



PHARMACY POLICY STATEMENT North Carolina Marketplace

DRUG NAME	Zoladex (goserelin acetate)
BILLING CODE	Must use a valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see “Dosage allowed” below
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Zoladex (goserelin acetate) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CANCER

Any request for **breast cancer** or **prostate cancer** must be submitted through [NantHealth/Eviti](#) portal.

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 will be undergoing endometrial ablation for dysfunctional uterine bleeding; AND
4. Member is **not** pregnant or breastfeeding.
5. **Dosage allowed:** Up to 2 implants (3.6 mg per implant) are allowed per ablation procedure.

If member meets all the requirements listed above, the medication will be approved for 28 days.

For **reauthorization**:

Retreatment is not allowed due to this is a one-time use prior to endometrial ablation.

ENDOMETRIOSIS

For **initial** authorization:

1. Member is premenopausal and 18 years of age or older; AND
2. Member is having painful symptoms (e.g., pelvic pain, dysmenorrhea, etc.) associated with endometriosis (documentation required); AND
3. Medication must be prescribed by or in consultation with a gynecologist; AND
4. Member has tried and failed to control symptoms after trials with **both** of the following, unless not tolerated or contraindicated:
 - a) 30 days of an NSAID;
 - b) 3 months of a hormonal contraceptive; AND
5. Member is **not** pregnant or planning to become pregnant while taking medication.

Qualified Health Plans offered in North Carolina by CareSource North Carolina Co., d/b/a CareSource.



6. **Dosage allowed:** 1 implant (3.6 mg) subcutaneously every 28 days.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

Retreatment will not be authorized due to a lack of clinical data available to support the use of Zoladex beyond 6 months.

CareSource considers Zoladex (goserelin acetate) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
10/26/2020	New policy for Zoladex created.
11/19/2021	Annual review, no changes

References:

1. Zoladex [package insert]. Lake Forest, IL: TerSera Therapeutics LLC; February, 2019.
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.

Effective date: 01/01/2023

Revised date: 11/19/2021