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

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:

To induce ovulation and pregnancy in anovulatory, infertile females; treatment of hypogonadotropic hypogonadism, prepubertal cryptorchidism; induction of spermatogenesis with follitropin alfa

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

Dosing: Adult:
Induction of ovulation: Females: I.M.: 5000-10,000 units 1 day following last dose of menotropins
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: Males: I.M.:
500-1000 units 3 times/week for 3 weeks, followed by the same dose twice weekly for 3 weeks or
4000 units 3 times/week for 6-9 months, then reduce dosage to 2000 units 3 times/week for additional 3 months

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: 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)

Generic Equivalent Available: U.S.-Yes

Administration:
I.M. administration only
Hazardous agent; use appropriate precautions for handling and disposal (NIOSH, 2012).

Exclusions:
Chorionic gonadotropin is not to be used in the treatment of obesity as it has not been proven to be effective.
Safety and efficacy have not been established in children <4 years of age.

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.
These medications should only be used by physicians who are thoroughly familiar with infertility problems and their management. 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. This syndrome develops rapidly with 24 hours to several days and generally occurs during the 7-10 days immediately following treatment. Ovarian enlargement may be accompanied by abdominal distention or abdominal pain and generally regresses without treatment within 2-3 weeks. If ovaries are abnormally enlarged on the last day of treatment, withhold hCG to reduce the risk of OHSS. In association with and separate from OHSS, thromboembolic events have been reported. May result from the use of these medications; advise patients of the potential risk of multiple births before starting the treatment.

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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

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