Clinical Policy: Goserelin Acetate (Zoladex)

Reference Number: PA.CP.PHAR.171
Effective Date: 01/18
Last Review Date: 02/17 Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® medical policy for the use of goserelin acetate (Zoladex®).

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness 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. Gender Dysphoria (off-label) (must meet all):
1. Diagnosis of gender dysphoria as evidenced by meeting the DSM V criteria for gender dysphoria;
2. Prescribed by or in consultation with pediatric endocrinologist, adolescent medicine specialist or medical provider with experience and/or training in transgender medicine;
3. Member has psychological and social support during treatment;
4. Member does not suffer from a psychiatric comorbidity that interferes with the diagnostic work-up or treatment;
5. Member demonstrates consent and understanding of the expected outcomes of GnRH analog treatment (*For minorities, when parental consent cannot be obtained,*

exceptions are reviewed on a case by case basis and in conjunction with a behavioral health provider);

6. For adults: failure to achieve physiologic hormone levels or an intolerance with use of gender-affirming hormonal therapy (e.g., estrogen, testosterone).

Approval duration: 12 months

E. Other diagnoses/indications: Refer to PA.CP.PMN.53 – off-label policy.

II. Continued Approval

A. All Indications (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy applies (*see PA.LTSS.PHAR.01*);
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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy, or the Continuity of Care policy applies (*see PA.LTSS.PHAR.01*); or
2. Refer to PA.CP.PMN.53 – off-label 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
	02/16	02/16

References

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5. Breast cancer (Version 2.2016). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed December 29, 2016.

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