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

Specialty Guideline Management Human Chorionic Gonadotropin (hCG)

Hereafter, hCG will be used to describe all products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Novarel	chorionic gonadotropin
Pregnyl	chorionic gonadotropin
Ovidrel	choriogonadotropin alfa

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[1-4]

Novarel and Pregnyl are 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 gonadotropins

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 (OI) and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure

Compendial Uses[5-8]

Acute graft-versus-host disease (GVHD) (chorionic gonadotropin, Novarel, and Pregnyl only)

Infertility, luteal phase support

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

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 the coverage criteria section. 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 the coverage criteria section.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Hypogonadotropic Hypogonadism

Chart notes, medical record documentation, or laboratory results to support pretreatment testosterone level, and either follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels.

Acute Graft-Versus-Host Disease (initial requests only)

Chart notes or medical record documentation of clinical reason to avoid systemic corticosteroid therapy, if applicable.

Coverage Criteria

Induction of Oocyte Maturation and/or Release[1-6]

Authorization of 12 months may be granted for members undergoing ovulation induction or assisted

reproductive technology (ART).

Prepubertal Cryptorchidism[1,2,4,5]

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

Hypogonadotropic Hypogonadism[1,2,4,5,7]

Authorization of 12 months may be granted for treatment of hypogonadotropic hypogonadism in members who meet both of the following criteria:

- Member has low pretreatment testosterone levels.
- Member has low or low to normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels.

Acute Graft-Versus-Host Disease (GVHD)(chorionic gonadotropin, Novarel, and Pregnyl only)[8]

Authorization of 12 months may be granted for steroid-refractory acute graft-versus-host disease when member meets either of the following:

- The requested medication will be taken in conjunction with systemic corticosteroids.
- Member has an intolerance or contraindication to systemic corticosteroids.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

References

1. Novarel [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; November 2024.
2. Pregnyl [package insert]. Jersey City, NJ: Organon USA LLC; March 2025.
3. Ovidrel [package insert]. Rockland, MA: EMD Serono, Inc.; December 2023.
4. Chorionic Gonadotropin for Injection [package insert]. Lake Zurich, IL: Fresenius Kabi; April 2025.
5. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, CO. Available at: http://www.micromedexsolutions.com Accessed May 14, 2025.
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.
8. The NCCN Drugs & Biologics Compendium 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 14, 2025.