UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2021 P 1134-8 |
| Program | Prior Authorization/Notification |
| Medication | Cetrotide® (cetrorelix acetate) and ganirelix acetate†* |
| P&T Approval Date | 8/2014, 5/2015, 5/2016, 5/2017, 10/2018, 8/2019, 8/2020, 8/2021 |
| Effective Date | 11/1/2021;<br>Oxford only: N/A |

**1. Background:**

Cetrotide (cetrorelix acetate) and ganirelix acetate are synthetic decapeptides with gonadotropin-releasing hormone (GnRH) antagonist activity. These agents are indicated for the inhibition of premature leutinizing hormone (LH) surges in women undergoing controlled ovarian stimulation.

**2. Coverage Criteria:**

**A. Controlled Ovarian Stimulation**

**1. Cetrotide (cetrorelix acetate)** or **ganirelix 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)

**Authorization will be issued for 2 months**

**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

†Ganirelix acetate (Ferring generic) is excluded from coverage for the majority of our benefits.

*Infertility is typically excluded from coverage for UnitedHealthcare. Please refer to member's specific benefits for coverage determination.

**4. References:**


1. Cetrotide [package insert]. Rockland, MA: EMD Serono, Inc.; May 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.


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|---|---|
| **Change Control** | |
| 8/2014 | New program. |
| 5/2015 | Reduced authorization duration to 2 months to align with gonadotropins and hCG programs. Updated references. |
| 5/2016 | Annual review. Changed fertility criteria to align with other programs. Updated references. |
| 5/2017 | Annual review. No changes to the program. Updated references. |
| 10/2018 | Annual review. No changes to the program. Updated references. |
| 8/2019 | Annual review. Updated program to reflect excluded medications. Updated references. |
| 8/2020 | Annual review with no changes to the clinical coverage criteria. |
| 8/2021 | Annual review with no changes to the clinical coverage criteria. Updated background, formatting and references. |