

Zoladex[®]
(goserelin implant)

Reimbursement, Coding, and Patient Financial Assistance Guide



ZOLADEX 3.6 mg syringe - For illustration only.



1-844-ZOLADEX
1-844-965-2339

For more information, call 1-844-965-2339 Monday through Friday, 8:00 AM to 8:00 PM ET.

ZOLADEX (goserelin implant) is a Gonadotropin Releasing Hormone (GnRH) agonist.

ZOLADEX in Breast Cancer and Benign Gynecology

ZOLADEX 3.6 mg is indicated for:

- Use in the palliative treatment of advanced breast cancer in pre- and perimenopausal women
- The management of endometriosis
- Use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding

ZOLADEX in Prostate Cancer

ZOLADEX 3.6 mg and ZOLADEX 10.8 mg are indicated for:

- Use in combination with flutamide for the management of locally confined carcinoma of the prostate
- Palliative treatment of advanced carcinoma of the prostate

Contraindications

Systemic hypersensitivity, antibody formation, and acute anaphylactic reactions have been reported in patients receiving ZOLADEX. ZOLADEX is contraindicated in patients with known hypersensitivity to GnRH, GnRH agonist, or any of the components in ZOLADEX.

ZOLADEX is contraindicated during pregnancy unless used for palliative treatment of advanced breast cancer. If used during pregnancy, the patient should be advised of the potential hazard to the fetus. Otherwise, pregnancy must be excluded and effective nonhormonal contraception must be used by all premenopausal women during ZOLADEX therapy and for 12 weeks following discontinuation of therapy.

Please see Full Important Safety Information on pages 10 and 11.

Please see accompanying Full Prescribing Information for [ZOLADEX 3.6 mg](#) and [ZOLADEX 10.8 mg](#).

Ordering ZOLADEX

TerSera has negotiated agreements with multiple Physician Specialty Group Purchasing Organizations (GPOs) and Specialty Distributors to provide ZOLADEX and discounted pricing.

GPOs offering discounted ZOLADEX pricing

SPECIALTY	PHYSICIAN SPECIALTY GPO	CONTACT INFORMATION
Oncology	ION (International Oncology Network) Solutions	(888) 536-7697, ext. 6847 Membership@iononline.com
	Unity (US Oncology)	MSH Multi-Specialty: (855) 477-9800 MSH Oncology: (800) 482-6700 MSH.providers@mckesson.com
Oncology/Urology	VitalSource™ GPO	(877) 453-3972 GMB-VitalSource@cardinalhealth.com
	Onmark GPO	MSH Multi-Specialty: (855) 477-9800 MSH Oncology: (800) 482-6700 MSH.providers@mckesson.com
Urology	IPN (International Physicians Network)	(888) 536-7697, ext. 6847 MemberServices@IPNOnline.com
	Contact Besse Medical Specialty Distributor Directly	(800) 543-2111

Specialty Distributors of ZOLADEX

SPECIALTY DISTRIBUTOR	CONTACT INFORMATION
Besse Medical	(800) 543-2111
Cardinal Health Specialty Solutions	(866) 677-4844
McKesson Specialty Health	MSH Multi-Specialty: (855) 477-9800 MSH Oncology: (800) 482-6700
Oncology Supply	(800) 633-7555

If you are not already affiliated with one of the organizations above, please contact them directly.

Call 1-844-ZOLADEX for any additional questions about ordering ZOLADEX.

