

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 (Zoladex 3.6 mg strength only)

B. Compendial Uses

- A. Breast cancer
Treatment of premenopausal women with hormone receptor (HR)-positive disease in combination with
 - a. Adjuvant endocrine therapy
 - b. Endocrine therapy for recurrent or metastatic disease
- B. Prostate cancer
 - a. Adjuvant therapy for lymph node-positive disease found during pelvic lymph node dissection (PLND)
 - b. Initial androgen deprivation therapy (ADT) for:
 - i. Intermediate risk group
 - ii. High or very high risk group
 - iii. Regional disease
 - iv. Metastatic disease
 - c. Recurrent disease in patients who experience biochemical failure after previous therapy
 - d. Progressive castration-naïve disease
- C. 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:

- A. Use of the 10.8 mg strength for diagnoses other than prostate cancer and gender dysphoria (if applicable)
- B. For prostate cancer: Use of Zoladex as neoadjuvant therapy prior to radical prostatectomy

III. CRITERIA FOR INITIAL APPROVAL

A. Breast Cancer

- 1. Authorization of 12 months may be granted for the treatment (including palliative treatment) of HR-positive advanced, metastatic, or recurrent breast cancer in a pre- or perimenopausal member.
- 2. Authorization of 12 months may be granted for the adjuvant treatment of HR-positive breast cancer in a pre- or perimenopausal member.

B. Prostate Cancer

- 1. Authorization of 12 months may be granted for treatment of lymph node-positive disease found during pelvic lymph node dissection (PLND) when Zoladex is used as adjuvant therapy.
- 2. Authorization of 12 months may be granted for treatment of prostate cancer with intermediate, high or very high risk stratification when Zoladex is used as initial androgen deprivation therapy (ADT).
- 3. Authorization of 12 months may be granted for treatment of regional or metastatic prostate cancer when Zoladex is used as initial androgen deprivation therapy (ADT).
- 4. Authorization of 12 months may be granted for treatment of recurrent prostate cancer in members who experience biochemical failure after previous therapy.
- 5. Authorization of 12 months may be granted for treatment of progressive castration-naïve prostate cancer.

C. Endometriosis

Authorization of 6 months may be granted for the 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.
3. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed January 9, 2017.
4. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: breast cancer. Version 2.2016. http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 18, 2017.
5. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 3.2016. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed November 9, 2016.
6. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2009;94:3152-3154.
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>.