Original Effective Date: 03/2016
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Last P&T Approval/Version: 07/29/2026
Next Review Due By: 07/2027
Policy Number: C8757-A

Zoladex (goserelin acetate)

PRODUCTS AFFECTED

Zoladex (goserelin acetate)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Prostate cancer, Breast cancer, Endometriosis, Dysfunctional uterine bleeding, Prevention of chemotherapy induced premature ovarian insufficiency

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. This clinical policy will be reviewed along with state and federal requirements, the benefit being administered, and formulary preferencing. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available. The Pharmacy and Therapeutics Committee has determined that biosimilars may be preferred.

A. PROSTATE CANCER:
   1. Documentation of a diagnosis of prostate cancer

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AND

2. Documentation the utilization of a Gonadotropin-Releasing Hormone Agonist is recommended for the members stage and disease per NCCN updated guidelines for prostate cancer
   AND
3. Documentation of trial and failure, serious side effects, or labeled contraindication to Eligard (leuprolide acetate)

B. BREAST CANCER:
1. Documented diagnosis of breast cancer meeting ONE of the following:
   (i) Female member who is pre-menopausal at diagnosis and requires ovarian suppression
   (ii) Male member requiring adjuvant endocrine therapy

C. ENDOMETRIOSIS:
1. Documentation of a diagnosis of endometriosis
   AND
2. Documentation member has tried/failed or has an absolute contraindication to ALL of the following:
   (i) One formulary NSAIDs (i.e., Ibuprofen, naproxen)
   AND
   (ii) One formulary preferred oral estrogen-progestin contraceptive, or medroxyprogesterone, or norethindrone acetate

D. DYSFUNCTIONAL UTERINE BLEEDING/UTERINE LEIOMYOMAS:
1. Documentation of uterine leiomyomas confirmed with pelvic imaging
   AND
2. Documentation member is symptomatic as evidenced by heavy or prolonged menstrual bleeding, bulk- related symptoms such as pelvic pressure and pain, or reproductive dysfunction (i.e., infertility or obstetric complications)
   AND
3. Documentation therapy is being used for ONE of the following:
   a) As preoperative therapy 3-6 months prior to surgery for ONE of the following reasons: Member has a contraindication to oral iron supplementation to facilitate the procedure and anemia correction is necessary OR Volume reduction is necessary prior to procedure
   OR
   b) As transitional therapy for members in late perimenopause as they move to menopause

E. PREVENTION OF CHEMOTHERAPY–INDUCED PREMATURE OVARIAN INSUFFICIENCY [Ref 5-13]:
1. Documentation member is post puberty
   AND
2. Documentation member is undergoing premenopausal gonadotoxic therapy or gonadotoxic surgery
   AND
3. Prescriber attests member is not a candidate for cryopreservation or is not eligible for cryopreservation [see Other Special Considerations for ASCO recommendations]

CONTINUATION OF THERAPY:

A. ENDOMETRIOSIS: N/A

B. DYSFUNCTIONAL UTERINE BLEEDING/UTERINE LEIOMYOMAS: N/A

C. ALL OTHER INDICATIONS:
1. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity (e.g., tumor flare, hyperglycemia/diabetes, cardiovascular disease

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[myocardial infarction, sudden cardiac death, stroke], QT/QTc prolongation, convulsions, etc.)
AND

2. Documentation of improvement in the condition's signs and symptoms and/or stabilization of disease due to therapy or member continues on gonadotoxic chemotherapy

