



LEUPROLIDE PRODUCTS (ELIGARD®), (LUPRON®), (LUPRON DEPOT®), (LUPRON DEPOT-PED®), (VIADUR®)
Length of Authorization
See each indication for approval length
FDA Indications
<ol style="list-style-type: none"> 1. Endometriosis 2. Uterine leiomyomata 3. Dysfunctional uterine bleeding (Endometrial thinning) 4. Breast Cancer 5. Ovarian cancer 6. Head and Neck Cancer 7. Central Precocious Puberty (CPP)
Clinical Criteria for Initial Approval
<p>This medication will be covered with prior authorization when the following criteria are met:</p> <ol style="list-style-type: none"> 1. Diagnosis of Endometriosis: (Lupron Depot) <ol style="list-style-type: none"> a. Patient older than 18; AND b. Diagnosis has been confirmed by a workup/evaluation (vs. presumptive treatment); AND c. Patient has not received prior-treatment with a gonadotropin releasing hormone (GnRH) agonist for this indication within a 6-month prior period Length of Authorization: 6 months, eligible for renewal one time 2. Diagnosis of Uterine leiomyomata (fibroids): (Lupron Depot) <ol style="list-style-type: none"> a. Patient older than 18; AND b. Diagnosis has been confirmed by a workup/evaluation (vs. presumptive treatment); AND c. Documentation patient is receiving iron therapy Length of Authorization: 3 months not eligible for renewal. 3. Diagnosis of Dysfunctional uterine bleeding (Endometrial thinning): <ol style="list-style-type: none"> a. Patient is at least 18 years old; AND b. Used prior to endometrial ablation Length of Authorization: coverage will be provided for 2 doses only (given 4 weeks apart) and medication is NOT eligible for renewal 4. Diagnosis of Breast Cancer: (Eligard, Lupron Depot) <ol style="list-style-type: none"> a. Patient is 18 years or older; AND b. Patient is pre-menopausal or peri-menopausal woman; or is a male with suppression of testicular steroidogenesis; AND c. Patient's disease is hormone receptor positive; AND <ol style="list-style-type: none"> i. Used in combination with adjuvant endocrine therapy; OR ii. Endocrine therapy for recurrent or metastatic disease Length of Authorization: 1 year, eligible for renewal(s)

5. **Diagnosis of Ovarian cancer: (Eligard, Lupron Depot)**
 - a. Patient is 18 years or older; **AND**
 - b. Used as single agent; **AND**
 - c. Patient has a diagnosis of stage II-IV granulosa cell tumors of the ovary; **AND**
 - i. Patient's disease has relapsed; **OR**
 - d. Patient has a diagnosis of Epithelial Ovarian Cancer or Fallopian Tube Cancer or Primary Peritoneal cancer; **AND**
 - i. Patient's disease is persistent or recurrent (excluding immediate treatment of biochemical relapse).
Length of Authorization: 1 year, eligible for renewal(s)

6. **Diagnosis of Head and Neck Cancer : (Lupron Depo)**
 - a. Patient is 18 years or older; **AND**
 - b. Patient has a diagnosis of androgen receptor-positive recurrent salivary gland tumor; **AND**
 - i. Patient has distant metastases with a performance status score of 0-3; **OR**
 - ii. Patient has unresectable locoregional recurrence or second primary with prior radiation therapy

Length of Authorization: 1 year, eligible for renewal(s)

7. **Diagnosis of Central Precocious Puberty (CPP): (Leuprolide acetate, Lupron Depot-Peds)**
 - a. Patient is less than 13 years old; **AND**
 - b. Onset of secondary sexual characteristics earlier than age 8 for girls and 9 for boys associated with pubertal pituitary gonadotropin activation; **AND**
 - c. Diagnosis is confirmed by a pubertal gonadal sex steroid levels and a pubertal LH response to stimulation by native GnRH; **AND**
 - d. Bone age advanced greater than 2 standard deviations (SD) beyond chronological age ; **AND**
 - e. Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor); **AND**
 - f. Will not be used in combination with growth hormone

Length of Authorization: 1 year, eligible for renewal(s)

8. **Diagnosis of Prostate Cancer: (Leuprolide (all formulations), Eligard)**
 - a. Patient is 18 years or older

Length of Authorization: 1 year, eligible for renewal(s)

Clinical Criteria for Continued Approval

This medication will have continued coverage with prior authorization when the following criteria are met:

1. **Diagnosis of Central Precocious Puberty**
 - a. Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in growth velocity and bone age advancement, and improvement in final height prediction; **AND**
 - b. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe QT/QTc interval prolongation, severe hyperglycemia and diabetes, cardiovascular toxicity, hypercalcemia, severe injection site reactions, tumor flare phenomenon, severe hypersensitivity reactions, etc.

2. **Diagnosis of Prostate Cancer; Breast/Ovarian Cancer; Head and neck cancer**
 - a. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

- b. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe QT/QTc interval prolongation, severe hyperglycemia and diabetes, cardiovascular toxicity, hypercalcemia, severe injection site reactions, tumor flare phenomenon, severe hypersensitivity reactions, etc.
3. Diagnosis of Endometriosis
- a. Patient has not received a total of 12 months of therapy of a GnRH-agonist (i.e., leuprolide acetate, etc.); **AND**
 - b. Patient continues to have symptoms of endometriosis or symptoms recur after the initial 6-month course of therapy; **AND**
 - c. Patient will have bone density assessment prior to retreatment; **AND**
 - d. Patient will use in combination with add-back therapy in combination with norethindrone; **AND**
 - e. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe QT/QTc interval prolongation, severe hyperglycemia and diabetes, cardiovascular toxicity, hypercalcemia, severe injection site reactions, tumor flare phenomenon, severe hypersensitivity reactions, etc.
4. Diagnosis of Uterine leiomyomata (fibroids)
- a. May not be renewed
5. Diagnosis of Endometrial Bleeding
- a. May not be renewed