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. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review: testosterone, FSH, and LH levels (for hypogonadotropic hypogonadism)

III. EXCLUSIONS
Coverage will not be provided for members with testicular hypogonadism not due to hypogonadotropism.

IV. CRITERIA FOR INITIAL APPROVAL
A. Induction of oocyte maturation and/or release for ovulation induction or as part of an assisted reproductive technology (ART) program
Authorization of 12 months may be granted to members with infertility 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 ART program.
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 testosterone levels
   2. Low or low-normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels

V. **CONTINUATION OF THERAPY**
   All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

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

VII. **REFERENCES**