SPECIALTY GUIDELINE MANAGEMENT

Novarel (chorionic gonadotropin)
Pregnyl (chorionic gonadotropin)
Ovidrel (choriogonadotropin alfa)

*Hereafter, hCG will be used to describe all three products

POLICY

A. 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.

FDA-Approved Indications

Novarel is indicated for:

- Prepubertal cryptorchidism not due to anatomic obstruction
- Selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males
- 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

Pregnyl is indicated for:

- Prepubertal cryptorchidism not due to anatomic obstruction
- Selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males
- 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:

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

Compendial Indication

- Diagnosis of prepubertal cryptorchidism
- Luteal phase support in female patients who underwent ovulation induction or an assisted reproductive technology procedure

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:
Oocyte Maturation: Documentation of the type of procedure to be conducted

Hypogonadotropic hypogonadism: Testosterone, FSH, and LH levels

C. EXCLUSION

- Testicular hypogonadism not due to hypogonadotropism

D. CRITERIA FOR APPROVAL

1. Induction Of Oocyte Maturation And/Or Release For Ovulation Induction Or As Part Of An Assisted Reproductive Technology Procedure

a. Authorization of 12 months may be granted to female members who are prescribed hCG, which may be continued in the luteal phase, for the induction of oocyte maturation and/or release for ovulation induction or as part of an assisted reproductive technology procedure

2. Prepubertal Cryptorchidism

a. Authorization of 6 months may be granted to male members who are prescribed hCG for prepubertal cryptorchidism

3. Hypogonadotropic Hypogonadism

a. Authorization of 12 months may be granted to male members who are prescribed hCG for hypogonadotropic hypogonadism who meet all of the following criteria:
   i. The member has low testosterone levels
   ii. The member has low or low-normal follicle stimulation hormone (FSH) or luteinizing hormone (LH) levels

E. CONTINUATION OF THERAPY

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

F. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Induction of oocyte maturation and/or release without hCG luteal support:

- Novarel: 20,000 U/month
- Pregnyl: 20,000 U/month
- Ovidrel: 500 mcg/month

Induction of oocyte maturation and/or release with hCG luteal phase support:

- Novarel: 40,000 U/month
- Pregnyl: 40,000 U/month
- Ovidrel: 1000 mcg/month

Prepubertal cryptorchidism:

- Novarel: 20,000 U/week
- Pregnyl: 20,000 U/week
- Ovidrel: 250mcg/day

Hypogonadotropic hypogonadism:

- Novarel: 12,000 U/week
- Pregnyl: 12,000 U/week
- Ovidrel: 250mcg/day

REFERENCES

1. Novarel [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.: July 2012.
2. Pregnyl [package insert]. Whitehouse Station, NJ: Merck & Co. Inc..: December 2013.
3. Ovidrel [package insert]. Rockland, MA: EMD Serono, Inc.: September 2014.
4. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado. Available at http://www.micromedexsolutions.com. Accessed May 13, 2015.
5. American Association of Clinical Endocrinologists. Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients – 2002 Update. *Endocrine Practice*. 2002:8(6):439-456.