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TerSera
SupportSource Programs



**PATIENT ASSISTANCE
PROGRAM**



1-855-686-8725

(8:00 AM-6:00 PM ET, Monday-Friday)

The TerSera Patient Assistance Program supports patients without any healthcare coverage*

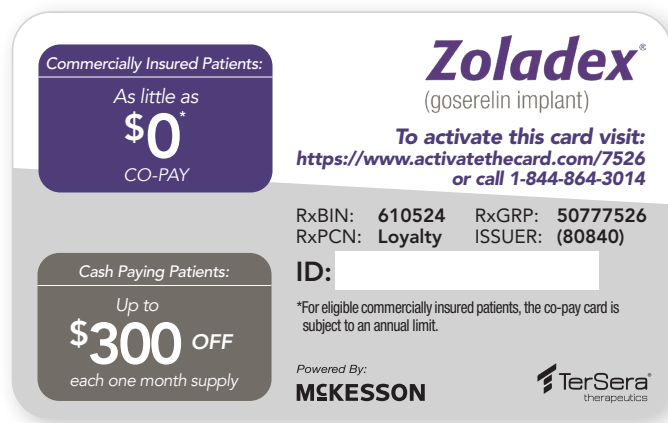
- Patients who establish financial need can receive free product
- If a patient qualifies, they may get free TerSera medicine for up to 1 year. TerSera will send an application for renewal once the patient's enrollment ends
- Assistance is available to legal US residents who do not have access to insurance coverage

*Terms and conditions apply.

Financial Assistance

ZOLADEX Co-pay Savings Program

- Commercially insured patients
 - Eligible patients may pay as little as \$0 of their co-pay or coinsurance amount (subject to an annual limit)
- Cash-paying patients
 - Eligible patients can save on each one-month supply



For eligible commercially insured patients, the co-pay card is subject to an annual limit. Patient is not eligible if prescriptions are paid for by any state or other federally funded programs, including, but not limited to, Medicare or Medicaid, VA, DOD, TRICARE, or where prohibited by law. Additional terms and conditions apply.

For more information, please visit ZOLADEXhcp.com/access-support or call 1-844-864-3014.

It is important to note that the codes identified below are examples only. Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient. The use of the following codes does not guarantee reimbursement. The ultimate responsibility for obtaining reimbursement lies with the physician, provider, or patient. Please consult with your counsel or reimbursement specialist for any practice-specific reimbursement or billing questions.

National Drug Code (NDC)

The National Drug Code (NDC) is a universal, unique, 3-segment number identifying drugs by manufacturer, dosage, and package size. Payers may require the submission of the 11-digit NDC on healthcare claim forms, and electronic claims may be denied for drugs billed without a valid 11-digit NDC. Contact your patient's health plan to determine claim submission requirements and to determine accurate reporting of NDC codes.

10-digit NDC

Dosage	Code
One, 10.8 mg implant	70720-951-30
One, 3.6 mg implant	70720-950-36

11-digit NDC

Dosage	Code
One, 10.8 mg implant	70720-0951-30
One, 3.6 mg implant	70720-0950-36

Current Procedural Terminology (CPT)

Submitting accurate codes and claims is important to ensure proper reimbursement of services. The chart below lists potential Current Procedural Terminology (CPT) code(s) for your reference when submitting claims for your ZOLADEX patients.

Code	Description
11980	Introduction or Removal Procedures on the Integumentary System
96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96402	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug

Healthcare Common Procedure Coding System (HCPCS)

Submitting accurate codes and claims is important to ensure proper reimbursement of services. The chart below lists potential code(s) for your reference when submitting claims for your ZOLADEX patients.

Code	Description
J9202	Goserelin acetate implant, per 3.6 mg
S9560	Home injectable therapy; hormonal therapy (eg, leuprolide, goserelin), including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

Coding Resource

Diagnosis Codes

When filing claims, providers often indicate a diagnosis code reflecting the patient's condition. Based on the indications for ZOLADEX, examples of diagnosis codes that may be appropriate are listed below.

It is important to note that the codes identified below are examples only. Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient.

The use of the following codes does not guarantee reimbursement. The ultimate responsibility for obtaining reimbursement lies with the physician, provider, or patient. Please consult with your counsel or reimbursement specialist for any practice-specific reimbursement or billing questions.

