Leuprolide Acetate, Lupron Depot, Fensolvi, Supprelin LA

HMSACOM - Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-866-237-5512**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-808-254-4414.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Patient's Phone Number: _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Additional Demographic Information:

Patient Weight: _____*kg*

Patient Height: _____*ft* _____*inches*

Indicate where the drug is being dispensed:

❑ Office ❑ Outpatient Hospital ❑ Ambulatory Surgical ❑ Inpatient Hospital
❑ Off Campus Outpatient Hospital ❑ Urgent Care ❑ Emergency Room ❑ Birthing Center
❑ Military Facility ❑ Skilled Nursing Facility ❑ Nursing Facility ❑ Hospice
❑ Inpatient Psychiatric ❑ Psychiatric Residential Treatment ❑ End Stage Renal Facility
❑ Psychiatric Facility ❑ Pharmacy ❑ Other

Indicate where the drug is being administered:

❑ Ambulatory surgical ❑ Home ❑ Inpatient Hospital
❑ Office ❑ Outpatient Hospital ❑ Pharmacy

What drug is being prescribed?

❑ Lupron Depot 3.75 mg
❑ Lupron Depot 7.5 mg
❑ Lupron Depot 11.25 mg
❑ Lupron Depot 22.5 mg
❑ Lupron Depot 30 mg
❑ Lupron Depot 45 mg
❑ Leuprolide acetate (generic)
❑ Other _____

❑ Lupron Depot-PED 7.5 mg (1-month)
❑ Lupron Depot-PED 11.25 mg (1-month)
❑ Lupron Depot-PED 15 mg (1-month)
❑ Lupron Depot-PED 11.25 mg (3-month)
❑ Lupron Depot-PED 30 mg (3-month)
❑ Fensolvi
❑ Supprelin LA

What is the ICD-10 code? _____

Send completed form to: CVS Caremark Specialty Programs. Fax: 1-866-237-5512

 Luprolide and Supprelin LA HMSACOM – 04/2024.

Criteria Questions:

1. What is the diagnosis?

❒ Anemia due to uterine leiomyomas (fibroids), *Continue to #200*

❒ Endometriosis, *Continue to #300*

❒ Central precocious puberty (CPP) (including use as a stimulation test to confirm diagnosis of CPP), *Continue to #700*

❒ Gender dysphoria, *Continue to #800*

❒ All oncology indications, *Continue to #950*

❒ Other, *No Further Questions*

UTERINE LEIOMYOMAS (FIBROIDS)

200. Which medication is being requested?

❒ Lupron Depot (3.75 mg or 11.25 mg), *Continue to #201*

❒ Other, *Continue to #201*

201. Is the member an adult female?

❒ Yes, *Continue to #202*

❒ No, *Continue to #202*

202. Does the member have undiagnosed abnormal vaginal bleeding?

❒ Yes, *Continue to #203*

❒ No, *Continue to #203*

203. Have pregnancy and breastfeeding been excluded?

❒ Yes, *Continue to #204*

❒ No, *Continue to #204*

204. Was the member diagnosed with iron deficiency anemia secondary to vaginal bleeding associated with uterine leiomyomas (fibroids)?

❒ Yes, *Continue to #205*

❒ No, *Continue to #205*

205. What is the member's hemoglobin level?

❒ < 11 g/dL, *Continue to #207*

❒ ≥ 11 g/dL, *Continue to #206*

❒ Not available, *Continue to #206*

206. What is the member's hematocrit?

❒ < 33%, *Continue to #207*

❒ ≥ 33%, *Continue to #207*

❒ Not available, *Continue to #207*

207. Will the member have surgery to remove the leiomyomas?

❒ Yes, *Continue to #208*

❒ No, *Continue to #208*

208. Is it necessary to increase the hemoglobin/hematocrit prior to surgery?

❒ Yes, *Continue to #209*

❒ No, *Continue to #209*

209. Has the member previously received treatment with leuprolide for uterine leiomyomas?

❒ Yes, *Continue to #210*

❒ No, *No Further Questions*

210. What is the previous duration of treatment with leuprolide?

❒ 0 to < 3 months, *No Further Questions*

❒ ≥ 3 to < 6 months, *Continue to #211*

❒ ≥ 6 months, *No Further Questions*

211. Has there been a delay in surgery to remove the leiomyoma? ***Documentation must be submitted indicating the reason for the delay in surgery***

