**Claim Submission**

* Claim processing may be delayed if the information submitted in this worksheet is illegible.
* If the worksheet is left blank or information is missing the claim will be rejected for not enough documentation and reimbursement will be delayed.
* A claim should not be submitted until the drug has been administered to the patient.
* The manufacturer invoice showing the acquisition cost of the drug administered, including all discounts, rebates, and incentives must be submitted with the claim. The invoice must be dated within 6 months prior to the date of service and/or should include the expiration date of the drug, or it will be rejected for not enough documentation.

# Enrollee Information

**Enrollee Last Name: Enrollee First Name:**

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**Date of Birth (MM/DD/YYYY): Enrollee Medicaid ID (2 letters, 5 numbers, 1 letter):**

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**Address:**

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**City, Town or Post Office: State: ZIP Code:**

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# Prescriber Information

**Prescriber Last Name: Prescriber First Name:**

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**National Provider Identifier (NPI) Number:**

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**Preferred Contact (Telephone Number)**

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**Enrollee Last Name: Enrollee First Name:**

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# Patient Assistance Program

* TerSera Therapeutics, the manufacturer of Zoladex®, voluntarily withdrew from participation in the Medicaid Drug Rebate Program (MDRP) effective 10/01/2021. CMS requires drug manufacturers to participate in the MDRP for their drugs to be eligible for coverage under Medicaid, except in certain circumstances.
* Zoladex® will be available free of charge for those who qualify through a Patient Assistance Program by TerSera Therapeutics. For program applications or additional information please visit: <https://www.zoladexhcp.com/access-support/> or call 855-686-8725.
* Coverage of Zoladex® will continue to be provided for enrollees who are unable to obtain the medication through the Patient Assistance Program ***and*** when used under the following conditions:
  + For an FDA-approved indication for which there are no alternative options
  + As a continuation of established therapy if another gonadotropin-releasing hormone (GnRH) product has been tried and failed or if transition to another GnRH is medically contraindicated

# Clinical Criteria – Drug Information

**Drug Administration:**

Provide the date of drug administration (MM/DD/YYYY):

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Provide the expiration date of the drug if the invoice date is greater than 6 months from the date of drug administration (MM/DD/YYYY):

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**Drug Name and Strength:**

ZOLADEX 3.6 MG IMPLANT SYRINGE

ZOLADEX 10.8 MG IMPLANT SYRINGE

**Directions:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Quantity:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**New Treatment:**  Yes  No

If **No**, date therapy initiated: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Enrollee Last Name: Enrollee First Name:**

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# Clinical Criteria – Diagnosis

1. Prostate Cancer, use in combination with flutamide for the management of locally confined Stage T2b-T4 (Stage B2-C) carcinoma of the prostate

Prostate Cancer, palliative treatment of advanced carcinoma of the prostate

Endometriosis

Endometrial Thinning, use prior to endometrial ablation for dysfunctional uterine bleeding ***(skip to question 4)***

Advanced Breast Cancer, palliative treatment in pre- and perimenopausal women ***(skip to question 4)***

Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. Has the patient been established on therapy with Zoladex®?

Yes  No

If **Yes**, please provide the dates and dosages of previous medication administrations:

Prior Doses :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If **No**, skip to question 4

1. Has the patient tried and failed therapy with another gonadotropin-releasing hormone (GnRH)?

Yes  No

If **Yes**, please provide name(s) of previous drug therapy and reason for discontinuation:

Previous Therapy :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If **No**, is there a documented history of successful therapeutic control with Zoladex® and transition to another GnRH is medically contraindicated?

Yes  No

1. Has the patient applied for the Zoladex Patient Assistance Program?

Yes (but was unable to obtain medication)  No

If **Yes**, please provide the date of application and reason medication was not obtained:

Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If **No**, please contact TerSera Therapeutics for program applications and additional information by visiting <https://www.zoladexhcp.com/access-support/> or calling 855-686-8725.

**Enrollee Last Name: Enrollee First Name:**

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# Attestation

*I attest that this is medically necessary for this patient and that all of the information on this form is accurate to the best of my knowledge. I attest that documentation of the above diagnosis and medical necessity is available for review if requested by the New York State Medicaid Program.*

|  |  |  |
| --- | --- | --- |
| Prescriber Signature (Required) |  | Date (MM/DD/YYYY) |