

Prior Authorization DRUG Guidelines

LUVERIS (Lutropin alfa)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Catherine Sanders, MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20,

2/2/21, 2/1/22, 1/31/23, 2/13/24, Archived 1/2/25

NOTE: NOT AVAILABLE IN THE U.S.

Luveris is a gonadotropin, ovulation stimulator. It is a recombinant luteinizing hormone prepared using Chinese hamster cell ovaries. Administration leads to increased follicular estradiol secretion needed for follicle stimulating hormone induced follicular development.

Pre-Authorization Criteria:

Luveris is used for stimulation of follicular development in infertile hypogonadotropic hypogonadal (HH) women with profound luteinizing hormone (LH) deficiency (<1.2 units/L). It is to be used in combination with follitropin alfa.

VCHCP requires that Luveris be prescribed by an infertility specialist.

Dosing: Adult:

Infertility: Females: SubQ: 75 units daily until adequate follicular development is noted; maximum duration of treatment: 14 days, unless signs of imminent follicular development are present; to be used concomitantly with follitropin alfa. Once adequate follicular development is evident, administer hCG to induce final follicular maturation in preparation for oocyte retrieval. Withhold hCG if the ovaries are abnormally enlarged.

Dosing Pediatric:

Pediatric dosing is not available or not applicable to this drug.

Dosing: Renal Impairment:

No dosage adjustment provided in manufacturer's labeling (has not been studied).

Dosing: Hepatic Impairment:

No dosage adjustment provided in manufacturer's labeling (has not been studied).

Generic Equivalent Available: U.S.-May be product dependent

Administration:

SubQ: Administer on the stomach, a few inches above or below the navel. Do not shake solution; allow any bubbles to settle prior to administration.

Adverse Reactions:

Headache, fatigue, ovarian hyperstimulation, breast pain, dysmenorrheal, ovarian disorder, nausea, constipation, diarrhea, thromboembolism.

Contraindications:

Hypersensitivity to lutropin alfa or any component of the formulation; primary ovarian failure; uncontrolled thyroid or adrenal dysfunction; uncontrolled organic intracranial lesion (eg, pituitary tumor); abnormal uterine bleeding of undetermined origin; ovarian cyst or enlargement of undetermined origin; sex hormone-dependent tumors of the reproductive tract and accessory organs; pregnancy

References:

1. <u>www.uptodate.com</u>: Lutropin alfa: Drug Information

REVISION HISTORY:

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD

Date Approved by P&T Committee: 1/27/15

Date Reviewed/No Updates: 1/26/16 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/26/16

Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/24/17

Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/23/18

Date Reviewed/No Updates: 1/22/19 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/22/19

Date Reviewed/No Updates: 2/18/20 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 2/18/20

Date Reviewed/No Updates: 2/2/21 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 2/2/21

Date Reviewed/No Updates: 2/1/22 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 2/1/22

Date Reviewed/No Updates: 1/31/23 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/31/23

Date Reviewed/No Updates: 2/13/24 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 2/13/24.

Date Reviewed/Updated: 2/18/25 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 2/18/25

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
2/18/20	No	Howard Taekman, MD; Robert Sterling, MD	Annual review

2/2/21	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
1/31/23	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/13/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Added note "NOT
			AVAILABLE IN
			THE US"