

Clinical Policy: Goserelin Acetate (Zoladex)

Reference Number: CP.PHAR.171

Effective Date: 02/16

Last Review Date: 02/17

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene[®] medical policy for the use of goserelin acetate (Zoladex[®]).

Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation[®] that Zoladex is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prostate Cancer (must meet all):

1. Diagnosis of prostate cancer;
2. Meets a or b:
 - a. FDA approved use (one of the following):
 - i. In combination with flutamide and radiation for locally confined prostate cancer (stage T2b through T4 or intermediate risk through nodal/metastatic disease);
 - ii. As palliative therapy for advanced prostate cancer (stages T3 through T4 or high risk through nodal/metastatic disease);
 - b. Off-label NCCN recommended use (one of the following):
 - i. As adjuvant therapy (i.e., administered after radical prostatectomy [RP] if positive for pelvic lymph nodes);
 - ii. As initial androgen deprivation therapy (ADT);
 - iii. As ADT for biochemical failure* following RP;
 - iv. As ADT for positive digital rectal examination following radiation therapy;
 - v. For progressive castration-naive disease (i.e., not on ADT at time of progression) or castration-recurrent/resistant disease (i.e., no longer responsive to traditional ADT);
3. Member has no known hypersensitivity to Gonadotropin Releasing Hormone (GnRH), GnRH analogs, or any excipient in the requested product.

**Biochemical failure: 1) Failure of prostate specific antigen (PSA) to fall to undetectable levels (PSA persistence) or 2) undetectable PSA after RP with a subsequent detectable PSA that increases on 2 more determinations (PSA recurrence).*

Approval duration: 12 months

B. Breast Cancer (must meet all):

1. Diagnosis of invasive breast cancer (does not include in situ disease);

2. Meets a or b:
 - a. FDA approved use (i and ii):
 - i. Member is pre- or perimenopausal;
 - ii. Prescribed as palliative therapy for advanced breast cancer (stage IV or recurrent/metastatic disease);
 - b. Off-label NCCN recommended use (i and ii):
 - i. Member is pre-menopausal and has hormone receptor-positive disease;
 - ii. Prescribed in combination with one of the following:
 - a) Adjuvant endocrine therapy;
 - b) Endocrine therapy for recurrent or metastatic disease;
3. Member has no known hypersensitivity to GnRH, GnRH agonist analogs, or any excipient in the requested product.

Approval duration: 12 months

C. Endometriosis or Endometrial Thinning/Dysfunctional Uterine Bleeding (must meet all):

1. Request is for Zoladex 3.6 mg implant;
2. One of the following diagnoses:
 - a. Endometriosis (i or ii):
 - i. Diagnosis surgically confirmed;
 - ii. Clinically diagnosed and failed a three-month trial of nonsteroidal anti-inflammatory drugs (NSAIDs) and/or combined oral estrogen-progesterone contraceptive within the last year;
 - b. Dysfunctional uterine bleeding used as an endometrial-thinning agent prior to endometrial ablation;
3. Prescribed dose of Zoladex does not exceed 3.6 mg every 28 days;
4. Member has none of the following contraindications:
 - a. Known hypersensitivity to GnRH, GnRH analogs, or any excipient in the requested product;
 - b. Pregnancy.

Approval duration:

Endometriosis: 6 months total

Endometrial Ablation: up to 2 depots total

D. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. All Indications (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;
3. Member has no known hypersensitivity to GnRH, GnRH analogs, or any of the excipient in the requested product.

Approval duration: 12 months

B. Other diagnoses/indications: (must meet 1 or 2)

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Goserelin acetate is a synthetic decapeptide analogue of GnRH and acts as an inhibitor of pituitary gonadotropin secretion when administered in the biodegradable formulation.