DURATION OF APPROVAL:
Prostate cancer: Initial authorization: 12 months, Continuation of therapy: 12 months
Breast cancer: Initial authorization: 12 months, Continuation of therapy: 12 months
Endometriosis: Initial authorization: 6 months (lifetime maximum), Continuation of therapy: N/A
Dysfunctional uterine bleeding/uterine leiomyomas: Initial authorization: 6 months, Continuation of therapy: N/A
Prevention of chemotherapy–induced premature ovarian insufficiency: Initial authorization: 6 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prostate cancer or Breast cancer: Prescribed by or in consultation with an oncologist or urologist.
Endometriosis or dysfunctional uterine bleeding/uterine leiomyomas: Prescribed by or in consultation with a gynecologist or specialist in women's health
Prevention of chemotherapy–induced premature ovarian insufficiency: Prescribed by or in consultation with a gynecologist or oncologist.
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
Prevention Of Chemotherapy–Induced Premature Ovarian Insufficiency: Member must be post-puberty
All other indications: 18 years of age and older

QUANTITY:
Prostate cancer: One 3.6 mg implant per 4 weeks OR One 10.8 mg implant per 12 weeks
Breast cancer: 3.6 mg every 28 days OR One 10.8 mg implant per 12 weeks
Endometriosis: 3.6 mg every 28 days for up to 6 months
Dysfunctional uterine bleeding/uterine leiomyomas: 3.6 mg every 28 days for up to 2 doses
Prevention of chemotherapy– induced premature ovarian insufficiency: 3.6 mg every 28 days

PLACE OF ADMINISTRATION:
The recommendation is that injectable implant medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable implant products administered in a place of service that is a non- hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous implant

DRUG CLASS:
LHRH analogs

FDA-APPROVED USES:
Zoladex 3-month implant 10.8mg indicated for: Use in combination with flutamide for the management of locally confined carcinoma of the prostate, Use as palliative treatment of advanced carcinoma of the prostate

Zoladex 1 month implant 3.6mg 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, The

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

COMPENDIAL APPROVED OFF-LABELED USES:
Prevention of Chemotherapy-induced premature ovarian insufficiency

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Zoladex (goserelin acetate) Implant 3.6 mg is a man-made form of a hormone used in men to treat symptoms of prostate cancer, and in women to treat breast cancer or endometriosis. Zoladex is also used in women to prepare the lining of the uterus for endometrial ablation (a surgery to correct abnormal uterine bleeding).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Zoladex (goserelin acetate) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Zoladex (goserelin acetate) include: hypersensitivity, and patients that are pregnant unless being used for advanced breast cancer.

OTHER SPECIAL CONSIDERATIONS:
FERTILITY PRESERVATION:
Fertility Preservation in People with Cancer: American Society of Clinical Oncology Guideline Update 2025
Fertility preservation in females
Recommendation 4.1 Embryo cryopreservation: Embryo cryopreservation should be offered as it is an established fertility preservation method, and it has routinely been used for storing embryos after in vitro fertilization.

Recommendation 4.2. Mature oocyte cryopreservation: Cryopreservation of unfertilized oocytes should be offered as it is an established fertility preservation method and may be especially well suited to females who do not have a male partner, do not wish to use donor sperm, or have religious or ethical objections to embryo freezing. Oocyte cryopreservation should be performed in centers with the necessary expertise.. Qualifying statement: Flexible ovarian stimulation protocols for oocyte collection are available. Timing of this procedure no longer depends on the menstrual cycle in most cases, and stimulation can be initiated with less delay compared with older protocols. Thus, oocyte harvesting for the purpose of oocyte or embryo cryopreservation is now possible on a cycle day–independent schedule. Of special concern in estrogen-sensitive breast and gynecologic malignancies is the possibility that these fertility preservation interventions (e.g., ovarian stimulation regimens that increase estrogen levels) may increase the risk of cancer progression or recurrence. Aromatase inhibitor–based stimulation protocols are now well established and may alleviate these concern. In particular, there is no increased cancer recurrence risk as a result of aromatase inhibitor– supplemented ovarian stimulation.

Recommendation 4.3. Post-treatment setting: Embryo and oocyte cryopreservation for fertility preservation may be offered in the post-treatment setting to patients who did not undergo fertility preservation before their cancer treatment but are at risk of primary ovarian insufficiency or infertility. They may also be offered to survivors who previously underwent fertility preservation but may not have enough cryopreserved tissue to meet their desired family size, as well as for those who want or need to delay childbearing and consequently face the risk of age-related fertility decline, which may be accelerated in cancer survivors.

