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, 2/2/21, 2/1/22, 1/31/23, 2/13/24, 2/18/25

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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 patients undergoing 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.
NOTE: Administer SubQ in abdomen (around upper navel) or upper thigh; rotate injection site.
NOTE: **Hazardous Drugs Handling** Considerations (**NIOSH 2016 [group 3**]). Double gloves and a protective gown are required during administration.

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~~ local 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. Ganirelix acetate injection [prescribing information]. Jersey City, NJ: Organon USA LLC; August 2023.
3. Bonduelle M, Oberyé J, Mannaerts B, Devroey P. Large prospective, pregnancy and infant follow-up trial assures the health of 1000 fetuses conceived after treatment with the GnRH antagonist ganirelix during controlled ovarian stimulation. Hum Reprod. 2010;25(6):1433-1440.

4. Boerrigter PJ, de Bie JJ, Mannaerts BM, van Leeuwen BP, Passier-Timmermans DP. Obstetrical and neonatal outcome after controlled ovarian stimulation for IVF using the GnRH antagonist ganirelix. Hum Reprod. 2002;17(8):2027-2034.

REVISION HISTORY:

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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
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2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Modified preauthorization criteria. Updated dosing information and references.