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Prior Authorization DRUG Guidelines

**OVIDREL**

**(Recombinant human chorionic gonadotropin)**

Effective Date: 7/28/05

Date Developed: 7/14/05 by C. Wilhelmy MD

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

Ovidrel is a Gonadotropin Ovulation Stimulator. It is a luteinizing hormone analogue produced by recombinant DNA techniques; stimulates rupture of the ovarian follicle once follicular development has occurred.

**Pre-Authorization Criteria:**

Ovidrel is used as part of an assisted reproductive technology (ART) program, induces ovulation in infertile females who have been pretreated with follicle stimulating hormones (FSH); induces ovulation and pregnancy in infertile females when the cause of infertility is functional.

VCHCP requires that Ovidrel be prescribed by an infertility specialist.

**MONITORING PARAMETERS** — Ultrasound and/or estradiol levels to assess follicle development; ultrasound to assess number and size of follicles; ovulation (basal body temperature, serum progesterone level, menstruation, sonography).

**DOSING: ADULTS** — Assisted reproductive technologies (ART) and ovulation induction in females: SubQ: 250 mcg given 1 day following the last dose of follicle stimulating agent. Use only after adequate follicular development has been determined.

**DOSING: ELDERLY** — Safety and efficacy have not been established.

**DOSING: RENAL IMPAIRMENT** — Safety and efficacy have not been established.

**DOSING: HEPATIC IMPAIRMENT** — Safety and efficacy have not been established.

**GENERAL INFORMATION**-- Preferred gonadotropins include: Gonal-F and Bravelle

## DOSAGE FORMS

Injection, powder for reconstitution: 285 mcg [packaged with 1 mL SWFI; delivers 250 mcg r-hCG following reconstitution] [DSC]

Injection, solution: 257.5 mcg/0.515 mL (0.515 mL) [prefilled syringe; delivers 250 mcg r-hCG/0.5 mL]

**CONTRAINDICATIONS** — Hypersensitivity to hCG preparations or any component of the formulation; primary ovarian failure; uncontrolled thyroid or adrenal dysfunction; uncontrolled organic intracranial lesion (ie, pituitary tumor); abnormal uterine bleeding, ovarian cyst or enlargement of undetermined origin; sex hormone dependent tumors; pregnancy

**WARNINGS / PRECAUTIONS** — For use by infertility specialists; may cause ovarian hyperstimulation syndrome (OHSS); if severe, treatment should be discontinued and patient should be hospitalized. OHSS results in a rapid (<24 hours to 7 days) accumulation of fluid in the peritoneal cavity, thorax, and possibly the pericardium, which may become more severe if pregnancy occurs; monitor for ovarian enlargement; use may lead to multiple births; risk of arterial thromboembolism with hCG products; safety and efficacy in pediatric and geriatric patients have not been established.

**PREGNANCY RISK FACTOR** — X

**PREGNANCY IMPLICATIONS** — Ectopic pregnancy, premature labor, postpartum fever, and spontaneous abortion have been reported in clinical trials. Congenital abnormalities have also been observed, however, the incidence is similar during natural conception.

**LACTATION** — Excretion in breast milk unknown/use caution

**PATIENT EDUCATION** — Instructions will be given on how to administer SubQ injections and proper disposal of syringes and needles. Use exactly as instructed by prescriber. Keep all ultrasound appointments. Report sudden weight gain, severe pelvic pain, nausea, vomiting, or shortness of breath to prescriber. Do not take if pregnant. As with other hCG products, there is a risk of multiple births associated with treatment. Avoid strenuous exercise, especially those with pelvic involvement.

## References:

1. MICROMEDEX,. <http://www.thomsonhc.com/>. Accessed June 2010.

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1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
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