
Prior Authorization DRUG Guidelines

LUPRON® (Leuprolide)

Effective Date: 7/28/05

Date Developed: 7/14/05 by C. Wilhelmy MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

Lupron is a Gonadotropin Releasing Hormone Agonist. It is a potent inhibitor of gonadotropin secretion; continuous daily administration results in suppression of ovarian and testicular steroidogenesis due to decreased levels of LH and FSH with subsequent decrease in testosterone (male) and estrogen (female) levels. Leuprolide may also have a direct inhibitory effect on the testes, and act by a different mechanism not directly related to reduction in serum testosterone.

Pre-Authorization Criteria:

Lupron is used for the palliative treatment of advanced prostate carcinoma; management of endometriosis as initial treatment and/or treatment of recurrent symptoms; preoperative treatment of anemia caused by uterine leiomyomata (fibroids); and central precocious puberty.

VCHCP requires that Lupron be prescribed by a gynecologist, oncologist, or pediatric endocrinologist.

MONITORING PARAMETERS — Bone mineral density

Precocious puberty: GnRH testing (blood LH and FSH levels), measurement of bone age every 6-12 months, testosterone in males and estradiol in females; Tanner staging

Prostatic cancer: LH and FSH levels, serum testosterone (2-4 weeks after initiation of therapy), PSA; weakness, paresthesias, and urinary tract obstruction in first few weeks of therapy

DOSING: ADULTS See [Lexi-Comp Online](#)™ for details.

DOSING: PEDIATRIC See [Lexi-Comp Online](#)™ for details.

DOSING: ELDERLY — Refer to adult dosing.

CONTRAINDICATIONS — Hypersensitivity to leuprolide, GnRH, GnRH-agonist analogs, or any component of the formulation; spinal cord compression (orchiectomy suggested); undiagnosed abnormal vaginal bleeding; pregnancy; breast-feeding

WARNINGS / PRECAUTIONS — Transient increases in testosterone serum levels occur at the start of treatment. Tumor flare, bone pain, neuropathy, urinary tract obstruction, and spinal cord compression have been reported when used for prostate cancer; closely observe patients for weakness, paresthesias, hematuria, and urinary tract obstruction in first few weeks of therapy. Observe patients with metastatic vertebral lesions or urinary obstruction closely. Exacerbation of endometriosis or uterine leiomyomata may occur initially. Decreased bone density has been reported when used for 6 months. Use caution in patients with a history of psychiatric illness; alteration in mood, memory impairment, and depression have been associated with use.

PREGNANCY RISK FACTOR — X

PREGNANCY IMPLICATIONS — Pregnancy must be excluded prior to the start of treatment. Although leuprolide usually inhibits ovulation and stops menstruation, contraception is not ensured and a nonhormonal contraceptive should be used. Fetal abnormalities and increased fetal mortality have been noted in animal studies.

LACTATION — Excretion in breast milk unknown/contraindicated

PATIENT EDUCATION — Do not discontinue medication without prescriber's advice. May cause depression; report changes in mood or memory immediately. For self administration, patient must be taught aseptic technique and SubQ injection technique; rotate SubQ injection sites frequently. Disease flare can briefly occur with initiation of therapy.

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Revision History:

Date Reviewed/Updated: 10/10/11 by A. Reeves MD
 Date Reviewed/No Updates: 4/2/12; 1/16/13 by A. Reeves, MD
 Date Approved by P&T Committee: 7/28/05; 10/25/11; 4/24/12; 1/29/13
 Date Reviewed/No Updates: 1/28/14 by C. Sanders MD
 Date Approved by P&T Committee: 1/28/14
 Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD
 Date Approved by P&T Committee: 1/27/15
 Date Reviewed/No Updates: 1/26/16 by C. Sanders, MD; R. Sterling, MD
 Date Approved by P&T Committee: 1/26/16
 Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD
 Date Approved by P&T Committee: 1/24/17
 Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD
 Date Approved by P&T Committee: 1/23/18
 Date Reviewed/Archived: 1/22/19 by C. Sanders, MD; R. Sterling, MD
 Date Approved by P&T Committee: 1/22/19

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – check ESI