



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 3125-5
Program	Step Therapy
Medication/Therapeutic Class	Cetrotide® (cetorelix acetate)*
P&T Approval Date	8/1/2019, 8/2020, 8/2021, 8/2022, 8/2023
Effective Date	11/1/2023

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires members to use ganirelix acetate (Merck and Co., Inc. and Organon Global, Inc. formulations) before providing coverage for Cetrotide.

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 controlled ovarian stimulation followed by insemination or assisted reproductive technology (ART) procedures.^{1-3,5}

Members continuing and new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria^a:

<p>A. Cetrotide* will be approved based on the following criterion:</p> <ol style="list-style-type: none">1. History of failure, contraindication, or intolerance to ganirelix acetate (Merck and Co., Inc. and Organon Global Inc. formulations) <p>Authorization will be issued for 2 months.</p> <p>^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.</p>

*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 Notification 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	Step Therapy - Cetrotide® (cetorelix acetate)*
Change Control	
8/2019	New program
8/2020	Annual review with no change to coverage criteria. Updated background and formatting.
8/2021	Annual review with no change to coverage criteria. Updated 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 references.