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Section:	Prescription Drugs	**Effective Date:**	July 1, 2026
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	March 14, 2011
Subject:	HCG	**Page:**	1 of 8

Last Review Date: June 11, 2026

HCG Powder, Novarel, Pregnyl, Ovidrel

Description

HCG Powder (human chorionic gonadotropin); Novarel, Pregnyl (chorionic gonadotropin); Ovidrel (choriogonadotropin alfa)

Background

Human chorionic gonadotropin (HCG), a polypeptide hormone produced by the human placenta, is composed of an alpha and a beta sub-unit. The alpha sub-unit is essentially identical to the alpha sub-units of the human pituitary gonadotropins, luteinizing hormone (LH) and follicle-stimulating hormone (FSH), as well as to the alpha sub-unit of human thyroid-stimulating hormone (TSH). The beta sub-units of these hormones differ in amino acid sequence. The action of HCG is virtually identical to that of pituitary LH, although HCG appears to have a small degree of FSH activity as well. It stimulates production of gonadal steroid hormones by stimulating the interstitial cells (Leydig cells) of the testes to produce androgens and the corpus luteum of the ovary to produce progesterone. Androgen stimulation in the male leads to the development of secondary sex characteristics and may stimulate testicular descent when no anatomical impediment to descent is present. During the normal menstrual cycle, LH participates with FSH in the development and maturation of the normal ovarian follicle, and the mid-cycle LH surge triggers ovulation. During a normal pregnancy, HCG secreted by the placenta maintains the corpus luteum after LH secretion decreases, supporting continued secretion of estrogen and progesterone and preventing menstruation (1-3).

HCG may be used as a pharmacologic intervention in the treatment of undescended testes, and the induction of ovulation in both coital reproduction and for controlled ovarian hyperstimulation (COH) with assisted reproductive technologies (ART). Off-label and alternative uses of HCG

such as enhancement of weight loss, improvement of muscle development and muscle injury recovery have been reported (1-3).

Regulatory Status
FDA-approved indications: HCG products are purified preparations obtained from the urine of pregnant women and standardized for injection by a biological assay.
Chorionic gonadotropin (HCG powder, Novarel, Pregnyl) is approved for prepubertal cryptorchidism not due to anatomic obstruction, selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males, and the 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 (1-3).

For the treatment of cryptorchidism therapy is usually instituted in children between the ages of 4 and 9 (1-3).

Choriogonadotropin alfa (Ovidrel) is indicated for the 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. Ovidrel is also indicated for the 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 (3).

Novarel and Pregnyl may also be used to induce puberty in boys and to treat androgen deficiency in hypogonadotropic hypogonadism; the major use of these preparations is in the initiation and maintenance of spermatogenesis in hypogonadotropic men who desire fertility. It may take 2 to 3 months to achieve normal levels of testosterone (4).

These medications if used for erectile or sexual dysfunction, weight loss, performance (athletic) enhancement, and anti-aging are not covered by the Plan.

Related policies
ART Drugs, Leuprolide

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

HCG powder, Novarel, Ovidrel, and Pregnyl may be considered **medically necessary** if the conditions indicated below are met.

HCG powder, Novarel, Ovidrel, and Pregnyl may be considered **investigational** for all other indications.

Prior-Approval Requirements

When used for medically assisted reproduction, HCG is limited to 3 cycles per benefit year for *in vitro* fertilization procedures. There are no cycle limits when used for artificial insemination procedures.

Diagnoses

Male patients must have **ONE** of the following (Novarel and Pregnyl **ONLY**):

1. Hypogonadotropic hypogonadism (hypogonadism secondary to pituitary deficiency)
2. Prepubertal cryptorchidism not caused by anatomic obstruction

AND NOT being used to treat:

1. Erectile or sexual dysfunction
2. Weight loss
3. Performance (athletic) enhancement
4. Anti-aging effects
5. Chronic pain management / neurogenesis

Female patients must have **ONE** of the following:

1. Infertility, **NOT** used in conjunction with assisted reproductive technology (ART) procedures
2. Infertility**,** used in conjunction with assisted reproductive technology (ART) procedures, which include but are not limited to:
    a. Artificial insemination (AI), including the following:
        a. Intravaginal insemination (IVI)
        b. Intracervical insemination (ICI)
        c. Intrauterine insemination (IUI)
    b. In vitro fertilization (IVF), including the following:

a. Embryo transfer and gamete intrafallopian transfer (GIFT)
b. Zygote intrafallopian transfer (ZIFT)
c. Intracytoplasmic sperm injection (ICSI)

AND NOT being used to treat:
1. Sexual dysfunction
2. Weight loss
3. Performance (athletic) enhancement
4. Anti-aging effects
5. Chronic pain management / neurogenesis

AND ALL of the following for **HCG powder:**
1. The requested dose is **NOT** commercially available
2. The requested dose/ strength does **NOT** exceed the maximum FDA-approved dose/strength for the requested ingredient
3. The requested dosage form is a FDA approved dosage form

Prior – Approval *Renewal* Requirements

Diagnoses

Male patients must have the following (Novarel and Pregnyl **ONLY**):

