



CIGNA PHARMACY COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject **Ganirelix**

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Hyperlink to Related Coverage Policies

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), 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 participant'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 participant's benefit plan document **always supercedes** 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 group 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. Proprietary information of CIGNA. Copyright ©2009 CIGNA

Coverage Policy

Note: Injectable fertility medications are specifically excluded under most benefit plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage.

If coverage is available for injectable fertility medications, then:

CIGNA covers ganirelix as medically necessary for the inhibition of premature luteinizing hormone (LH) surges in females undergoing controlled ovarian stimulation (COS) in conjunction with assisted reproductive procedures.

General Background

FDA Approved Indications

Ganirelix Acetate Injection is indicated for the inhibition of premature LH surges in women undergoing controlled ovarian hyperstimulation.

FDA Recommended Dosing

After initiating FSH therapy on Day 2 or 3 of the cycle, Ganirelix Acetate Injection 250 µg may be administered subcutaneously once daily during the mid to late portion of the follicular phase. By taking advantage of endogenous pituitary FSH secretion, the requirement for exogenously administered FSH may be reduced.

Treatment with Ganirelix Acetate should be continued daily until the day of hCG administration. When a sufficient number of follicles of adequate size are present, as assessed by ultrasound, final maturation of follicles is induced by administering hCG. The administration of hCG should be withheld in cases where the ovaries are abnormally enlarged on the last day of FSH therapy to reduce the chance of developing OHSS (Ovarian Hyperstimulation Syndrome).

Ganirelix is a gonadotropin-releasing hormone (GnRH) antagonist indicated for the prevention of premature luteinizing hormone (LH) surges in subfertile women undergoing controlled ovarian stimulation (COS) in conjunction with assisted reproductive procedures. Ganirelix is a synthetic decapeptide GnRH antagonist which competitively blocks GnRH receptors. Ganirelix competes with endogenous GnRH for receptor binding sites on gonadotropic cells of the pituitary. Binding of ganirelix to the receptor suppresses the release of the gonadotropins LH and follicle stimulating hormone (FSH), key regulatory hormones that govern ovarian growth and follicular development. The effects of ganirelix on gonadotropins are reversible. When administered subcutaneously, peak concentrations are reached within one hour, with an absolute bioavailability of 91.1%. The mean terminal half-life ranges from 13–16 hours. Ganirelix is hepatically metabolized to two primary metabolites, with elimination occurring primarily through the bile and, to a lesser extent, through the urine.

The efficacy of ganirelix in the treatment of COS was established in nine published trials. Ganirelix 0.25 mg/day was demonstrated to prevent LH surges and have the best clinical outcomes. Ganirelix shortened the median treatment duration by 18–21 days, reduced the amount of FSH used, and avoided the initial flare of LH that is observed with GnRH agonist therapy. A trend toward decreased pregnancy rates was seen with ganirelix compared to GnRH agonist therapy. Ongoing pregnancy rates were 20–31% for ganirelix patients and 26–36% for patients receiving GnRH agonist therapy.

Ganirelix is well-tolerated. The most frequent adverse events include headache, abdominal pain, nausea, vaginal bleeding, and local injection site reactions. The most severe complication of ganirelix is ovarian hyperstimulation syndrome (OHSS), which occurred in approximately 2% of patients in clinical trials with ganirelix. The majority of women had mild-to-moderate forms, and only 1–2% of cases were considered severe. The incidence of OHSS is similar between ganirelix and GnRH agonists.

No formal drug interaction studies have been conducted with ganirelix. Ganirelix use is contraindicated in women who: are allergic to ganirelix acetate or any of its components; are allergic to GnRH or any other GnRH analogs; or are pregnant or think they are pregnant.

Ganirelix safely and effectively inhibits LH surges in women undergoing COS. The advantage of ganirelix over GnRH agonists is a flexible therapy with a shorter treatment option. A small but consistent trend in decreased pregnancy rates occurs with GnRH antagonists compared with GnRH agonists.

Coding/Billing Information

Note: This section is not in use.

*Current Procedural Terminology (CPT®) ©2008 American Medical Association: Chicago, IL.

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