

PREFERRED SPECIALTY MANAGEMENT POLICY

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

- Cetrotide® (cetrotirelix acetate for injection – EMD Serono, Inc.)
- Ganirelix acetate injection (generics)

REVIEW DATE: 09/02/2020

OVERVIEW

Cetrotide and ganirelix are indicated for the inhibition of premature luteinizing hormone (LH) surges in women undergoing controlled ovarian stimulation.^{1,2}

Cetrotide and Ganirelix are synthetic decapeptides that are analogs of native gonadotropin-releasing hormone (GnRH) with GnRH antagonist activity.^{1,2} 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

Currently, utilization of these products is not managed by a Prior Authorization (PA) 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 the Preferred Product. The program direct the patient to try the Preferred Product prior to the approval of the Non-Preferred Product. Requests for the 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. This PSM program requires the patient to meet ESI Standard *Infertility – Gonadotropin-Releasing Hormone Antagonists Benefit Exclusion Overrides* criteria and requires the patient to try the preferred product, when clinically appropriate, prior to the approval of the non-preferred product. Patient meeting the ESI Standard *Infertility – Gonadotropin-Releasing Hormone Antagonists Benefit Exclusion Overrides* criteria who have not tried the preferred product will receive authorization for the preferred product, if clinically appropriate.

If the patient's benefit does not include infertility coverage and benefit exclusion overrides are not utilized, coverage will be denied.

Automation: A patient with a history of one preferred product within the 130-day look-back period is excluded from this program.

Preferred Product: Cetrotide

Non-Preferred Product: Ganirelix

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Ganirelix	1. If patient's benefit includes infertility coverage, approve for 1 year if patient has tried Cetrotide.

	<ol style="list-style-type: none">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):<ol style="list-style-type: none">A) The patient meets the ESI Standard <i>Infertility – Gonadotropin-Releasing Hormone Antagonists Benefit Exclusion Overrides</i> criteria; ANDB) The patient has tried Cetrotide.3. If the patient has met exception criterion 2A, but has not tried the preferred product, approve Cetrotide for 1 year.4. If patient’s benefit does NOT include infertility coverage and benefit exclusion overrides are NOT utilized: not reviewable.
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REFERENCES

1. Cetrotide [prescribing information]. Rockland, MA: EMD Serono, Inc.; May 2018.
2. Ganirelix acetate injection [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals Inc; March 2019.
3. Infertility – Gonadotropin-Releasing Hormone (GnRH) Antagonists Benefit Exclusion Overrides Policy. Express Scripts, Inc. Updated 09/02/2020.