

## Zoladex® (goserelin acetate) (Subcutaneous)

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### I. Length of Authorization

- Endometriosis: Coverage will be provided for 6 months and is NOT eligible for renewal.
- Endometrial Thinning: Coverage will be provided for 2 doses only (given 4 weeks apart) and is NOT eligible for renewal.
- All other indications: Coverage will be provided for 12 months and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [NDC Unit]:

- 3.6mg injection – 1 injection every 28 days
- 10.8mg injection – 1 injection every 12 weeks (Prostate and Breast Cancer only)

#### B. Max Units (per dose and over time) [HCPCS Unit]:

- Prostate & Breast Cancer – 3 billable units every 84 days
- All Other Indications – 1 billable unit every 28 days

### III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

#### Universal Criteria <sup>1,2</sup>

- Females of reproductive potential have a negative pregnancy test prior to start of therapy and will use an effective method of nonhormonal contraception during treatment and for 12 weeks after treatment (*Note: This excludes use in patients receiving palliative treatment of advanced breast cancer*); **AND**

**Breast Cancer † <sup>2,3</sup>**

- Patient is a pre- or peri-menopausal woman or a male with suppression of testicular steroidogenesis; **AND**
- Patient’s disease is hormone receptor-positive; **AND**
  - Used in combination with adjuvant endocrine therapy; **OR**
  - Used in combination with endocrine therapy for recurrent unresectable or metastatic disease; **OR**
  - Used as palliative treatment for advanced disease

**Prostate Cancer †<sup>1-3</sup>**

**Dysfunctional Uterine Bleeding (Endometrial Thinning) †<sup>2</sup>**

- Used prior to endometrial ablation

**Endometriosis †<sup>2</sup>**

- Patient has not received prior-treatment with a gonadotropin releasing hormone (GnRH) agonist for this indication within a 6-month prior period

† FDA Approved Indication(s), ‡ Compendia Recommended Indication(s); **Φ** Orphan Drug

**IV. Renewal Criteria<sup>1</sup>**

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe QT/QTc interval prolongation, severe hyperglycemia and diabetes, cardiovascular toxicity (e.g., myocardial infarction, stroke, etc.), hypercalcemia, severe injection site injury, tumor flare phenomenon, severe hypersensitivity reactions, etc.; **AND**

**Prostate Cancer/Breast Cancer**

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

**Endometriosis/ Dysfunctional Uterine Bleeding (Endometrial Thinning)**

- May not be renewed

**V. Dosage/Administration<sup>1,4</sup>**

Indication	Dose
Breast cancer	Administer 3.6 mg depot every 4 weeks OR Administer 10.8 mg depot every 12 weeks

Dysfunctional Uterine Bleeding (Endometrial Thinning)	<b>(3.6 mg only)</b> Administer 3.6 mg for 1 or 2 doses with each depot given 28 days apart. <ul style="list-style-type: none"> <li>When 1 depot is given, endometrial ablation surgery should be performed at 4 weeks. If 2 depots are given, surgery should be performed within 2-4 weeks following the second depot dosage.</li> </ul>
Endometriosis	<b>(3.6 mg only)</b> Administer 3.6 mg depot every 28 days for 6 months
Prostate Cancer	<u>Stage B2-C Prostatic Carcinoma</u> <ul style="list-style-type: none"> <li>Administer 3.6 mg depot 8 weeks before radiotherapy, followed in 28 days by 10.8 mg depot. Alternatively, four injections of 3.6 mg depot can be administered at 28-day intervals, two depots prior to and two during radiotherapy.</li> </ul> <u>Palliative Treatment of Advanced Prostate Cancer</u> <ul style="list-style-type: none"> <li>Administer 3.6 mg depot every 4 weeks OR</li> <li>Administer 10.8 mg depot every 12 weeks</li> </ul>

## VI. Billing Code/Availability Information

### HCPCS Code:

- J9202 – Goserelin acetate implant, per 3.6 mg: 1 billable unit = 3.6 mg.

### NDC:

- Zoladex 10.8mg 3-Month Implant: 70720-0951-XX
- Zoladex 3.6mg Implant: 70720-0950-XX

## VII. References

- Zoladex 10.8mg [package insert]. Deerfield, IL; TerSera Therapeutics LLC; December 2020. Accessed February 2022.
- Zoladex 3.6mg [package insert]. Deerfield, IL; TerSera Therapeutics LLC; December 2020. Accessed February 2022.
- Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for goserelin acetate National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed February 2022.
- Noguchi S, Kim HJ, Jesena A, et al. Phase 3, open-label, randomized study comparing 3-monthly with monthly goserelin in pre-menopausal women with estrogen receptor-positive advanced breast cancer. Breast Cancer. 2016; 23(5): 771–779. Published online 2015 Sep 9. doi: 10.1007/s12282-015-0637-4
- First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A57655). Centers for Medicare & Medicaid Services, Inc. Updated on 11/21/2019 with effective date 10/03/2018. Accessed March 2022.

6. National Government Services, Inc. Local Coverage Article: Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A52453). Centers for Medicare & Medicaid Services, Inc. Updated on 12/22/2021 with effective date 01/01/2022. Accessed March 2022.
7. Novitas Solutions, Inc. Local Coverage Article: Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A56776). Centers for Medicare & Medicaid Services, Inc. Updated on 10/08/2021 with effective date 10/01/2021. Accessed March 2022.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right female breast
C50.022	Malignant neoplasm of nipple and areola, left female breast
C50.029	Malignant neoplasm of nipple and areola, unspecified female breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast

C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C61	Malignant neoplasm of prostate
N80.0	Endometriosis of uterus
N80.1	Endometriosis of ovary
N80.2	Endometriosis of fallopian tube
N80.3	Endometriosis of pelvic peritoneum
N80.4	Endometriosis of rectovaginal septum and vagina
N80.5	Endometriosis of intestine
N80.6	Endometriosis in cutaneous scar
N80.8	Other endometriosis
N80.9	Endometriosis, unspecified
N92.4	Excessive bleeding in the premenopausal period
N92.5	Other specified irregular menstruation
N93.8	Other specified abnormal uterine and vaginal bleeding
Z85.46	Personal history of malignant neoplasm of prostate

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

<b>Jurisdiction(s):</b> N	<b>NCD/LCD Document (s):</b> A57655
<a href="https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a57655&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%2C6%2C3%2C5%2C1%2CF%2CP">https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a57655&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%2C6%2C3%2C5%2C1%2CF%2CP</a>	
<b>Jurisdiction(s):</b> L, H	<b>NCD/LCD Document (s):</b> A56776
<a href="https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56776&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%2C6%2C3%2C5%2C1%2CF%2CP">https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56776&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%2C6%2C3%2C5%2C1%2CF%2CP</a>	
<b>Jurisdiction(s):</b> 6, K	<b>NCD/LCD Document (s):</b> A52453
<a href="https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a52453&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%2C6%2C3%2C5%2C1%2CF%2CP">https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a52453&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%2C6%2C3%2C5%2C1%2CF%2CP</a>	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)

### Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
15	KY, OH	CGS Administrators, LLC