POLICY Document for ganirelix acetate

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
GONADOTROPIN RELEASING HORMONE ANTAGONISTS

PREFERRED PRODUCT: CETROTIDE, GANIRELIX ACETATE

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the gonadotropin releasing hormone agonist products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Gonadotropin releasing hormone antagonists

	Product(s)
Preferred*	• **Cetrotide** (cetrorelix acetate) • **ganirelix acetate** (generic for Fyremadel)
Targeted	• **cetrorelix acetate** (generic for Cetrotide) • **Fyremadel** (ganirelix acetate)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

A. Cetrorelix acetate

Coverage for the targeted product is provided when the member has had a documented inadequate response, contraindication, or intolerable adverse event to Cetrotide.

B. Fyremadel
Coverage for the targeted product is provided when the member has had a documented inadequate response, contraindication, or intolerable adverse event to ganirelix acetate.

Section 2: Clinical Criteria

Specialty Guideline Management cetrorelix-Cetrotide-Fyremadel-Ganirelix

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Cetrotide	cetrorelix acetate
Fyremadel	ganirelix acetate

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1-4]

Cetrotide, Fyremadel, cetrorelix, and ganirelix are indicated for the inhibition of premature luteinizing hormone (LH) surges in women undergoing controlled ovarian stimulation.

All other indications are considered experimental/investigational and not medically necessary.

Medical Benefit Alignment

Specialty Guideline Management coverage review will be bypassed for drug(s) being requested for a procedure that has been approved under a member's medical benefit plan. Such members will be

exempt from the requirements in the coverage criteria section. A medical authorization number and confirmation of the approved procedure(s) will be required.

NOTE: Some plans may opt-out of medical benefit alignment. Members receiving coverage under such plans must meet the requirements in the coverage criteria section.

Coverage Criteria

Inhibition of premature luteinizing hormone (LH) surges[1-4]

Authorization of 12 months may be granted for the inhibition of premature LH surges in members undergoing ovulation induction or assisted reproductive technology (ART).

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

REFERENCES:

SECTION 1

1. Cetrotide [package insert]. Rockland, MA: EMD Serono, Inc.; June 2024.
2. cetrorelix acetate [package insert]. Rockland, MA: EMD Serono, Inc.; May 2024.
3. Fyremadel [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2020.
4. Ganirelix acetate [package insert]. Rockland, MA: EMD Serono, Inc.; November 2023.

SECTION 2

1. Cetrotide [package insert]. Rockland, MA: EMD Serono; December 2023.
2. Fyremadel [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; October 2023.
3. Ganirelix [package insert]. Jersey City, NJ: Organon USA LLC; February 2024.
4. Cetrorelix [package insert]. Parsippany, NJ: Teva Pharmaceuticals; March 2024.
5. Bakas P, Konidaris S, Liapis A, et al. Role of gonadotropin-releasing hormone antagonist in the management of subfertile couples with intrauterine insemination and controlled ovarian stimulation. Fertil Steril. 2011;95:2024-2028.