PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Infertility – Gonadotropin-Releasing Hormone Antagonists Preferred Specialty Management Policy

- Cetrotide® (cetrorelix acetate subcutaneous injection – EMD Serono, brand only)
- Ganirelix (ganirelix acetate subcutaneous injection – Organon, generic)
- Fyremadel® (ganirelix acetate subcutaneous injection – Ferring, generic only)

REVIEW DATE: 9/6/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Cetrotide (brand only), Ganirelix (brand and generic), and Fyremadel (generic only) are indicated for the **inhibition of premature luteinizing hormone** (LH) surges in women undergoing controlled ovarian stimulation.[1-3]

Cetrotide, Ganirelix, and Fyremadel are synthetic decapeptides that are analogs of native gonadotropin-releasing hormone (GnRH) with GnRH antagonist activity.[1-3] GnRH induces the production and release of LH and follicle stimulating hormone (FSH) from the anterior pituitary. Both agents compete with natural GnRH for binding to membrane receptors on pituitary cells and control the release of LH and FSH in a reversible manner.

POLICY STATEMENT

Utilization of these products for infertility is not managed by a *Prior Authorization Policy*, but rather based on whether a patient's benefit includes infertility coverage. If the patient's benefit includes infertility coverage, this Preferred Specialty Management program has been developed to encourage the use of a Preferred Product. The program directs the patient to try one Preferred Product prior to the approval of a Non-Preferred Product. Requests for a Non-Preferred Product will be reviewed using the exception criteria (below). All approvals are provided for the duration noted below.

If the patient's benefit does not include infertility coverage, benefit exclusion overrides may be in place for indications other than infertility. This Preferred Specialty Management program requires the patient to meet the standard *Infertility – Gonadotropin-Releasing Hormone Antagonists Benefit Exclusion Overrides Policy* criteria and requires the patient to try a Preferred Product, when clinically appropriate, prior to the approval of a Non-Preferred Product. Patient meeting the standard *Infertility – Gonadotropin-Releasing Hormone Antagonists Benefit Exclusion Overrides Policy* criteria who have not tried a Preferred Product will receive authorization for a Preferred Product, if clinically appropriate.

If the patient's benefit does not include infertility coverage and benefit exclusion overrides are not utilized, coverage is not reviewable.

Preferred Product: Cetrotide, generic Fyremadel
Non-Preferred Product: Ganirelix (brand and generic)

Infertility – Gonadotropin-Releasing Hormone Antagonists non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Ganirelix (brand and generic)	**1.** If patient's benefit includes infertility coverage, approve for 1 year if patient has tried one of Cetrotide or generic Fyremadel. **2.** If patient's benefit does NOT include infertility coverage and benefit exclusion overrides ARE utilized, approve for 1 year if patient meets the following criteria (A and B): **A)** The patient meets the standard *Infertility – Gonadotropin-Releasing Hormone Antagonists Benefit Exclusion Overrides Policy* criteria; AND **B)** The patient has tried one of Cetrotide or generic Fyremadel. **3.** If the patient has met exception criterion 2A, but has not tried a Preferred Product, approve Cetrotide and generic Fyremadel for 1 year.

	4. If patient's benefit does NOT include infertility coverage and benefit exclusion overrides are NOT utilized: not reviewable.

References

1. Cetrotide subcutaneous injection [prescribing information]. Rockland, MA: EMD Serono; May 2018.
2. Ganirelix acetate subcutaneous injection [prescribing information]. Parsippany, NJ: Ferring; June 2021.
3. Fyremadel® (ganirelix acetate subcutaneous injection) [prescribing information]. Parsippany, NJ; Ferring; January 2022.

History

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Generic Fyremadel:** Generic Fyremadel was added to the list of Preferred Products. **Generic Ganirelix:** Generic Ganirelix was added to the list of Non-Preferred Products.	09/07/2022
Annual Revision	No criteria changes.	09/06/2023

"Cigna Companies" refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. © 2023 Cigna