VENTURA COUNTY
HEALTH CARE PLAN

**Prior Authorization DRUG Guidelines**

# Chorionic Gonadotropin (Pregnyl, Novarel)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Catherine Sanders, MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20, 8/3/21, 2/1/22, 1/31/23

Chorionic Gonadotropin is an ovulation stimulator. It stimulates production of gonadal steroid hormones by causing production of androgen by the testes and is used as a substitute for luteinizing hormone (LH) to stimulate ovulation.

**Pre-Authorization Criteria:**

**Hypogonadotrophic hypogonadism:** Treatment of hypogonadism secondary to a pituitary deficiency in males.

**Ovulation induction:** Induction of ovulation and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not caused by primary ovarian failure, and who has been appropriately pretreated with human menotropins.

**Prepubertal cryptorchidism:** Treatment of prepubertal cryptorchidism not caused by anatomic obstruction.

**NOTE:**
VCHCP requires that Chorionic Gonadotropin (Pregnyl, Novarel) be prescribed by an infertility specialist.

**Dosing: Adult (NOTE:** I.M. administration only**):**
**Induction of ovulation: Females:** I.M.: 5000-10,000 units 1 day following last dose of menotropins
**Hypogonadotropic hypogonadism:** Males: IM: Various regimens:

500 to 1,000 units 3 times/week for 3 weeks, followed by the same dose twice weekly for 3 weeks

**-or-**

4,000 units 3 times/week for 6 to 9 months, then reduce dosage to 2,000 units 3 times/week for additional 3 months

**Off-label Use:**
**Spermatogenesis induction associated with hypogonadotropic hypogonadism:**
Males: Treatment regimens vary (range: 1000-2000 units 2-3 times a week). Administer hCG until serum testosterone levels are normal (may require 2-3 months of therapy), then may add follitropin alfa or menopausal gonadotropin if needed to induce spermatogenesis; continue hCG at the dose required to maintain testosterone levels.

**Dosing: Pediatric:**
Various regimens:
**Prepubertal cryptorchidism:** I.M.:
4000 units 3 times/week for 3 weeks, or
5000 units every second day for 4 injections, or
500 units 3 times/week for 4-6 weeks, or
15 injections of 500-1000 units given over 6 weeks
**Hypogonadotropic hypogonadism:**
**Hypogonadotropic hypogonadism, puberty induction:** Limited data available: Children ≥12 years and Adolescents: Males: IM: 500 to 3,000 units 2 to 3 times weekly; adjust dose based on serum testosterone levels, every 3 to 6 months

NOTE: Safety and efficacy have not been established in children <4 years of age.

**Dosing: Geriatric:**
Refer to adult dosing.

**Dosing: Renal Impairment:**
No dosage adjustment provided in manufacturer's labeling; use with caution.

**Dosing: Hepatic Impairment:**
No dosage adjustment provided in manufacturer's labeling.

**Dosage Forms: U.S.:**
Excipient information presented when available (limited, particularly for generics); consult specific product labeling.
Solution Reconstituted, Intramuscular:
Novarel: 5,000, 10,000 units (1 ea) [contains benzyl alcohol]
Pregnyl: 10,000 units (1 ea) [contains benzyl alcohol, sodium chloride]
Generic: 10,000 units (1 ea)

**Contraindications:**
Hypersensitivity to chorionic gonadotropin or any component of the formulation; precocious puberty; prostatic carcinoma or similar neoplasms; pregnancy

**Adverse Reactions:**
Edema, depression, fatigue, headache, irritability, restlessness, gynecomastia, precocious puberty, injection site reaction, hypersensitivity reaction
Other Serious Less Common Reactions: arterial thrombus, ovarian cyst rupture, ovarian hyperstimulation syndrome.

May cause ovarian hyperstimulation syndrome (OHSS); characterized by severe ovarian enlargement, abdominal pain/distention, nausea, vomiting, diarrhea, dyspnea, and oliguria, and may be accompanied

by ascites, pleural effusion, hypovolemia, electrolyte imbalance, hemoperitoneum, and thromboembolic events. If severe hyperstimulation occurs, stop treatment and hospitalize patient.

**References:**

1. American Association of Clinical Endocrinologists, "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(6):440-56. [PubMed 15260010]
2. National Institute for Occupational Safety and Health (NIOSH), "NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012." Available at http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf. Accessed January 21, 2013.
3. www.uptodate.com: Human chorionic gonadotropin: Drug Information
4. www.epocrates.com: chorionic gonadotropin Drug information

**REVISION HISTORY:**

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD
Date Approved by P&T Committee: 1/27/15
Date Reviewed/Updated: 2/17/15 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/26/16
Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/24/17
Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/23/18
Date Reviewed/No Updates: 1/22/19 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/22/19
Date Reviewed/No Updates: 2/18/20 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/18/20
Date Reviewed/ Updated: 8/3/21 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 8/3/21
Date Reviewed/No Updates: 2/1/22 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 2/1/22
Date Reviewed/No Updates: 1/31/23 by H. Taekman, MD; R. Sterling, MD
Date Approved by P&T Committee: 1/31/23

| Revision Date | Content Revised (Yes/No) | Contributors | Review/Revision Notes |
|---|---|---|---|
| 1/24/17 | No | Catherine Sanders, MD; Robert Sterling, MD | Annual review |
| 1/23/18 | No | Catherine Sanders, MD; Robert Sterling, MD | Annual review |
| 1/22/19 | No | Catherine Sanders, MD; Robert Sterling, MD | Annual review |
| 2/18/20 | No | Howard Taekman, MD; Robert Sterling, MD | Annual review |
| 8/3/21 | Yes | Howard Taekman, MD; Robert Sterling, MD | Updated preauthorization criteria, dosage and Off Label Use section |

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| 2/1/22 | No | Howard Taekman, MD; Robert Sterling, MD | Annual review |
| 1/31/23 | No | Howard Taekman, MD; Robert Sterling, MD | Annual review |