



CIGNA PHARMACY COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Choriogonadotropin Alfa (Ovidrel®)**

Effective Date 12/15/2008
Next Review Date.....3/15/2010
Coverage Policy Number 7002

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Hyperlink to Related Coverage Policies

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

Coverage Policy

Note: Injectable fertility medications are specifically excluded under most benefit plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage.

If coverage is available for injectable fertility medications, then:

CIGNA covers choriogonadotropin alfa as medically necessary for use in female patients in combination with ovulation stimulation therapy when EITHER of the following criteria is met:

- as part of Assisted Reproductive Technology (ART) program
- anovulatory infertile patients in whom the cause of anovulation is secondary and not due to primary ovarian failure

General Background

FDA Approved Indications

Ovidrel® preFilled syringe (choriogonadotropin alfa injection) is indicated for the induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been appropriately pretreated with follicle stimulating hormones as part of an Assisted Reproductive Technology

(ART) program such as in vitro fertilization and embryo transfer. Ovidrel® PreFilled Syringe is also indicated for the induction of ovulation (OI) and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure.

FDA Recommended Dosing

Ovidrel is for subcutaneous use only. For infertile women undergoing Assisted Reproductive Technologies (ART), Ovidrel® PreFilled Syringe 250 µg should be administered one day following the last dose of the follicle stimulating agent. Ovidrel® PreFilled Syringe should not be administered until adequate follicular development is indicated by serum estradiol and vaginal ultrasonography. Administration should be withheld in situations where there is an excessive ovarian response, as evidenced by clinically significant ovarian enlargement or excessive estradiol production.

Choriogonadotropin alfa is a recombinant DNA-derived form of human chorionic gonadotropin (hCG), which is a gonad-stimulating polypeptide hormone secreted by the placenta. The action of hCG is virtually identical to that of pituitary LH (luteinizing hormone), although hCG appears to have a small degree of FSH (follicle-stimulating hormone) activity as well. It stimulates production of gonadal steroid hormones by stimulating the interstitial cells (Leydig cells) of the testis to produce androgens and the corpus luteum of the ovary to produce progesterone. Androgen stimulation in the male leads to the development of secondary sex characteristics and may stimulate testicular descent when no anatomical impediment to descent is present. This descent is usually reversible when hCG is discontinued. During the normal menstrual cycle, LH participates with FSH in the development and maturation of the normal ovarian follicle, and the mid-cycle LH surge triggers ovulation; hCG can substitute for LH in this function.

Due to its polypeptide nature, chorionic gonadotropin is destroyed in the gastrointestinal tract and, therefore, must be administered parenterally. Choriogonadotropin alfa must be administered subcutaneously. One-tenth of the dose of choriogonadotropin alfa is excreted in the urine.

Principal serious adverse reactions with choriogonadotropin alfa include ovarian hyperstimulation; enlargement of preexisting ovarian cysts or rupture of ovarian cysts with resultant hemoperitoneum; multiple births; and arterial thromboembolism. Other adverse effects of choriogonadotropin alfa include injection site disorders (i.e., pain, bruising), abdominal pain, nausea, and vomiting. Drug interaction studies are lacking.

Choriogonadotropin alfa is contraindicated in women who exhibit: primary ovarian failure; uncontrolled thyroid or adrenal dysfunction; an uncontrolled organic intracranial lesion such as pituitary tumor; sex hormone dependent tumors of the reproductive tract and accessory organs; abnormal uterine bleeding of undetermined origin; ovarian cyst or enlargement of undetermined origin; prior hypersensitivity to hCG preparations or one of their excipients; or pregnancy.

Coding/Billing Information

Note: This section is currently unavailable.

***Current Procedural Terminology (CPT®) ©2008 American Medical Association: Chicago, IL.**

References

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2. ACOG technical bulletin. Managing the anovulatory state: medical induction of ovulation. Number 197--September 1994 (replaces no. 120, September 1988). Committee on Technical Bulletins of the American College of Obstetricians and Gynecologists. *Int J Gynaecol Obstet* 1994; 47:305-312.

3. EMD Serono, Inc. Ovidrel[®] PreFilled Syringe (choriogonadotropin alfa injection) for subcutaneous use package insert. Rockland, MA: EMD Serono, Inc., July 2007.
4. McEvoy GK, ed. AHFS 2008 Drug Information. Bethesda, MD: American Society of Health-Systems Pharmacists, Inc; 2008.
5. Speroff L, Glass RH, Kase NG, editors. Clinical Gynecologic Endocrinology and Infertility 6th ed. Baltimore, MD: Lippincott Williams and Wilkins, 1999.
6. Strehler E, Abt M, El-Danasouri I, De Santo M, Sterzik K. Impact of recombinant follicle-stimulating hormone and human menopausal gonadotropins on in vitro fertilization outcome. Fertil Steril 2001; 75:332-6.
7. Westergaard LG, Erb K, Laursen SB, Rex S, Rasmussen PE. Human menopausal gonadotropin versus recombinant follicle-stimulating hormone in normogonadotropic women down-regulated with a gonadotropin-releasing hormone agonist who were undergoing in vitro fertilization and intracytoplasmic sperm injection: a prospective randomized study. Fertil Steril 2001; 76:543-9.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	1/15/2008	7002	Choriogonadotropin Alfa (Ovidrel [®])
Great-West Healthcare	1/2007	P05.103.1	Infertility

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA’s subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.