Lupron Hormonal Therapy

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 1-855-330-1720**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518.** 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:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ❑ **Same as Referring Provider** ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

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

Required Demographic Information:

Patient Weight: _____*kg*

Patient Height: _____*cm*

Please indicate the place of service for the requested drug:

❑ *Ambulatory Surgical* ❑ *Home* ❑ *Off Campus Outpatient Hospital*
❑ *On Campus Outpatient Hospital* ❑ *Office* ❑ *Pharmacy*

Exception Criteria Questions:

A. Is the product being requested for the treatment of prostate cancer?
❑ Yes ❑ No *If No, skip to Criteria Questions*

B. The preferred product for your patient's health plan is Eligard. Can the patient's treatment be switched to the preferred product? *If Yes, please obtain Form for preferred product and submit for corresponding PA.*
❑ Yes ❑ No

C. Does the patient have a documented hypersensitivity to the preferred product (Eligard)? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s)*** ❑ Yes ❑ No

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

 Lupron Hormonal Other Ind MR SGM – 02/2023.

Criteria Questions:

1. Which drug and strength is being prescribed?
   - ❑ Lupron Depot 7.5 mg
   - ❑ Lupron Depot-3 month 22.5 mg
   - ❑ Lupron Depot-4 month 30 mg
   - ❑ Lupron Depot-6 month 45 mg
   - ❑ Lupron Depot 3.75 mg
   - ❑ Lupron Depot-3 month 11.25 mg
   - ❑ leuprolide kit
   - ❑ leuprolide acetate depot 3-month 22.5 mg
   - ❑ Lupron Depot-**PED** 7.5 mg
   - ❑ Lupron Depot-**PED-1 month** 11.25 mg
   - ❑ Lupron Depot-**PED-3 month** 11.25 mg
   - ❑ Lupron Depot-**PED** 15 mg
   - ❑ Lupron Depot-**PED** 30 mg
   - ❑ Lupaneta Pack
   - ❑ Other _____

   Indicate prescribed dose and frequency: _____

2. What is the requested drug being used for?
   - ❑ Uterine leiomyomata (fibroids)
   - ❑ Epithelial ovarian cancer
   - ❑ Ovarian cancer - Malignant sex cord-stromal tumor (granulosa cell tumors)
   - ❑ Endometriosis
   - ❑ Breast cancer
   - ❑ Prostate cancer
   - ❑ Primary peritoneal cancer
   - ❑ Fallopian tube cancer
   - ❑ Recurrent salivary gland tumors
   - ❑ Grade 1 endometrioid carcinoma
   - ❑ Low-grade serous carcinoma
   - ❑ Mucinous carcinoma of the ovary
   - ❑ Clear cell carcinoma of the ovary
   - ❑ Carcinosarcoma (malignant mixed Müllerian tumors)
   - ❑ Preservation of ovarian function
   - ❑ Gender dysphoria
   - ❑ Recurrent menstrual related attacks in acute porphyria
   - ❑ Central precocious puberty (CPP)
   - ❑ Other _____

3. What is the ICD-10 code? _____

Complete the following section based on the patient's diagnosis, if applicable.

Section A: Central Precocious Puberty

4. Is the patient currently receiving the prescribed therapy for central precocious puberty through a paid pharmacy or medical benefit? ❑ Yes ❑ No *If No, skip to #6*

5. Is the patient experiencing signs of treatment failure such as clinical pubertal progression, lack of growth deceleration and continued excessive bone age advancement*?* ❑ Yes ❑ No *No further questions*.

6. Has the patient been evaluated for intracranial tumor(s) by appropriate lab tests and diagnostic imaging, such as computed tomography (CT scan), magnetic resonance imaging (MRI), or ultrasound? ❑ Yes ❑ No

7. Has the diagnosis of central precocious puberty been confirmed by a pubertal response to a GnRH (gonadotropin-releasing hormone) agonist test or a pubertal level of a third-generation LH (luteinizing hormone) assay? ***Action Required: If yes, collect laboratory report or medical record of pubertal response to a GnRH agonist test or a pubertal level of a third-generation LH assay***. ❑ Yes ❑ No

8. Does the assessment of bone age versus chronological age support the diagnosis of central precocious puberty? ❑ Yes ❑ No

9. How old was the patient **AT THE ONSET** of secondary sexual characteristics? _____ years

Section B: Uterine leiomyomata (Fibroids)

10. Has the patient received previous therapy with Lupron Depot or Lupaneta Pack? ❑ Yes ❑ No *If No, skip to #12*

11. How long has the patient received prior therapy with Lupron Depot and Lupaneta Pack? _____ months

    Indicate dates and doses received: _____

12. Does the patient have a diagnosis of anemia due to uterine leiomyomata? ❑ Yes ❑ No
    Provide at least one lab value and date drawn:

Hematocrit (Hct): _____ % Date drawn: _____
Hemoglobin (Hgb): _____ g/dL Date drawn: _____

13. Will prescribed agent be used prior to surgery for uterine leiomyomata (fibroids)? ❑ Yes ❑ No

Section C: Endometriosis

14. Has the patient received previous therapy with Lupron Depot or Lupaneta Pack?
❑ Yes ❑ No *If No, no further questions*.

