

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

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| Program Number    | 2021 P 1134-8  |
| Program           | Prior Authorization/Notification                                   |
| Medication        | Cetrotide® (cetorelix acetate) and ganirelix acetate <sup>†*</sup> |
| 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 (cetorelix 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 (cetorelix acetate) or ganirelix acetate<sup>†</sup> 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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| Program               | Prior Authorization/Notification - Cetrotide (cetorelix acetate) and ganirelix acetate                          |
| <b>Change Control</b> |   |
| 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. |