

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2025 P 2173-7
Program	Prior Authorization/Medical Necessity
Medication	Cetrotide® (cetorelix acetate)*
P&T Approval Date	8/2019, 8/2020, 8/2021, 8/2022, 8/2023, 5/2024, 6/2025
Effective Date	9/1/2025

**1. Background:**

Cetrotide (cetorelix acetate) and ganirelix acetate are synthetic decapeptides with gonadotropin-releasing hormone (GnRH) antagonist activity. These agents are indicated to inhibit premature leuteinizing hormone (LH) surges in women undergoing ovarian stimulation followed by insemination or assisted reproductive technology (ART) procedures.

**2. Coverage Criteria<sup>a</sup>:****A. Ovarian Stimulation**

1. **Cetrotide (cetorelix acetate)\*** will be approved based on **one** of the following criteria:

a. **All** of the following:

(1) Diagnosis of infertility

**-AND-**

(2) **One** of the following exists:

- (a) Unexplained infertility
- (b) Endometriosis
- (c) Male factor infertility
- (d) Tubal factor infertility
- (e) Diminished ovarian reserve
- (f) Uterine factor infertility
- (g) Ovulatory dysfunction
- (h) Recurrent pregnancy loss
- (i) Failure to achieve conception with other treatment modalities

**-AND-**

(3) For the development of one or more follicles (ovarian stimulation)

**-AND-**

(4) Will be used in conjunction only with assisted reproductive technology (ART)

**-AND-**

- (5) History of failure, contraindication, or intolerance to ganirelix acetate (Merck and Co., Inc. and Organon Global Inc. formulations)

**-OR-**

b. **All** of the following:

- (1) Used for fertility preservation

**-AND-**

- (2) The individual will undergo gonadotoxic therapy (e.g., exposure to cytotoxic agents, invasive surgery, prolonged hormonal ovarian suppression, radiation therapy)

**-AND-**

- (3) Will be used as part of an assisted reproductive technology (e.g., in vitro fertilization) procedure

**-AND-**

- (4) History of failure, contraindication, or intolerance to ganirelix acetate (Merck and Co., Inc. and Organon Global Inc. formulations)

**Authorization will be issued for 2 months**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

\*Infertility is typically excluded from coverage. Please refer to plan specifics to determine exclusion status.

### **3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply Limits and/or Step Therapy may also be in place

### **4. References:**

1. Cetrotide [package insert]. Rockland, MA: EMD Serono, Inc.; June 2024.
2. Ganirelix acetate [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; November 2024.
3. Sahakyan M, Harlow BL, Hornstein MD. Influence of age, diagnosis, and cycle number on pregnancy rates with gonadotropin-induced controlled ovarian hyperstimulation and intrauterine insemination. *Fertil Steril* 1999; 72: 500-504.
4. Ganirelix acetate [package insert]. Jersey City, NJ: Organon Global Inc.; February 2024.

Program	Prior Authorization/Medical Necessity - Cetrotide (cetorelix acetate)
<b>Change Control</b>	
8/2019	New program.
8/2020	Annual review with no changes to coverage criteria. Updated formatting.
8/2021	Annual review with no changes to the clinical coverage criteria. Updated background, formatting and references.
8/2022	Annual review. Added Organon Global ganirelix acetate generic as a preferred product. Updated exclusion statements and references.
8/2023	Annual review. Updated background and references.
5/2024	Added coverage criteria for fertility preservation for iatrogenic infertility. Updated term "controlled ovarian stimulation" to "ovarian stimulation".
6/2025	Updated coverage criteria for fertility preservation for iatrogenic infertility to include additional examples of gonadotoxic therapy such as prolonged hormonal ovarian suppression. Updated references.