15. Has the patient had a recurrence of symptoms? ❑ Yes ❑ No

16. Is the patient's bone mineral density within normal limits? ❑ Yes ❑ No

17. How long has the patient received previous therapy with Lupron Depot and Lupaneta Pack? _____ months

Indicate dates and doses received: _____

Section D: Gender Dysphoria

18. Is the patient less than 18 years of age? ❑ Yes ❑ No *If No, skip to #20*.

19. Is the requested medication prescribed by or in consultation with a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist) that has collaborated care with a mental health care provider? ❑ Yes ❑ No

20. Are the patient's comorbid conditions reasonably controlled? ❑ Yes ❑ No

21. Has the patient been educated on any contraindications and side effects to therapy? ❑ Yes ❑ No

22. Is the request for continuation of therapy? *If Yes, skip to #28* ❑ Yes ❑ No

23. Has the patient been informed of fertility preservation options? ❑ Yes ❑ No

24. Is the prescribed agent prescribed for pubertal hormonal suppression in an adolescent patient?
❑ Yes ❑ No *If No, skip to #26*

25. Which Tanner Stage of puberty has the patient reached?
❑ Tanner Stage I
❑ Tanner Stage II
❑ Tanner Stage III
❑ Tanner Stage IV
❑ Tanner Stage V
❑ Unknown
No further questions

26. Is the patient undergoing gender transition? ❑ Yes ❑ No

27. Will the patient receive the prescribed agent concomitantly with gender-affirming hormones?
❑ Yes ❑ No *If Yes or No, no further questions*

28. Has the patient been informed of fertility preservation options before the start of therapy? ❑ Yes ❑ No

29. Is the prescribed agent prescribed for pubertal hormonal suppression in an adolescent patient?
❑ Yes ❑ No *If No, skip to #31*

30. Which Tanner Stage of puberty has the patient reached?
❑ Tanner Stage I
❑ Tanner Stage II
❑ Tanner Stage III
❑ Tanner Stage IV
❑ Tanner Stage V
❑ Unknown
No further questions

31. Is the patient undergoing gender transition? ❑ Yes ❑ No

32. Will the patient receive the prescribed agent concomitantly with gender-affirming hormones?
❑ Yes ❑ No *No further questions*

Section E: Recurrent Salivary Gland Tumors

33. Is the patient currently receiving treatment with the requested medication?
❑ Yes ❑ No *If No, skip to #36*

34. Has the patient experienced clinical benefit to therapy while on the current regimen? ❑ Yes ❑ No

35. Has the patient experienced an unacceptable toxicity while on the current regimen?
❑ Yes ❑ No *No further questions*

36. Is the tumor androgen receptor positive? ❑ Yes ❑ No

37. Will the requested drug be used as a single agent? ❑ Yes ❑ No

Section F: Prostate Cancer

38. Is the patient currently receiving treatment with the requested medication?
❑ Yes ❑ No *If No, no further questions*

39. Has the patient experienced clinical benefit to therapy while on the current regimen (e.g., serum testosterone less than 50 ng/dL)? ❑ Yes ❑ No

40. Has the patient experienced an unacceptable toxicity while on the current regimen? ❑ Yes ❑ No

Section G: Breast Cancer

41. Is the patient currently receiving treatment with the requested medication?
❑ Yes *If Yes, skip to #43* ❑ No

42. What is the patient's hormone receptor (HR) status?
❑ Positive *No further questions*
❑ Negative *No further questions*
❑ Unknown *No further questions*

43. Has the patient experienced an unacceptable toxicity or disease progression while receiving the requested drug?
❑ Yes ❑ No

Section H: Preservation of Ovarian Function

44. Is the patient premenopausal and undergoing chemotherapy? ❑ Yes ❑ No

Section I: Prevention of Recurrent Menstrual Related Attacks in Acute Porphyria

45. Is Lupron Depot being requested to prevent recurrent menstrual related attacks in acute porphyria?
❑ Yes ❑ No

46. Is Lupron Depot prescribed by, or in consultation with, a physician experienced in the management of porphyrias?
❑ Yes ❑ No

Section J: Ovarian Cancer - Malignant Sex Cord-Stromal Tumor (granulosa cell tumors), Epithelial Ovarian Cancer, Fallopian tube cancer, Primary Peritoneal Cancer, Grade 1 Endometrioid Cancer, Low-grade Serous Carcinoma, Carcinosarcoma (malignant mixed Müllerian tumors), Mucinous Carcinoma of the Ovary, Clear Cell Carcinoma of the Ovary

47. Is the patient currently receiving treatment with the requested medication?
❑ Yes *If Yes, skip to #50* ❑ No
For Ovarian Cancer – malignant sex cord-stromal tumor (granulosa cell tumor) requests: *If No, skip to #49*

48. Does the patient have persistent or recurrent disease? ❑ Yes ❑ No

49. Will the requested medication be used as a single agent? ❑ Yes ❑ No *No further questions*

50. Has the patient experienced an unacceptable toxicity or disease progression while receiving the requested drug?
❑ Yes ❑ No

Step Therapy Override: Complete if Applicable for the state of Maryland.	Please Circle	
Is the requested drug being used to treat stage four advanced metastatic cancer?	Yes	No
Is the requested drug's use consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer and is supported by peer-reviewed medical literature?	Yes	No
Is the requested drug being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)?	Yes	No
Do patient chart notes document the requested drug was ordered with a paid claim at the pharmacy, the pharmacy filled the prescription and delivered to the patient or other documentation that the requested drug was prescribed for the patient in the last 180 days?	Yes	No
Has the prescriber provided proof documented in the patient chart notes that in their opinion the requested drug is effective for the patient's condition?	Yes	No

Step Therapy Override: Complete if Applicable for the state of Virginia.	Please Circle	
Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
Is the request for a brand drug that has an AB-rated generic equivalent or interchangeable biological product available?	Yes	No
Has the patient had a trial and failure of the AB-rated generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient?	Yes	No
Is the preferred drug contraindicated?	Yes	No
Is the preferred drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen?	Yes	No
Has the patient tried the preferred drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?	Yes	No
Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition?	Yes	No

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)**

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