Reference number(s)
1925-A, 1926-A

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 Use
Infertility, luteal phase support

All other indications are considered experimental/investigational and not medically necessary.

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 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 IV.

III. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review for hypogonadotropic hypogonadism: testosterone, FSH, and LH levels.

IV. CRITERIA FOR INITIAL APPROVAL

A. Induction of oocyte maturation and/or release
Authorization of 12 months may be granted for members undergoing ovulation induction or assisted reproductive technology (ART).

B. Prepubertal cryptorchidism
Authorization of 6 months may be granted for treatment of prepubertal cryptorchidism.

C. Hypogonadotropic hypogonadism
Authorization of 12 months may be granted for treatment of hypogonadotropic hypogonadism in members who meet both of the following criteria:
1. Member has low pretreatment testosterone levels
2. Member has low or low to 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. REFERENCES

1. Novarel [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; November 2020
2. Pregnyl [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; March 2023.
3. Ovidrel [package insert]. Rockland, MA: EMD Serono, Inc.; February 2022.
4. Chorionic Gonadotropin for Injection [package insert]. Lake Zurich, IL: Fresenius Kabi; April 2020.
5. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, CO. Available at: http://www.micromedexsolutions.com Accessed May 2, 2023.
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.