



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: Lutropin alpha

Brand Name: Luveris

Medication Class: recombinant human luteinizing hormone

FDA Approved Uses: Stimulation of follicular development in infertile hypogonadotropic hypogonadal (HH) women with profound luteinizing hormone (LH) deficiency (LH <1.2 IU/L); to be used in combination with Gonal-F

Usual Dose: 75 units SC daily; to be used concomitantly with Gonal-F

Duration of Therapy: until adequate follicular development is noted; normal maximum duration of treatment: 14 days

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

- Must be female
- Must be undergoing follicular stimulation in the treatment of infertility
- Must have profound luteinizing hormone (LH) deficiency (LH < 1.2 IU/L)
- Must be prescribed by a prescriber experienced in fertility treatment
- Being used concomitantly with Gonal-F as two separate injections (safety and effectiveness of concomitant Luveris and any other recombinant human FSH or urinary human FSH is unknown)
- Contraindicated in patients with prior sensitivity to other hLH preparations, primary ovarian failure, uncontrolled thyroid or adrenal dysfunction, uncontrolled organic intracranial lesion such as pituitary tumor, abnormal uterine bleeding of undetermined origin, ovarian cyst or enlargement of undetermined origin, sex hormone dependent tumors of reproductive tract and accessory organs, pregnancy.

Not Approved if:

- Patient has any contraindication to the use of Luveris
- Patient does not meet the above criteria

Monitoring:

- Prior to therapy: Baseline LH <1.2 int. units/L, FSH <5 int. units/L, negative progestin challenge test
- During therapy: Signs and symptoms of OHSS, ovarian enlargement; follicular development (ultrasound, serum estradiol levels); ovulation (basal body temperature, serum progesterone, menstruation, sonographic evidence)

P&T Approval: _____ Date: _____

