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, 2/13/24, 2/18/25

Chorionic Gonadotropin is an ovulation stimulator. It stimulates production of gonadal steroid hormones by causing production of androgen by the testes and the development of secondary sex characteristics in males and is used as a substitute for luteinizing hormone (LH) to stimulate ovulation in females. Pregnyl and Novarel are derived from the urine of pregnant women.

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.

Off Label: 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/SubQ: Various regimens:

1000-2000 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 FSH or menopausal

gonadotropin if needed to induce spermatogenesis; continue hCG at the dose required to maintain testosterone levels.

Dosing: Pediatric: Refer to product literature.

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

Dosing: Geriatric:
Refer to adult dosing.

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.(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:

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6. 7. varel (chorionic gonadotropin) [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals Inc; May 2023
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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
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8/3/21	Yes	Howard Taekman, MD; Robert Sterling, MD	Updated preauthorization criteria, dosage and Off Label Use section

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2/13/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Updated Chorionic Gonadotropin definition and dosing section. Added “Off Label: Treatment of prepubertal cryptorchidism not caused by anatomic obstruction.”