UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2173-5
Program	Prior Authorization/Medical Necessity
Medication	Cetrotide® (cetrorelix acetate)*
P&T Approval Date	8/2019, 8/2020, 8/2021, 8/2022, 8/2023
Effective Date	11/1/2023

1. Background:

Cetrotide (cetrorelix 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 controlled ovarian stimulation followed by insemination or assisted reproductive technology (ART) procedures.[1-3,5]

2. Coverage Criteria[a]:

A. Controlled Ovarian Stimulation

1. **Cetrotide (cetrorelix acetate)*** will be approved based on **all** of the following criteria**:**

   a. Diagnosis of infertility

   -AND-

   b. **One** of the following exists:

      (1) Unexplained infertility
      (2) Endometriosis
      (3) Male factor infertility
      (4) Tubal factor infertility
      (5) Diminished ovarian reserve
      (6) Uterine factor infertility
      (7) Ovulatory dysfunction
      (8) Recurrent pregnancy loss
      (9) Failure to achieve conception with other treatment modalities

   -AND-

   c. For the development of one or more follicles (controlled ovarian stimulation)

   -AND-

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

   -AND-

   e. 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

[a] 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.; September 2018.
2. Ganirelix acetate [package insert]. Whitehouse Station, NJ: Merck and Co., Inc.; June 2021.
3. Ganirelix acetate [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; June 2021.
4. 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.
5. Ganirelix acetate [package insert]. Jersey City, NJ: Organon Global Inc.; June 2021.

Program	Prior Authorization/Medical Necessity - Cetrotide (cetrorelix acetate)
Change Control	
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.