Formulations:

Zoladex (goserelin acetate) for subcutaneous administration:

3.6 mg implant

- Designed for continuous release over a 28-day period

10.8 mg implant

- Designed for continuous release over a 12-week period

FDA Approved Indications:

Zoladex is a GnRH agonist/subcutaneous implant indicated for:

- Use in combination with flutamide for the management of locally confined Stage T2b-T4 (Stage B2-C) carcinoma of the prostate; treatment with Zoladex and flutamide should start 8 weeks prior to initiating radiation therapy and continue during radiation therapy:
 - Zoladex – 3.6 mg implant
 - Zoladex – 10.8 mg implant
- Palliative treatment of advanced carcinoma of the prostate:
 - Zoladex – 3.6 mg implant
 - Zoladex – 10.8 mg implant
- Use in the palliative treatment of advanced breast cancer in pre- and perimenopausal women:
 - Zoladex – 3.6 mg implant
- Management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy; experience with Zoladex for the management of endometriosis has been limited to women 18 years of age and older treated for 6 months:
 - Zoladex – 3.6 mg implant
- Use as an endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding:
 - Zoladex – 3.6 mg implant

Appendices

Appendix A: Abbreviation Key

ADT: Androgen deprivation therapy

GnRH: Gonadotropin-releasing hormone

PSA: Prostate specific antigen

RP: Radical prostatectomy

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9202	Goserelin acetate implant, per 3.6 mg

Reviews, Revisions, and Approvals	Date	Approval Date
<p>Policy split from CP.PHAR.118.GnRH Analogs.</p> <p>Prostate cancer – locally confined with radiation therapy; age added 18 or older per PI; max dose added; staging restated per PI</p> <p>Approval period limited to 6 months total with radiation therapy per guidelines</p> <p>Prostate cancer – advanced/palliative; age added 18 or older per PI; max dose added; removed preferencing other than a trial of injectables before receiving implant; staging of advanced prostate cancer restated as stage T3 through T4 or high risk through nodal/metastatic disease per guidelines; added confirmation that treatment intent is palliative if designated in PI; approval period extended to q 12 months</p> <p>Breast cancer – advanced/palliative; age added 18 or older per PI; max dose added; defined advanced as stage IV or recurrent metastatic disease per guidelines; removed requirement for ER/PR+ status as guidelines note status not always clear and that GnRH analogs can be effective in either case; add peri-menopausal status per Zoladex guideline; FDA approved and off-label breast cancer criteria is stated the same based on Zoladex PI and guidelines; added confirmation that treatment intent is palliative as designated in Zoladex PI; approval period; extended to q 12 months</p> <p>Endometriosis - age added 18 or older per PI; max dose added; removed that surgical diagnosis had to be within last year; for clinical diagnosis, restated failure of one three-month trial to analgesics and/or contraceptives per UpToDate; approval period restated per PIs as follows: 6 months total if Zoladex, up to 12 months total for all others per products.</p> <p>Endometrial thinning prior to ablation - age added 18 or older per PI; max dose added</p>	02/16	02/16
Endometriosis: Changed 3 month trial of analgesics and/or hormonal contraceptives to NSAIDS and/or hormonal contraceptives.	05/16	
Per the PI, pregnancy is not a contraindication in cases of advanced breast cancer so it is removed as such in sections I.B and II.B above.	10/16	
<p>Age removed.</p> <p>Formulations added.</p> <p>Off-label NCCN recommended uses added (prostate and breast cancer; doses removed; 3-month injectable requirement removed).</p>	01/17	02/17

References

1. Zoladex (3.6 mg) prescribing information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2016. Available at <https://www.zoladex.com>. Accessed December 28, 2016.
2. Zoladex (10.8 mg) prescribing information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2016. Available at <https://www.zoladex.com>. Accessed December 28, 2016.
3. Goserelin acetate. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed December 29, 2016.
4. Prostate cancer (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed December 29, 2016.
5. Breast cancer (Version 2.2016). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed December 29, 2016.
6. Schenken RS. Endometriosis: Pathogenesis, clinical features, and diagnosis. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at UpToDate.com. Accessed December 28, 2016.
7. Schenken RS. Endometriosis: Treatment of pelvic pain. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at UpToDate.com. Accessed December 28, 2016.
8. Hornstein MD and Gibbons WE. Endometriosis: Long-term treatment with gonadotropin-releasing hormone agonists. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at UpToDate.com. Accessed December 28, 2016.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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