Recommendation 4.4. In vitro maturation (IVM): IVM of oocytes may be offered as an emerging FP method.

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Recommendation 4.5. Ovarian transposition: Ovarian transposition (oophoropexy) may be offered to reproductive-aged patients when pelvic irradiation is required. However, because of radiation scatter, ovaries are not always protected, and patients should be aware that this technique is not always successful. Because of the risk of remigration of the ovaries, this procedure should be performed as close to the time of radiation treatment as possible.
Qualifying Statement: Ovarian transposition is not suitable for patients with a moderate or high risk of ovarian metastasis, or those receiving concomitant gonadotoxic chemotherapy.

Recommendation 4.6. Uterine transposition: Uterine transposition in reproductive-aged patients remains experimental and should be offered only as part of a clinical trial or approved experimental protocols.

Recommendation 4.7. Conservative gynecologic surgery: For patients with stage IA2 to IB1 cervical cancer, radical trachelectomy may be offered to preserve fertility if the tumor diameter is <2 cm and invasion depth is <10 mm. For patients with well-differentiated (grade 1) endometrial tumors with minimal myometrial invasion, as confirmed by magnetic resonance imaging, fertility-sparing surgery may be offered. Hormonal therapy using progestins, either orally or via an intrauterine device, is the primary fertility-preserving option for early-stage endometrial cancer. Patients with stage IA grade 1 epithelial ovarian cancer after thorough staging may be offered fertility-sparing surgery. Uterine preservation may be considered in other stages and grades to enable future use of assisted reproductive technologies. In other gynecologic malignancies, less radical surgeries may be offered to spare reproductive organs when clinically appropriate.

Recommendation 4.8. Ovarian suppression: Gonadotropin-releasing hormone agonists (GnRHa) should not be used in place of established fertility preservation methods such as oocyte, embryo, or ovarian tissue cryopreservation. GnRHa may be offered as an adjunct to females with breast cancer. Beyond breast cancer, the potential benefits and risks of GnRHa warrant further investigation, and trials are encouraged.

Recommendation 4.9. Ovarian suppression: For patients with oncologic emergencies requiring urgent chemotherapy, GnRHa may be offered and can provide benefits such as menstrual suppression.

Recommendation 4.10. Ovarian tissue cryopreservation and transplantation: Ovarian tissue cryopreservation (OTC) for the purpose of future transplantation may be offered to patients with cancer as an established fertility preservation method. As it does not require ovarian stimulation, it can be performed immediately in those unable to delay chemotherapy. In addition, it does not require sexual maturity and hence may be the only method available in prepubertal patients. This method may also be offered as an emerging method to restore global ovarian function. While this option may be offered as an alternative to embryo or oocyte cryopreservation, it may also serve as an adjunct option. Proceeding with OTC should be guided by patient preferences, clinical considerations, and individual circumstances including future flexibility, success rates, and legal considerations.

Fertility preservation in children
Recommendation 5.1. Clinicians should offer established methods of fertility preservation (e.g., semen or oocyte cryopreservation) in children and adolescents who have initiated puberty, with patient assent and parent or guardian consent. For prepubertal children, the only fertility preservation options are ovarian and testicular cryopreservation, the latter of which is currently investigational.

CODING/BILLING INFORMATION

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HCPCS CODE	DESCRIPTION
J9202	Goserelin acetate implant, per 3.6mg

AVAILABLE DOSAGE FORMS:
Zoladex IMPL 3.6MG
Zoladex IMPL 10.8MG

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity References	Q3 2026
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements FDA-Approved Uses Other Special Considerations References	Q3 2025
REVISION- Notable revisions: Continuation of Therapy Duration of Therapy References	Q3 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Contraindications/Exclusions/Discontinuation References	Q3 2023
REVISION- Notable revisions: Duration of Approval Compendial Approved Off Labeled uses References	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file

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