International Classification of Diseases, Tenth Revision, Clinical Modification = ICD-10-CM

ICD-10-CM	Description
ADVANCED BREAST CANCER	
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
C50.111	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
C50.211	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
C50.311	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
C50.411	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
C50.511	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

Diagnosis Codes *(continued)*

ICD-10-CM	Description
ADVANCED BREAST CANCER <i>(continued from previous page)</i>	
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
C50.811	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
C50.911	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
PERSONAL HISTORY STATUS	
Z85.3	Personal history of malignant neoplasm of breast

Coding Resource

Diagnosis Codes *(continued)*

ICD-10-CM	Description
ENDOMETRIOSIS AND DYSFUNCTIONAL UTERINE BLEEDING	
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 of cutaneous scar
N80.8	Other endometriosis
N80.9	Endometriosis, unspecified
N89.7	Hematocolpos
N92.1	Excessive and frequent menstruation with irregular cycle
N92.4	Excessive bleeding in the premenopausal period
N92.5	Other specified irregular menstruation
N92.6	Irregular menstruation, unspecified
N93.8	Other specified abnormal uterine and vaginal bleeding
N93.9	Abnormal uterine and vaginal bleeding, unspecified
N95.0	Postmenopausal bleeding
CARCINOMA OF THE PROSTATE	
C61	Malignant neoplasm of prostate

INDICATIONS

ZOLADEX (goserelin implant) is a Gonadotropin Releasing Hormone (GnRH) agonist.

ZOLADEX 3.6 mg is indicated for:

- Use in the palliative treatment of advanced breast cancer in pre- and perimenopausal women
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ZOLADEX 3.6 mg and ZOLADEX 10.8 mg are indicated for:

- Use in combination with flutamide for the management of locally confined carcinoma of the prostate
- Palliative treatment of advanced carcinoma of the prostate

IMPORTANT SAFETY INFORMATION

GENERAL

Systemic hypersensitivity, antibody formation, and acute anaphylactic reactions have been reported in patients receiving ZOLADEX. ZOLADEX is contraindicated in patients with known hypersensitivity to GnRH, GnRH agonist, or any of the components in ZOLADEX.

Tumor Flare Phenomenon: Transient worsening of tumor symptoms may occur in the first few weeks of therapy in patients being treated for cancer. Monitor patients at risk for complications of tumor flare including ureteral obstruction, spinal cord compression, and increased bone pain.

Hypercalcemia has been reported in patients with bone metastases treated with ZOLADEX. Monitor and manage appropriately.

ZOLADEX can cause severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP). SCARs, including SJS/TEN, DRESS, and AGEP, occurred in patients receiving ZOLADEX or other GnRH agonists, including cases with visceral involvement and/or requiring skin grafts. Monitor patients for the development of SCARs. If a SCAR is suspected, interrupt ZOLADEX until the etiology of the reaction has been determined. Consultation with a dermatologist is recommended. If a SCAR is confirmed, or for other grade 4 skin reactions, permanently discontinue ZOLADEX.

Injection site injury and vascular injury have been reported with ZOLADEX. Extra care should be taken when administering ZOLADEX to patients with low BMI and/or to patients receiving full dose anticoagulation.

Important Safety Information continued on next page.

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FEMALES

ZOLADEX is contraindicated during pregnancy unless used for palliative treatment of advanced breast cancer. If used during pregnancy, the patient should be advised of the potential hazard to the fetus. Otherwise, pregnancy must be excluded and effective nonhormonal contraception must be used by all premenopausal women during ZOLADEX therapy and for 12 weeks following discontinuation of therapy.

ZOLADEX may cause an increase in cervical resistance. Therefore, caution is recommended when dilating the cervix for endometrial ablation.

Depression may occur or worsen in women receiving GnRH agonists, including ZOLADEX. Monitor and manage appropriately.

MALES

Hyperglycemia and an increased risk of developing diabetes have been reported in men receiving GnRH agonists. Monitor blood glucose levels and manage according to current clinical practice.

