



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: Leuprolide; Nafarelin; Triptorelin

Brand Name: Lupron 2-week Kit®, Synarel®, Trelstar®

Medication Class: Synthetic gonadotropin-releasing hormones used in infertility

FDA Approved Uses: Investigational use as part of the *in vitro fertilization* (IVF) programs for patients with infertility

Available Dosage Forms:

- Leuprolide: sterile, aqueous solution for SC
- Nafarelin: sterile, solution for reconstitution for intranasal spray
- Triptorelin: sterile, lyophilized powder for reconstitution for SC

Usual Dose:

- Leuprolide: 0.5 mg sc daily
- Nafarelin: 1 spray (200 mcg) in 1 nostril each morning and evening
- Triptorelin: 0.2 mg sc daily

Duration of Therapy: Depend on the success or failure of IVF. Usually, 2 weeks

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

- Patients undergoing IVF, whom physician recommended to use GnRH analog
- Patients aged > 18 and < 65 for infertility use
- Infertile patients with regular menstrual cycles (25-35 days in length)
- No relevant systemic disease or uterine and ovarian abnormalities
- No more than three previous IVF cycles
- No previous cycle with a poor response or ovarian hyperstimulation syndrome
- Negative pregnant test

Criteria for Continuation of Therapy: Must be approved for ensuing cycle(s) of IVF

Cautions:

- Should only be used by physicians who are thoroughly familiar with infertility problems
- Possibility of anaphylactic reaction
- Possibility of experiencing a temporary increase in bone pain (transient increases in testosterone) (for male only?)
- Possibility of spinal cord compression
- Possibility of presenting as sudden headache, vomiting, visual or mental status changes, and infrequently cardiovascular collapse
- Use caution in patients with active allergic conditions or a history of allergies
- Pregnancy must be excluded before starting medication



Monitoring:

- Ultrasound to assess follicle's size
- Bone mineral density
- Serum levels of testosterone and prostate-specific antigen (for male only?)

Contraindications:

- Known hypersensitivity to any component of the formulation
- Known hypersensitivity to gonadotropin releasing hormone (GnRH) or GnRH analogs
- Undiagnosed abnormal vaginal bleeding
- Known or suspected pregnancy, and lactation

Not Approved if:

- Prescribed by anyone other than an infertility specialist
- Patients aged < 18 or aged ≥ 65 for infertility use
- Patients with severe systemic disease
- Patients with low or no ovarian reserve

Special Considerations: Medications can be started at day 2 or day 21 of the cycle, and should be stopped 3 days before embryo implantation.

P&T Approval: _____ Date: _____