocity, or with exogenous estrogen exposure	Pre-pubertal ^Δ
Serum testosterone concentration (boys, or girls with virilization) †	Pre-pubertal to pubertal	Pubertal and increasing	Pre-pubertal ^Δ
Basal (unstimulated) serum LH concentration †	Pubertal [◇]	Suppressed or pre-pubertal [◇]	Pre-pubertal ^{Δ◇}

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GnRH (or GnRHa) stimulation test [¶]	LH peak elevated (in the pubertal range) [§] Higher stimulated LH to FSH ratio [¥]	No change from baseline, or LH peak in the pre-pubertal range	LH peak in the pre-pubertal range ^{Δ§} Lower stimulated LH to FSH ratio [¥]
<p>CPP: central precocious puberty; LH: luteinizing hormone; GnRH: gonadotropin-releasing hormone; GnRHa: gonadotropin-releasing hormone agonist; FSH: follicle-stimulating hormone.</p> <p>* UNLESS the patient has concomitant growth hormone deficiency (as in the case of a neurogenic form of CPP), or has already passed his or her peak height velocity at the time of evaluation, in which case growth velocity may be normal or decreased for chronological age.</p> <p>¶ Using most commercially available immunoassays, serum concentrations of gonadal steroids have poor sensitivity to differentiate between pre-pubertal and early pubertal concentrations.</p> <p>Δ In most cases these levels will be pre-pubertal, however in children with intermittently progressive CPP, these levels may reach pubertal concentrations during times of active development.</p> <p>◇ Using ultrasensitive assays with detection limit of LH < 0.1 mIU/L, pre-pubertal basal LH concentrations are < 0.2 to 0.3 mIU/L.</p> <p>§ In most laboratories, the upper limit of normal for LH after GnRH stimulation is 3.3-5.0 mIU/mL. Stimulated LH concentrations above this normal range suggests CPP.</p> <p>¥ A peak stimulated LH/FSH ratio < 0.66 usually suggests non-progressive precocious puberty, whereas a ratio > 0.66 is typically seen with CPP.</p> <p>Reference: Oerter KE, Uriarte MM, Rose SR, et al. Gonadotropin secretory dynamics during puberty in normal girls and boys. <i>J Clin Endocrinol Metab</i> 1990; 71:1251.</p>			

Leuprolide acetate products and uses:

Medication Name	Strength	Use
Leuprolide acetate SQ multi-dose vial	1mg/0.2 mL	Prostate cancer
Eligard SQ 1 month kit	7.5 mg	Prostate cancer
Eligard SQ 3 month kit	22.5 mg	Prostate cancer
Eligard SQ 4 month kit	30 mg	Prostate cancer
Eligard SQ 6 month kit	45 mg	Prostate cancer
Lupron Depot IM 1 month kit	7.5 mg	Prostate cancer
Lupron Depot IM 3 month kit	22.5 mg	Prostate cancer
Lupron Depot IM 4 month kit	30 mg	Prostate cancer
Lupron Depot IM 6 month kit	45 mg	Prostate cancer
Lupron Depot IM 1 month kit	3.75 mg	Endometriosis/Fibroids
Lupron Depot IM 3 month kit	11.25 mg	Endometriosis/Fibroids

ORIGINAL EFFECTIVE DATE: 05/17/2018 | ARCHIVE DATE: | LAST REVIEW DATE: 05/19/2022 | LAST CRITERIA REVISION DATE: 08/18/2022

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Lupron Depot-PED IM 1 month kit	7.5 mg	Central Precocious Puberty
Lupron Depot-PED IM 1 month kit	11.25 mg	Central Precocious Puberty
Lupron Depot-PED IM 1 month kit	15 mg	Central Precocious Puberty
Lupron Depot-PED IM 3 month kit	11.25 mg	Central Precocious Puberty
Lupron Depot-PED IM 3 month kit	30 mg	Central Precocious Puberty
Fensolvi SQ 6 months	45 mg	Central Precocious Puberty

Gonadotropin releasing hormone analog (GnRH analog):

- o Supprelin LA (histrelin acetate) – CPP, subcutaneous implant (12 months)
- o Synarel (nafarelin acetate) intranasal spray – CPP, endometriosis
- o Triptodur (triptorelin) – CPP, intramuscular injection, extended release (24 weeks)
- o Zoladex (goserelin acetate) implant – prostate cancer, breast cancer, endometriosis (3.6 mg only)

Resources:

Fensolvi (leuprolide) product information, revised by Tolmar Pharmaceuticals, Inc. 03-2022. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed May 13, 2022.

Lupron Depot-PED (leuprolide) product information, revised by AbbVie Inc. 04-2022. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed May 13, 2022.

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Harrington J, Palmert MR. Definition, etiology, and evaluation of precocious puberty. In: UpToDate, Snyder PJ, Crowley WF, Geffner ME, Hoppin AG, Martin KA (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Topic last updated April 20, 2022. Accessed May 13, 2022.

Harrington J, Palmert MR. Treatment of precocious puberty. In: UpToDate, Snyder PJ, Crowley WF, Geffner ME, Hoppin AG, Martin KA (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Topic last updated May 09, 2022. Accessed May 13, 2022.

Schenken RS. Endometriosis: Pathogenesis, epidemiology, and clinical impact. In: UpToDate, Barbieri RL, Eckler K (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Topic last updated April 29, 2022. Accessed May 13, 2022.

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Stewart EA. Uterine fibroids (leiomyomas): Treatment overview. In: UpToDate, Barbieri RL, Chakrabarti A (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Topic last updated March 25, 2022. Accessed May 13, 2022.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.



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Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

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