CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Zoladex (goserelin acetate)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Zoladex, originally approved by the FDA in 1989, is a gonadotropin releasing hormone (GnRH) agonist indicated for the management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy as well as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding.

Zoladex (goserelin acetate) will be considered for coverage when the following criteria are met:

Dysfunctional Uterine Bleeding

For **initial** authorization:
1. Member is premenopausal and 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a gynecologist; AND
3. Member is undergoing endometrial ablation for dysfunctional uterine bleeding; AND
4. Provider attests that member is **NOT** pregnant or breastfeeding.
5. **Dosage allowed/Quantity limit:** Insert one or two depot (3.6 mg per depot) with each depot given four weeks apart prior to endometrial ablation. Quantity Limit: 2 syringes per 28 days.

If all the above requirements are met, the medication will be approved for 28 days.

For **reauthorization**:
1. Zoladex will not be reauthorized.

Endometriosis

For **initial** authorization:
1. Member is premenopausal and 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a gynecologist; AND
3. Member has a diagnosis of endometriosis confirmed by imaging or laparoscopy; AND
4. Member must have documentation of painful symptoms (e.g., pelvic pain, dysmenorrhea, etc.) associated with endometriosis; AND
5. Member has failed a 3-month trial of a hormonal contraceptive; AND
6. Provider attests that member is **NOT** pregnant or breastfeeding.
7. **Dosage allowed/Quantity limit:** Insert 1 implant (3.6 mg) subcutaneously every 28 days. Quantity Limit: 1 syringe per 28 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Zoladex will not be reauthorized.

Breast Cancer or Prostate Cancer

Any request for cancer must be submitted through NantHealth/Eviti portal.

CareSource considers Zoladex (goserelin acetate) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/26/2020	New policy for Zoladex created.
03/11/2024	Updated references; changed benefit from pharmacy to medical. Dysfunctional uterine bleeding: simplified reauthorization statement; added quantity limit Endometriosis: added quantity limit; added that member is not breastfeeding; simplified reauthorization statement; added confirmation by imaging or laparoscopy of endometriosis diagnosis; removed 30-day NSAID trial

References:

1. Zoladex [package insert]. Deerfield, IL: TerSera Therapeutics LLC; 2023.
2. Donnez J, Vilos G, Gannon MJ, et al. Goserelin acetate (Zoladex) plus endometrial ablation for dysfunctional uterine bleeding: a 3-year follow-up evaluation. *Fertil Steril.* 2001;75(3):620-622.
3. Schrager S, Falleroni J, Edgoose J. Evaluation and treatment of endometriosis. *Am Fam Physician.* 2013 Jan 15;87(2):107-13.
4. DiVasta AD, Feldman HA, Sadler Gallagher J, et al. Hormonal Add-Back Therapy for Females Treated With Gonadotropin-Releasing Hormone Agonist for Endometriosis: A Randomized Controlled Trial. *Obstet Gynecol.* 2015;126(3):617-627.
5. Armstrong C. ACOG updates guideline on diagnosis and treatment of endometriosis. *Am Fam Physician.* 2011 Jan 1;83(1):84-85.
6. Becker CM, Bokor A, Heikinheimo O, et al. ESHRE guideline: endometriosis. *Hum Reprod Open*. 2022;2022(2):hoac009. Published 2022 Feb 26. doi:10.1093/hropen/hoac009

Effective date: 10/01/2024
Revised date: 03/20/2024