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

ENDOMETRIOSIS

300. Which medication is being requested?

❒ Lupron Depot (3.75 mg or 11.25), *Continue to #301*

❒ Other, *Continue to #301*

301. Is the member an adult female (≥ 18 years of age)?

❒ Yes, *Continue to #302*

❒ No, *Continue to #302*

302. Does the member have undiagnosed abnormal vaginal bleeding?

❒ Yes, *Continue to #303*

❒ No, *Continue to #303*

303. Have pregnancy and breastfeeding been excluded?

❒ Yes, *Continue to #304*

❒ No, *Continue to #304*

304. Does the member have symptomatic endometriosis?

❒ Yes, *Continue to #305*

❒ No, *Continue to #305*

305. Has the member previously received treatment with leuprolide for endometriosis?

❒ Yes, *Continue to #306*

❒ No, *No Further Questions*

306. What is the previous duration of treatment with leuprolide?

❒ 0 to < 6 months, *No Further Questions*

❒ ≥ 6 to < 12 months, *Continue to #307*

❒ ≥ 12 months, *No Further Questions*

307. Is there a clinical reason that retreatment with leuprolide is necessary for this member? ***Documentation must***

be submitted indicating the reason that retreatment is necessary

❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

CENTRAL PRECOCIOUS PUBERTY (CPP)

700. Is leuprolide being requested for use as a stimulation test to confirm diagnosis of CPP?
❒ Yes, *No Further Questions*
❒ No, *Continue to #701*

701. Which medication is being requested?
❒ Leuprolide acetate (generic), *Continue to #702*
❒ Lupron Depot-PED, *Continue to #702*
❒ Supprelin LA, *Continue to #702*
❒ Fensolvi, *Continue to #702*
❒ Other, *Continue to #702*

702. Is this a request for a new start or continuation of therapy?
❒ New start, *Continue to #704*
❒ Continuation of therapy, *Continue to #703*

703. Was the requested product previously authorized by HMSA/CVS?
❒ Yes, *Continue to #900*
❒ No, *Continue to #704*
❒ Unknown, *Continue to #704*

704. Was the diagnosis confirmed by a pubertal response to a GnRH agonist test or a third-generation basal LH assay? ***Documentation such as clinical notes, growth charts, or imaging studies that supports the diagnosis of pubertal response to a GnRH agonist test or a third-generation basal LH assay***
❒ Yes, *Continue to #705*
❒ No, *Continue to #705*

705. Does the member have advanced bone age (bone age is at least one year greater than chronological age)?
❒ Yes, *Continue to #706*
❒ No, *Continue to #706*

706. Has appropriate diagnostic imaging of the brain been done to exclude an intracranial tumor?
❒ Yes, *Continue to #707*
❒ No, *Continue to #707*

707. What is the member's gender?
❒ Female, *Continue to #708*
❒ Male, *Continue to #710*

708. At which age did the onset of secondary sexual characteristics occur?
_____ years, *Continue to #709*

709. What is the member's current age?

❒ < 12 years, *No Further Questions*

❒ ≥ 12 years to 17 years, *Continue to #712*

❒ ≥ 18 years, *No Further Questions*

710. At which age did the onset of secondary sexual characteristics occur?

❒_____ years, *Continue to #711*

711. What is the member's current age?

❒ < 13 years, *No Further Questions*

❒ ≥ 13 years to 17 years, *Continue to #712*

❒ ≥ 18 years, *No Further Questions*

712. Is there a continued need to delay puberty such as extreme short stature (e.g.,, height is more than 2 standard deviations below the mean and growth plates are open)? ***Documentation such as clinical notes, growth charts, or imaging studies that supports the continued need to delay puberty must be submitted***

