

Reference number(s)
1918-A, 1919-A

## SPECIALTY GUIDELINE MANAGEMENT

### ZOLADEX (goserelin acetate)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

###### A. FDA-Approved Indications

1. Prostate cancer
  - a. 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.
  - b. In the palliative treatment of advanced carcinoma of the prostate
2. Endometriosis  
For the 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 strength only)
3. Endometrial thinning  
For use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding (Zoladex 3.6 mg strength only)
4. Advanced breast cancer  
For use in the palliative treatment of advanced breast cancer in pre-and perimenopausal women

###### B. Compendial Uses

1. Breast cancer
2. Prostate cancer
3. Gender dysphoria (also known as gender non-conforming or transgender persons)  
**NOTE: Some plans may opt-out of coverage for gender dysphoria.**

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions: Use of the 10.8 mg strength for diagnoses other than prostate cancer, breast cancer, and gender dysphoria (if applicable).

##### III. CRITERIA FOR INITIAL APPROVAL

###### A. **Breast Cancer**

Authorization of 12 months may be granted for the treatment of HR-positive breast cancer in a pre- or perimenopausal member.

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**B. Prostate Cancer**

Authorization of 12 months may be granted for treatment of prostate cancer.

**C. Endometriosis**

Authorization of 6 months may be granted for treatment of endometriosis.

**D. Endometrial-thinning agent**

Authorization of 2 doses may be granted for endometrial thinning prior to endometrial ablation for dysfunctional uterine bleeding.

**E. Gender Dysphoria**

1. Authorization of 12 months may be granted for pubertal suppression in preparation for gender reassignment in an adolescent member when ALL of the following criteria are met:
  - a. The member has a diagnosis of gender dysphoria
  - b. The member has reached Tanner stage 2 of puberty
2. Authorization of 12 months may be granted for gender reassignment in an adult member when ALL of the following criteria are met:
  - a. The member has a diagnosis of gender dysphoria
  - b. The member will receive Zoladex concomitantly with cross sex hormones

**IV. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**V. REFERENCES**

1. Zoladex 3.6mg [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2016.
2. Zoladex 10.8mg [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2016.
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4. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: breast cancer. Version 3.2017. [http://www.nccn.org/professionals/physician\\_gls/pdf/breast.pdf](http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf). Accessed January 25, 2018.
5. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 2.2017. [http://www.nccn.org/professionals/physician\\_gls/pdf/prostate.pdf](http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf). Accessed November 29, 2017.
6. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869–3903.
7. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
8. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 7th version. ©2012 World Professional Association for Transgender Health. Available at <http://www.wpath.org>.
9. Noguchi S, Kim HJ, Jesena A, et al. Phase 3, open-label, randomized study comparing 3-monthly with monthly goserelin in pre-menopausal women with estrogen receptor-positive advanced breast cancer. *Breast Cancer (Tokyo, Japan)*. 2016;23(5):771-779. doi:10.1007/s12282-015-0637-4.