Description:

Luveris® (lutropin alfa for injection) is a sterile lyophilized powder composed of recombinant human luteinizing hormone, r-hLH. r-hLH is a heterodimeric glycoprotein consisting of two non-covalently linked subunits (designated α and β) of 92 and 121 amino acids, respectively. The carbohydrate chain attachment to the r-hLH protein core occurs via N- but not O-linkage. The N-glycosylation sites are Asn-52 and Asn-78 for the α–subunit and Asn-30 for the β–subunit. The β-chain has an N-glycosylation site and its structure and glycosylation pattern are very similar to that of pituitary-derived hLH.

Covered Indications:

Luveris® (lutropin alfa for injection) is indicated for stimulation of follicular development in infertile hypogonadotropic hypogonadal women with profound LH deficiency (LH < 1.2 IU/L) and not due to primary ovarian failure who have not responded to adequate clomiphene citrate therapy

1) Non-in vitro fertilization (IVF) fertility (Natural methods only)

Reasons for Prior Authorization:

☐ Cost
☐ Potential for misuse
☐ Toxicity
☒ Prevention of use for infertility- via in vitro fertilization

Criteria for Approval:

1) Diagnosis is an FDA-labeled indication and
2) Patient has profound LH Deficiency
3) Patient has a negative progestin challenge test
4) Prescribed by an Endocrinologist or Obstetrician/Gynecologist
5) Patient is 21 years of age or older
6) Patient does not have any contraindications to use (see below)

Reasons for Denial of Benefit:

1) Patient does not meet Criteria for Approval
2) Patient has any of the following contraindications
   a) Pregnancy or lactation
   b) Undiagnosed abnormal vaginal bleeding
   c) Ovarian cysts or enlargement not due to polycystic ovary syndrome
   d) Sex hormone dependent tumors of the reproductive tract and accessory organs
3) Patient has not had adequate trial of Clomiphene citrate therapy
4) Patient is planning pregnancy via in vitro fertilization
5) Patient has already had a trial of an ovulation induction medication in the last 12 months.
6) hypersensitivity to hLH preparations or one of their excipients

Benefit Approval:

1) Non-IVF pregnancy; 4-cycles per calendar year (4 months);

Limited to one ovulation induction medication per year.

Notes:

1) This medication will not be approved for purposes of IVF fertility

References:

1. Package insert, Luveris® Rockland, MA 02370