



Prior Authorization Approval Criteria

Cetrotide (cetrotirelix acetate)

Generic name:	Cetrotirelix acetate
Brand name:	Cetrotide
Medication class:	Infertility drug
FDA-approved use:	Inhibits premature luteinizing hormone (LH) surges in women undergoing controlled ovarian hyperstimulation (COH).
Available dosage form:	0.25 mg and 3 mg sterile, lyophilized powder for reconstitution for SC
Usual dose range:	Multiple-dose: 0.25 mg SC once daily during the mid to late portion of the follicular phase after initiating FSH on day 2 or 3 of cycle, continue until hCG is administered Single-dose: 3 mg SC when serum estradiol levels show appropriate stimulation response, usually stimulation day 7 (range days 5-9). If hCG is not administered within 4 days, continue cetrotirelix at 0.25 mg/day until hCG is administered
Duration of therapy:	Usually 1 to 6 days

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- Patients undergoing COH for in vitro fertilization (IVF), for whom physician recommended ART
- Infertile women with regular menstrual cycles (25-35 days in length)
- Screening follicular phase FSH levels within normal limits
- A transvaginal ultrasound reveals no clinically significant abnormal findings

Criteria for continuation of therapy:

Must be approved for ensuing cycle(s) of IVF or COH.

Cautions:

- Cetrotirelix should only be used by physicians who are thoroughly familiar with infertility problems
- Possibility of anaphylactic reaction
- Use caution in women with active allergic conditions or a history of allergies;
- Pregnancy must be excluded before starting medication

Monitoring:

- Ultrasound to assess follicle's size
- WBC, LFT's

Contraindications:

- Known hypersensitivity to cetorelix or any component of the formulation
- Known hypersensitivity to extrinsic peptide hormones, mannitol, gonadotropin releasing hormone (GnRH) or GnRH analogs
- Known or suspected pregnancy, and lactation
- Severe renal impairment

Not approved if:

- Prescribed by anyone other than an infertility specialist
- Patients aged 65 or over
- Patients with polycystic ovary syndrome (PCOS)
- Patients with low or no ovarian reserve
- Patients with stage III-IV endometriosis
- More than four cycles

Special considerations: The pharmacokinetics of medications have been not studied in the hepatically impaired patients

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 3/15/06