Clinical Criteria Worksheet:
Zoladex® (goserelin implant)

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:

Date of Birth (MM/DD/YYYY):

/ /

Enrollee Medicaid ID (2 letters, 5 numbers, 1 letter):

Address:

City, Town or Post Office:

State:

ZIP Code:

Prescriber Information

Prescriber Last Name:

Prescriber First Name:

National Provider Identifier (NPI) Number:

Preferred Contact (Telephone Number)

– –

Enrollee Last Name:

Enrollee First Name:

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):

		/			/				

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):

		/			/				

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: | | | | | | | | | | | | |

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

3. 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

4. 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:

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)