



**Prior Authorization Approval Criteria**  
*Department of Pharmacy Services*

**Generic Name:** Chorionic Gonadotropin

**Brand Name:** Novarel, Pregnyl

**Medication Class:** Infertility hormones

**FDA Approved Uses:**

- Prepubertal cryptorchidism not due to anatomical obstruction, usually instituted in children ages 4 to 9 years old
- Hypogonadotropic hypogonadism in males (secondary to pituitary deficiency)
- 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 menopausal gonadotropins.

**Available Dosage Forms:** Intramuscular injection.

**Usual Dose:**

- Prepubertal cryptorchidism not due to anatomical obstruction one of:
  1. 4,000 USP Units three times weekly for three weeks.
  2. 5,000 USP Units every second day for four injections.
  3. 15 injections of 500 to 1,000 USP Units over a period of six weeks
  4. 500 USP Units three times weekly for four to six weeks. If this course of treatment is not successful, another is begun one month later giving 1,000 USP Units per injection.
- Hypogonadotropic hypogonadism in males:
  1. 500 to 1,000 USP Units three times a week for three weeks, followed by the same dose twice a week for three weeks.
  2. 4,000 USP Units three times weekly for six to nine months, following which the dosage may be reduced to 2,000 USP Units three times weekly for an additional three months.
- 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 menopausal gonadotropins.
  1. 5,000 to 10,000 USP Units one day following the last dose of menopausal gonadotropins.

**Duration of Therapy:**

Prepubertal cryptorchidism: depending on dosing, from one week to 16 weeks

Hypogonadotropic hypogonadism: depending on dosing, from six weeks to 12 months

Ovulation induction: usually one day, administered a day after the last dose of menopausal gonadotropins

**Approximate Monthly Cost (based on AWP 2006):**

- Prepubertal cryptorchidism: \$33 to \$129
- Hypogonadotropic hypogonadism: \$54 to \$186
- Ovulation induction: \$18 to \$36



**Criteria for Use:** *(bullet points below are all inclusive unless otherwise noted)*

- Prepubertal cryptorchidism not due to anatomical obstruction. Usually instituted in children ages 4 to 9
- Hypogonadotropic hypogonadism in males secondary to a pituitary deficiency
- 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 menopausal gonadotropins.

**Criteria for Continuation of Therapy:**

- Drug prescribed and patient followed by a pediatric endocrinologist. Continuation of therapy based on physician experience and child's response.
- In males with secondary hypogonadotropic hypogonadism, duration depends upon patient response and whether or not he is being treated for infertility. A duration of up to 24 months is not unusual.
- In women, continuation would be at the discretion of the reproductive endocrinologist, and the number of fertility cycles prescribed.

**Cautions:**

- Possibility of induction of precocious puberty
- May cause fluid retention, so use with caution in patients with cardiac or renal disease, epilepsy, migraine or asthma.
- Ovarian over stimulation syndrome

**Monitoring:**

- In males, testosterone levels can be checked, and sperm counts and motility can be checked
- In females, ultrasound checks for follicle size may be employed

**Contraindications:**

- Precocious puberty
- prostatic carcinoma or other androgen-dependent neoplasm
- pregnancy
- prior allergic reaction to hCG.

**Not Approved if:**

- Not being followed by an appropriate endocrinologist—pediatric, adult, or reproductive.

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_