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

GENDER DYSPHORIA

800. Which medication is being requested?

❒ Leuprolide acetate (generic), *Continue to #801*

❒ Lupron Depot (3.75 mg or 11.25 mg), *Continue to #801*

❒ Lupron Depot (7.5 mg, 22.5 mg, 30 mg or 45 mg), *Continue to #801*

❒ Lupron Depot-PED, *Continue to #801*

❒ Supprelin LA, *Continue to #801*

❒ Fensolvi, *Continue to #801*

❒ Other, *Continue to #801*

801. Will the requested medication be used for pubertal hormonal suppression therapy in an adolescent patient with gender dysphoria?

❒ Yes, *Continue to #802*

❒ No, *Continue to #802*

802. Is this request for a new start or continuation of therapy?

❒ New start, *Continue to #804*

❒ Continuation of therapy, *Continue to #803*

803. Was the requested product previously authorized by CVS/HMSA for this member?

❒ Yes, *Continue to #900*

❒ No, *Continue to #804*

❒ Unknown, *Continue to #804*

804. Has the patient been diagnosed with persistent, well-documented gender dysphoria as defined by the current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria and gender identity disorder as defined by the current International Classification of Diseases (ICD) criteria?

❒ Yes, *Continue to #805*

❒ No, *Continue to #805*

805. Was the patient diagnosed with gender dysphoria by a qualified health professional?

❒ Yes, *Continue to #806*

❒ No, *Continue to #806*

806. Has the patient exhibited the first physical changes of puberty indicated by a minimum tanner stage of 2?

❒ Yes, *Continue to #807*

❒ No, *Continue to #807*

807. Do clinical records document that the patient assents to treatment and the parent/guardian has made a fully informed decision and consents to treatment? ***Documentation must be submitted showing that the patient or parent/guardian has made a fully informed decision and consents to treatment***

❒ Yes, *Continue to #808*

❒ No, *Continue to #808*

808. Are the patient's comorbid medical and mental health conditions (if present) reasonably well controlled?

❒ Yes, *Continue to #809*

❒ No, *Continue to #809*

❒ Not applicable (no comorbid conditions), *Continue to #809*

809. Will pubertal hormonal suppression therapy be administered in a safe, appropriate, medically supervised manner?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

CONTINUATION CRITERIA

900. What is the member's age?

❒ < 18 years, *Continue to #901*

❒ ≥ 18 years, *Continue to #901*

901. Is there a continued need to delay puberty? Please attach documentation including clinical notes that support the need to continue puberty suppression

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

ONCOLOGIC INDICATIONS

950. Please list or describe all agents in the oncology regimen. ❑ Single agent ❑ Multiple agents

_____

_____

951. What is the patient's diagnosis and ICD 10 code? Action Required: Please attach relevant and supportive data of patient's diagnosis.

_____

_____

952. Is the requested medication/regimen prescribed for an FDA-approved indication, an indication supported by NCCN with a I or IIA recommendation? ❑ Yes ❑ No

953. Does the patient have a contraindication to the use of the requested medication(s) as listed in the medication(s) prescribing information? ❑ Yes ❑ No

954. Was the single agent or entire drug regimen previously authorized by HMSA/CVS for this member?
❑ Yes ❑ No ❑ Unknown *If No or unknown, no further questions*

955. Is there evidence to support the patient is benefitting from treatment (e.g. positive clinical response, lack of disease progression)? ***Action required*: Please attach current clinical documentation (e.g., office visit notes and applicable studies) that supports treatment is beneficial.** ❑ Yes ❑ No *No further questions*

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____
Prescriber or Authorized Signature **Date (mm/dd/yy)**

Send completed form to: CVS Caremark Specialty Programs. Fax: 1-866-237-5512