Zoladex (goserelin implant)

Clinical Criteria Worksheet

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): _____

PATIENT ASSISTANCE PROGRAM

- TerSera Therapeutics, the manufacturer of Zoladex, voluntarily withdrew from participation in the Medicaid Drug Rebate Program (MDRP) effective 10/1/21. 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 who meet the following criteria:
    - Use for an FDA-approved indication for which there are no alternative options.
    - 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.

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

_____ _____

CLINICAL CRITERIA – DRUG INFORMATION

Drug Name and Strength:

☐ ZOLADEX 3.6 MG IMPLANT SYRINGE

☐ ZOLADEX 10.8 MG IMPLANT SYRINGE

Drug Administration:

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

☐☐ / ☐☐ / ☐☐☐☐

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

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

_____ _____

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.

Attestation

I attest that this drug 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)**