Increased risk of myocardial infarction, sudden cardiac death and stroke has been reported in association with use of GnRH agonists in men. Patients should be monitored for cardiovascular disease and be managed according to current clinical practice.

Androgen deprivation therapy may prolong the QT interval. Consider risks and benefits.

ADVERSE REACTIONS

In men, the most common adverse reactions (>10%) include hot flashes, sexual dysfunction, decreased erections and lower urinary tract symptoms.

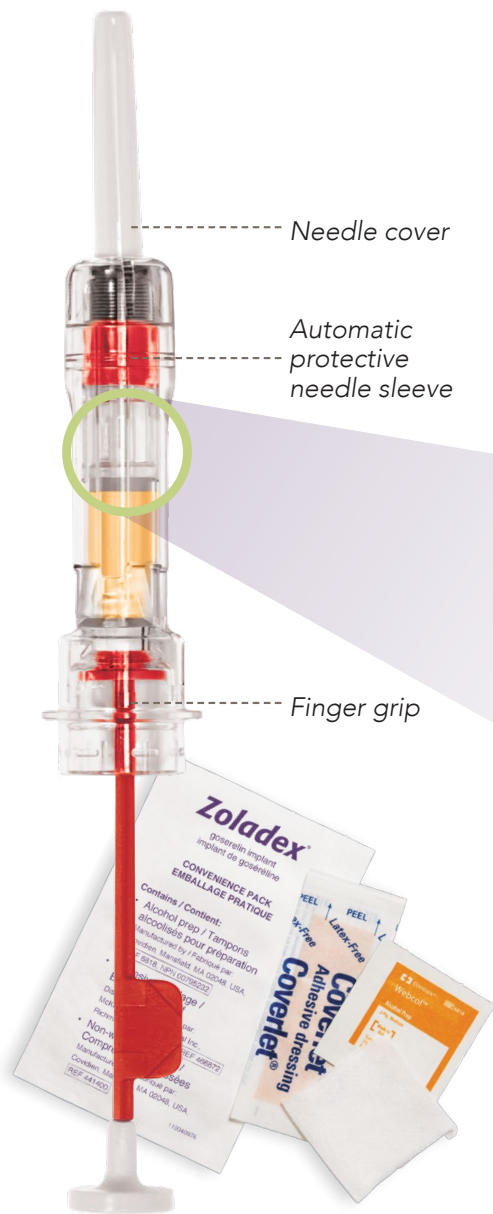
In women, the most common adverse reactions (>20%) include hot flashes, vaginitis, headache, emotional lability, decreased libido, sweating, depression, acne, breast atrophy, seborrhea, and peripheral edema.

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch. You may also contact TerSera Therapeutics at 1-844-334-4035 or medicalinformation@tersera.com.

Please see accompanying Full Prescribing Information for [ZOLADEX 3.6 mg](#) and [ZOLADEX 10.8 mg](#).

The ZOLADEX SafeSystem[®] Syringe:

*Purpose-built to provide consistent reliable delivery of ZOLADEX –
no assembly, mixing, or refrigeration required^{1,2}*



The ONLY subcutaneous, biodegradable GnRH agonist implant:

- Delivered through a triple-beveled, siliconized needle
- Each syringe is provided with a convenience pack (contains gauze, alcohol wipe, and bandage)
- Designed with a protective needle sleeve to reduce needlestick injuries by automatically covering the needle upon withdrawal³

Biodegradable implant
delivered through the
ZOLADEX SafeSystem[®] Syringe –
For illustration only.

ZOLADEX 3.6 mg SafeSystem[®] Syringe and
convenience pack – For illustration only.

GnRH=gonadotropin-releasing hormone.

References: **1.** ZOLADEX[®] (goserelin implant) 3.6 mg. Prescribing Information. TerSera Therapeutics LLC. **2.** Data on file. TerSera Therapeutics LLC. **3.** Moser MA. Engineering out needle stick injuries (safety devices). *The Safe Angle*. Summer 2004;5-7.