Zoladex

Zoladex (Goserelin Acetate) J9202

Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ Prostate Cancer – Advanced (Palliative Treatment)
- ☐ Patient has confirmed diagnosis of advanced prostate cancer (e.g., metastatic, locally advanced)
- ☐ Therapy is intended for palliative treatment (hormone-sensitive disease)
- ☐ Prescribed by or in consultation with urologist or oncologist
- ☐ No known hypersensitivity to goserelin or LHRH agonists

☐ Breast Cancer – Advanced (Palliative Treatment)
- ☐ Patient is premenopausal or perimenopausal
- ☐ Confirmed diagnosis of advanced breast cancer (e.g., metastatic, locally advanced)
- ☐ Tumor is hormone receptor-positive (ER+ and/or PR+)
- ☐ Therapy is intended for palliative treatment
- ☐ Prescribed by or in consultation with oncologist
- ☐ No known hypersensitivity to goserelin or LHRH agonists

☐ **Breast Cancer – Adjuvant Treatment (Early Stage)**

- ☐ Patient is premenopausal or perimenopausal
- ☐ Confirmed diagnosis of early-stage breast cancer (Stage I-III)
- ☐ Tumor is hormone receptor-positive (ER+ and/or PR+)
- ☐ Therapy is intended as adjuvant treatment in combination with tamoxifen or aromatase inhibitor
- ☐ Prescribed by or in consultation with oncologist
- ☐ No known hypersensitivity to goserelin or LHRH agonists

☐ **Endometriosis (for duration of therapy, typically ≤6 months)**

- ☐ Patient is premenopausal
- ☐ Confirmed diagnosis of endometriosis
- ☐ Patient has failed, intolerant, or has contraindication to first-line therapies (e.g., NSAIDs, hormonal contraceptives)
- ☐ Duration of therapy limited to 6 months (repeat courses not recommended)
- ☐ Prescribed by or in consultation with gynecologist
- ☐ No known hypersensitivity to goserelin or LHRH agonists

☐ **Uterine Leiomyomata (Fibroids) – Preoperative Hematologic Improvement**

- ☐ Patient is premenopausal
- ☐ Confirmed diagnosis of uterine fibroids
- ☐ Therapy is intended for preoperative hematologic improvement in anemic patients
- ☐ Duration of therapy limited to 3 months
- ☐ Prescribed by or in consultation with gynecologist
- ☐ No known hypersensitivity to goserelin or LHRH agonists

If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ **Continuation Requests: (Clinical documentation required for all requests)**

☐ Patient had an **adequate response** or **significant improvement** while on this medication.

If not, please provide clinical rationale for continuing this medication: _____
_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Zoladex Prior Authorization

Drug Name(s):

ZOLADEX **GOSERELIN ACETATE**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per CMS recognized compendia, authoritative medical literature, evidence based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and tiering will be determined by the Plan, in accordance with the Label.

Exclusion Criteria:

N/A

Prescriber Restrictions:

Oncologist or other related specialist

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Zoldadex

- Breast cancer, For palliation of advanced disease in pre- and peri-menopausal women
- Endometriosis
- Hypoplasia of endometrium
- Prostate cancer, Advanced (palliative treatment)
- Prostate cancer, In combination with flutamide for locally confined stage B2-C disease

Off-Label Uses:

Zoldadex

- Abnormal uterine bleeding
- Breast cancer, Adjuvant treatment of hormone receptor-positive, axillary lymph node-positive disease in premenopausal women
- Fertility preservation procedure, In women with cancer
- Gender dysphoria - Transgender female; Adjunct
- In vitro fertilization
- Precocious puberty
- Prostate cancer

Age Restrictions:

Safety and effectiveness in pediatric patients have not been established

Other Clinical Consideration:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Zoladex%0A&SearchFilter=filterNone#