

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, 2/2/21, 8/3/21, 2/1/22, 1/31/23

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.

NOTE: 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 progestin 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.

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

DOSAGE FORMS

Subcutaneous solution: 250 mcg/0.5 mL (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

PRECAUTIONS — May-cause ovarian hyperstimulation syndrome (OHSS: sudden weight gain, pelvic pain, nausea, vomiting, or shortness of breath); if severe, treatment should be discontinued and patient should be hospitalized. OHSS may result 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 IMPLICATIONS — Do not take if pregnant. 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. Report sudden weight gain, severe pelvic pain, nausea, vomiting, or shortness of breath to prescriber. 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.
- 2. Corbett S, Shmorgun D, Claman P, et al; Reproductive Endocrinology Infertility Committee. The prevention of ovarian hyperstimulation syndrome. J Obstet Gynaecol Can. 2014;36(11):1024-1033. doi: 10.1016/S1701-2163(15)30417-5
- 3. Ovidrel (choriogonadotropin alfa) [prescribing information]. Rockland, MA: Serono; June 2018.
- 4. The Practice Committee of the American Society for Reproductive Medicine, Birmingham, Alabama (November 2008). "Gonadotropin preparations: past, present, and future perspectives". *Fertility and Sterility*. **90** (5 Suppl): S13–20.
- Cole, Laurence A (2010-08-24). <u>"Biological functions of hCG and hCG-related</u> <u>molecules"</u>. *Reproductive Biology and Endocrinology*. 8: 102. <u>doi:10.1186/1477-7827-8-102</u>

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2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
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