VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

GANIRELIX ACETATE (Orgalutran)

Effective Date: 1/28/14
Date Developed: 1/28/14 by Catherine Sanders, MD
Last Approval Date: 1/26/16, 1/24/17, 1/22/19, 2/18/20
(Archived: 1/1/18)
Unarchived Date: 1/22/19 (Formulary Exclusion – For Exception Review Use Only)

Ganirelix Acetate is a gonadotropin releasing hormone antagonist which competitively blocks the gonadotropin-release hormone receptors on the pituitary gonadotroph and transduction pathway. This suppresses gonadotropin secretion and luteinizing hormone secretion preventing ovulation until the follicles are of adequate size.

Pre-Authorization Criteria: Ganirelix is used to inhibit premature luteinizing hormone (LH) surges in non-pregnant women without primary ovarian failure who will undergo controlled ovarian hyper-stimulation.

NOTE: must be prescribed by an infertility specialist.

Dosing: Adult:
Adjunct to controlled ovarian hyperstimulation: SubQ: 250 mcg/day during the mid-to-late phase after initiating follicle-stimulating hormone on day 2 or 3 of cycle. Treatment should be continued daily until the day of chorionic gonadotropin administration.

Dosing: Pediatric:
Pediatric dosing is currently unabailable or not applicable for this drug.

Dosing: Geriatric:
Refer to adult dosing.

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).

Dosage Forms: U.S.:
Excipient information presented when available (limited, particularly for generics); consult specific product labeling.
Solution, Subcutaneous, as acetate:
Generic: 250 mcg/0.5 mL (0.5 mL)

Generic Equivalent Available: U.S.-Yes

Administration:
Administer SubQ in abdomen (around upper navel) or upper thigh; rotate injection site.

Hazardous agent; use appropriate precautions for handling and disposal (NIOSH, 2012).

Adverse Reactions:
Anaphylactoid reaction, fetal harm or death, ovarian hyperstimulation syndrome, abdominal pain, nausea, pelvic pain, vaginal bleeding, loac injection site reaction, headache, neutrophils increased.

References:

1. National Institute for Occupational Safety and Health (NIOSH), "NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012." Available at http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf. Accessed January 21, 2013.
2. www.uptodate.com: Ganirelix: Drug Information.
3. www.epocrates.com: ganirelix acetate Drug information.

REVISION HISTORY:

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD
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Date Reviewed/No Updates: 2/18/20 by H. Taekman, MD; R. Sterling, MD
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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/1/18	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – excluded from the Formulary effective 1/1/18
1/22/19	Yes	Catherine Sanders, MD; Robert Sterling, MD	Unarchived – Formulary Exclusion – For Exception Review Use Only

			Annual Review
2/18/20	No	Howard Taekman, MD; Robert Sterling, MD	Annual review