1. Prepubertal cryptorchidism not caused by anatomic obstruction

AND NOT being used to treat:
1. Erectile or sexual dysfunction
2. Weight loss
3. Performance (athletic) enhancement
4. Anti-aging effects
5. Chronic pain management / neurogenesis

Female patients must have **ONE** of the following:

1. Infertility, **NOT** used in conjunction with assisted reproductive technology (ART) procedures
2. Infertility**,** used in conjunction with assisted reproductive technology (ART) procedures, which include but are not limited to:

c. Artificial insemination (AI), including the following:
    a. Intravaginal insemination (IVI)
    b. Intracervical insemination (ICI)
    c. Intrauterine insemination (IUI)
d. In vitro fertilization (IVF), including the following:
    a. Embryo transfer and gamete intrafallopian transfer (GIFT)
    b. Zygote intrafallopian transfer (ZIFT)
    c. Intracytoplasmic sperm injection (ICSI)

AND NOT being used to treat:

1. Sexual dysfunction
2. Weight loss
3. Performance (athletic) enhancement
4. Anti-aging effects
5. Chronic pain management / neurogenesis

AND ALL of the following for **HCG powder:**

1. The requested dose is **NOT** commercially available
2. The requested dose/ strength does **NOT** exceed the maximum FDA-approved dose/strength for the requested ingredient
3. The requested dosage form is a FDA approved dosage form

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Females

When used for medically assisted reproduction, HCG is limited to 3 cycles per benefit year for *in vitro* fertilization procedures. There are no cycle limits when used for artificial insemination procedures.

Diagnosis	Duration
ART - IVF procedures	4 months
ART - AI procedures	12 months

Infertility, no ART	12 months

Males

Quantity Novarel 18 vials/ 84 days
Pregnyl 18 vials /84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Females

Diagnosis	Duration
Art - IVF procedures	4 months* ***ONLY** two renewals every calendar year
ART - AI procedures	12 months
Infertility, no ART	12 months

Males

NO renewal for hypogonadotropic hypogonadism
Prepubertal cryptorchidism only

Quantity Novarel 18 vials/ 84 days
Pregnyl 18 vials /84 days

Duration 12 months

Rationale

Summary
Human chorionic gonadotropin (HCG), a polypeptide hormone produced by the human placenta, is composed of an alpha and a beta sub-unit. The alpha sub-unit is essentially identical to the alpha sub-units of the human pituitary gonadotropins, luteinizing hormone (LH) and follicle-stimulating hormone (FSH). The action of HCG is virtually identical to LH and, therefore, has therapeutic potential (1-3).

Chorionic gonadotropin (HCG powder, Novarel, Pregnyl) is approved for prepubertal cryptorchidism not due to anatomic obstruction, selected cases of hypogonadotropic

hypogonadism (hypogonadism secondary to a pituitary deficiency) in males, and the induction of ovulation and pregnancy. Choriogonadotropin alfa (Ovidrel) is indicated for the induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization (1-3).

These medications if used for erectile or sexual dysfunction, weight loss, performance (athletic) enhancement, or anti-aging are not covered by the Plan.

Prior authorization is required for chorionic gonadotropin and choriogonadotropin alfa to ensure their safe, clinically appropriate, and cost-effective use while maintaining optimal therapeutic outcomes.

References

1. Novarel [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; August 2025.
2. Pregnyl [package insert]. Bloomington, IN: Baxter Pharmaceutical Solutions LLC; March 2023.
3. Ovidrel [package insert]. Rockland, MA: EMD Serono Inc.; February 2022.
4. American Association of Clinical Endocrinologists (AACE); Medical guidelines for clinical practice for the evaluation and treatment of hypogonadism. 2002;8(No.6).

Policy History

Date	Action
March 2011	Adding human chorionic gonadotropin (HCG) powder to the list of drugs used in infertility and ART; HCG is used to induce ovulation and spermatogenesis.
September 2011	Weight loss, performance enhancing, and anti-aging are not covered benefits. To date no clinical evidence has established clinical efficacy of the use of HCG in any formal study to be used in weight loss therapy (3). Prior approval is required to exclude coverage of use in weight loss, performance enhancing, anti-aging, and in conjunction with ART.
December 2012	Annual editorial review and update
March 2013	Interval editorial review and update
September 2014	Annual editorial review and reference update
May 2015	Reference update, addition of quantity limits to males, removal of renewal for hypogonadotropic hypogonadism, additional criteria for powder for compounding
June 2015	Annual editorial review

September 2016	Annual editorial review and reference update Policy number change from 5.08.09 to 5.30.43
June 2018	Annual editorial review and reference update
December 2019	Annual review
March 2020	Added requirement of no sexual dysfunction for female patients
June 2020	Annual review
September 2020	Annual review
June 2021	Annual review and reference update
June 2022	Annual editorial review and reference update
September 2022	Annual review
September 2023	Annual review
January 2024	Per FEP, added infertility with ART as an approvable diagnosis with a limit of 3 cycles per year for IVF-related procedures and unlimited cycles of AI-related procedures. Changed ovulation induction to infertility with no ART and changed approval duration to 12 months to match ART diagnoses
June 2024	Annual review and reference update
September 2024	Annual review
June 2025	Annual review
June 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.