

HUMAN CHORIONIC GONADOTROPIN (HCG)**HCG POWDER (human chorionic gonadotropin)****NOVAREL / PREGNYL (chorionic gonadotropin), OVIDREL (choriogonadotropin)****RATIONALE FOR INCLUSION IN PA PROGRAM****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

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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.

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).

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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.; May 2023.
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).