

PHARMACY POLICY STATEMENT	
Georgia Medicaid	
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.
- 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.

Care Source 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.	

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. 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.

Effective date: 04/01/2021 Revised date: 10/26/2020