POLICY Document for
NOVAREL (chorionic gonadotropin)
PREGNYL (chorionic gonadotropin)
OVIDREL (choriogonadotropin alfa)
chorionic gonadotropin

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
HUMAN CHORIONIC GONADOTROPIN (hCG) PRODUCTS

PREFERRED PRODUCT: OVIDREL, PREGNYL

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the human chorionic gonadotropin products specified in this policy. Coverage for targeted product is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Human chorionic gonadotropin (hCG) products

	Products
Preferred*	• **Ovidrel** (choriogonadotropin alfa) • **Pregnyl** (chorionic gonadotropin)
Targeted	• **chorionic gonadotropin** (generic for Pregnyl)

	• **Novarel** (chorionic gonadotropin)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for a targeted product is provided when the following criteria is met:

A. Member has had a documented inadequate response, contraindication, or intolerable adverse event to Ovidrel or Pregnyl.

Section 2: Clinical Criteria

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 gonadotropins.

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 (OI) 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, follicle stimulating hormone (FSH), and luteinizing hormone (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.

REFERENCES:

SECTION 1

1. Chorionic gonadotropin [package insert]. Schaumburg, IL: APP Pharmaceuticals, LLC; April 2011.
2. Novarel [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; May 2023.
3. Ovidrel [package insert]. Rockland, MA: EMD Serono, Inc.; June 2018.
4. Pregnyl [package insert]. Whitehouse Station, NJ: Merck & Co., Inc; March 2023.

SECTION 2

1. Novarel [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; April 2024
2. Pregnyl [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; March 2023.
3. Ovidrel [package insert]. Rockland, MA: EMD Serono, Inc.; December 2023.
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 14, 2024.
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.