

PHARMACY POLICY STATEMENT

North Carolina Marketplace

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. <u>Dysfunctional uterine bleeding</u> : simplified reauthorization statement; added quantity limit <u>Endometriosis</u> : 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. Schragger 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

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Revised date: 03/20/2024