



Zoladex

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.

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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

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

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CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062
Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

Exception Criteria Questions:

- A. Is the product being requested for the treatment of prostate cancer?
 Yes No *If No, skip to Clinical 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. Is this request for continuation of therapy with the requested product? Yes No, *If No, skip to Question E*
- D. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program? If unknown, answer Yes. Yes No, *skip to Clinical Criteria Questions*
- E. Does the patient have a documented hypersensitivity to the preferred product (Eligard)? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s).*** Yes No

Clinical Criteria Questions:

1. What dose of the requested drug is being prescribed?
 Zoladex 3.6 mg, *Continue to #2*
 Zoladex 10.8 mg, *Continue to #3*
2. What is the diagnosis?
 Prostate cancer, *Continue to #4*
 Breast cancer, *Continue to #4*
 Dysfunctional uterine bleeding (use as an endometrial thinning agent) (3.6 mg dose only), *Continue to #50*
 Chronic anovulatory uterine bleeding (use as an endometrial thinning agent) (3.6 mg dose only), *Continue to #50*
 Endometriosis (3.6 mg dose only), *Continue to #60*
 Preservation of ovarian function (3.6 mg dose only), *Continue to #80*
 Prevention of recurrent menstrual related attacks in acute porphyria (3.6 mg dose only), *Continue to #100*
 Uterine leiomyomata (fibroids) (3.6 mg dose only), *Continue to #70*
 Gender dysphoria, *Continue to #90*
 Other, *No Further Questions*
3. What is the diagnosis?
 Prostate cancer, *Continue to #5*
 Breast cancer, *Continue to #5*
 Gender dysphoria, *Continue to #90*
 Other, *No Further Questions*
4. Is this a request for continuation of therapy with Zoladex 3.6 mg?
 Yes, *Continue to #20*
 No, *Continue to #30*
5. Is this a request for continuation of therapy with Zoladex 10.8 mg?
 Yes, *Continue to #10*
 No, *Continue to #28*

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Continuation: Zoladex 10.8 mg

10. What is the diagnosis?

- Prostate cancer, *Continue to #11*
- Breast cancer, *Continue to #12*

11. Has the patient experienced clinical benefit while on the current regimen (e.g., serum testosterone less than 50 ng/dL)?

- Yes, *Continue to #13*
- No, *Continue to #13*

12. Has the patient experienced clinical benefit while on the current regimen?

- Yes, *Continue to #13*
- No, *Continue to #13*

13. Has the patient experienced an unacceptable toxicity while on the current regimen?

- Yes, *No Further Questions*
- No, *No Further Questions*

Continuation: Zoladex 3.6 mg

20. What is the diagnosis?

- Prostate cancer, *Continue to #21*
- Breast cancer, *Continue to #22*

21. Has the patient experienced clinical benefit while on the current regimen (e.g., serum testosterone less than 50 ng/dL)?

- Yes, *Continue to #23*
- No, *Continue to #23*

22. Has the patient experienced clinical benefit while on the current regimen?

- Yes, *Continue to #23*
- No, *Continue to #23*

23. Has the patient experienced an unacceptable toxicity while on the current regimen?

- Yes, *No Further Questions*
- No, *No Further Questions*

Initial: Zoladex 10.8 mg

Prostate cancer

28. What is the diagnosis?

- Prostate cancer, *No Further Questions*
- Breast cancer, *Continue to #40*

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Initial: Zoladex 3.6 mg

Prostate cancer

30. What is the diagnosis?

- Prostate cancer, *No Further Questions*
 Breast cancer, *Continue to #40*

Breast cancer

40. What is the patient's hormone receptor (HR) status? **Action: Attach hormone receptor testing results**

- HR-positive, *No Further Questions*
 HR-negative, *No Further Questions*
 Unknown, *No Further Questions*

Endometrial thinning agent

50. Will the requested drug be used as an endometrial thinning agent prior to endometrial ablation or resection for dysfunctional uterine bleeding?

- Yes, *No Further Questions*
 No, *Continue to #51*

51. Will the requested drug be used for treatment of chronic anovulatory uterine bleeding in a patient with severe anemia?

- Yes, *Continue to #52*
 No, *Continue to #52*

52. For how many months has the patient already received the requested drug for this indication?
_____ months, *No Further Questions*

Endometriosis

60. For how many months has the patient already received the requested drug for this indication?
_____ months, *No Further Questions*

Uterine leiomyomata (fibroids)

70. Will the requested drug be given prior to surgery?

- Yes, *Continue to #71*
 No, *Continue to #71*

71. For how many months has the patient already received the requested drug for this indication?
_____ months, *No Further Questions*

Preservation of ovarian function

80. Is the patient premenopausal and undergoing chemotherapy?

- Yes, *No Further Questions*
 No, *No Further Questions*

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Gender dysphoria

90. Is the patient less than 18 years of age?

- Yes, *Continue to #91*
 No, *Continue to #92*

91. Is the requested drug prescribed by or in consultation with a pediatric endocrinologist that has collaborated care with a mental health care provider?

- Yes, *Continue to #92*
 No, *Continue to #92*

92. Are the patient's comorbid conditions reasonably controlled?

- Yes, *Continue to #93*
 No, *Continue to #93*

93. Has the patient been educated on any contraindications and side effects to therapy?

- Yes, *Continue to #94*
 No, *Continue to #94*

94. Has the patient been informed of fertility preservation options?

- Yes, *Continue to #95*
 No, *Continue to #95*

95. Is the requested drug being prescribed for pubertal hormonal suppression in an adolescent patient?

- Yes, *Continue to #96*
 No, *Continue to #97*

96. Which Tanner Stage of puberty has the patient reached?

- Tanner Stage I, *No Further Questions*
 Tanner Stage II, *No Further Questions*
 Tanner Stage III, *No Further Questions*
 Tanner Stage IV, *No Further Questions*
 Tanner Stage V, *No Further Questions*
 Unknown, *No Further Questions*

97. Is the patient undergoing gender transition?

- Yes, *Continue to #98*
 No, *Continue to #98*

98. Will the patient receive the requested drug concomitantly with gender-affirming hormones?

- Yes, *No Further Questions*
 No, *No Further Questions*

Prevention of recurrent menstrual related attacks in acute porphyria

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100. Is the requested drug being prescribed by, or in consultation with, a physician experienced in the management of porphyrias?

- Yes, *No Further Questions*
 No, *No Further Questions*

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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