Specialty Guideline Management

BRAND (generic)

POLICY

SPECIALTY GUIDELINE MANAGEMENT

NOVAREL (chorionic gonadotropin)
PREGNYL (chorionic gonadotropin)
OVIDREL (choriogonadotropin alfa)
chorionic gonadotropin
*Hereafter, hCG will be used to describe all products

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

Novarel and Pregnyl are indicated for:

1. Prepubertal cryptorchidism not due to anatomic obstruction
2. Selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males
3. Induction of ovulation and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure, and who has been appropriately pretreated with human menotropins

Ovidrel is indicated for:

1. 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
2. Induction of ovulation and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure

B. Compendial Uses

1. Prepubertal cryptorchidism
2. Hypogonadotropic hypogonadism in males
3. Infertility, luteal phase support

All other indications are considered experimental/investigational and are not a covered benefit.

II. MEDICAL BENEFIT ALIGNMENT

Specialty Guideline Management coverage review will be bypassed for drug(s) being requested for a procedure that has been approved under a member's medical benefit plan. Such members will be exempt from the requirements in Sections III and IV. A medical authorization number and confirmation of the approved procedure(s) will be required.

NOTE: Some plans may opt-out of medical benefit alignment. Members receiving coverage under such plans must meet the requirements in Sections III and IV.

III. CRITERIA FOR INITIAL APPROVAL

A. Induction of oocyte maturation and/or release

Authorization of 12 months may be granted to members with infertility prescribed hCG.

B. Prepubertal cryptorchidism

Authorization of 6 months may be granted to members prescribed hCG for prepubertal cryptorchidism.

C. Hypogonadotropic hypogonadism

Authorization of 12 months may be granted to members prescribed hCG for hypogonadotropic hypogonadism who meet both of the following criteria:

1. Low pretreatment testosterone levels
2. Low or low-normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. REFERENCES

1. Novarel [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; January 2015.
2. Pregnyl [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2015.
3. Ovidrel [package insert]. Rockland, MA: EMD Serono, Inc.; September 2014.
4. DRUGDEX System (electronic version). Truven Health Analytics, Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed May 18, 2016.
5. Clinical Consult. CVS Caremark Clinical Program Review: Reproductive Endocrinology and Contraceptive Clinical Programs; September 2011.
6. Nosarka S, Kruger T, Siebert I, et al. Luteal phase support in in vitro fertilization: meta-analysis of randomized trials. *Gynecol Obstet Invest*. 2005;60:67-74.
7. American Association of Clinical Endocrinologists. Medical guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients – 2002 Update. *Endocr Pract*. 2002:8:439-456.