Drug Coverage Policy

Effective Date.....7/15/2026
Coverage Policy Number.....IP0804
Policy Title.....Chorionic Gonadotropins

Infertility - Chorionic Gonadotropins

- Pregnyl® (chorionic gonadotropin intramuscular injection [urine-derived] – Organon)
- Novarel® (chorionic gonadotropin intramuscular injection [urine-derived] – Ferring)
- Chorionic gonadotropin intramuscular injection (urine-derived) – Fresenius Kabi, others
- Ovidrel® (choriogonadotropin alfa subcutaneous injection [recombinant] – EMD Serono)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Pregnyl, Novarel, and chorionic gonadotropin for injection are indicated for the following uses:[1-3]

- **Induction of ovulation and pregnancy** in the anovulatory, infertile women in whom the cause of anovulation is secondary and not due to primary ovarian failure, and who has been appropriately pretreated with human menotropins.
- Selected cases of **hypogonadotropic hypogonadism** (hypogonadism secondary to a pituitary deficiency) in males.

Other FDA-labeled uses include:

- **Prepubertal cryptorchidism** not due to anatomical obstruction.

Ovidrel is indicated for the following uses:[4]

- **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.
- **Induction of ovulation and pregnancy** in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure.

Pregnyl, Novarel, and chorionic gonadotropin for injection are highly purified preparations obtained from the urine of pregnant females and are administered intramuscularly.[1-3] Ovidrel is a recombinant human chorionic gonadotropin (hCG) and is for subcutaneous use only.[4] The physicochemical, immunological, and biological activities of recombinant hCG are comparable to those of placental and human pregnancy-urine derived hCG.

The action of hCG is very similar to the pituitary luteinizing hormone (LH), although hCG possesses slight follicle-stimulating hormone (FSH) activity.[1-3] hCG also stimulates production of gonadal steroid hormones by stimulating the interstitial cells of the testis to produce androgens and the corpus luteum of the ovary to produce progesterone.

In males, androgen stimulation by hCG results in the development of secondary sex characteristics that may lead to testicular descent when no anatomical obstruction is present.[1-3] When hCG is discontinued, the descent is usually reversible. During the normal menstrual cycle, LH acts with FSH in the maturation and development of the normal ovarian follicle and the mid-cycle LH surge causes ovulation; hCG can replace LH in this capacity. When pregnancy occurs, hCG produced by the placenta maintains the corpus luteum after LH secretion decreases, supporting continued secretion of estrogen and progesterone and preventing menstruation.

Table 1. Chorionic Gonadotropin Product Descriptions/Dosing Regimens.[1-4]

Detail	Pregnyl, Novarel, chorionic gonadotropin	Ovidrel
Formulation type	Urine-derived	Recombinant
Availability	**Pregnyl:** 10,000 USP units of hCG. **Novarel Vial:** 5,000 USP and 10,000 USP units of hCG. **Chorionic gonadotropin:** 10,000 USP units of hCG.	**Prefilled single-dose syringe** contains 250 mcg/0.5 mL.
Administration route	IM only	SC only
Dosing	• **Prepubertal cryptorchidism dosing options*:**	**Infertile women undergoing ART or**

Detail	Pregnyl, Novarel, chorionic gonadotropin	Ovidrel
	○ 4,000 USP units TIW for 3 weeks. ○ 5,000 USP units every second day for 4 injections. ○ 15 injections of 500 to 1,000 USP units over a 6-week period. ○ 500 USP units TIW for 4 to 6 weeks. If unsuccessful, then another series starting 1 month later is given, using 1,000 USP units per injection. • **Selected cases of hypogonadotropic hypogonadism in males dosing options*:** ○ 500 to 1,000 USP units TIW for 3 weeks, followed by the same dose twice a week for 3 weeks. ○ 4,000 USP units TIW for 6 to 9 months, then decreased to 2,000 USP units TIW for an additional 3 months. • **Induction of ovulation dosing***: ○ 5,000 to 10,000 USP units 1 day following the last dose of menotropins. A dosage of 10,000 USP units is recommended in the labeling for menotropins.	**ovulation induction:** 250 mcg 1 day following the last dose of follicle stimulating agent. Administer only if there is adequate follicular development as indicated by serum estradiol and vaginal ultrasonography. Withhold dose if there is an excessive ovarian response (clinically significant ovarian enlargement or excessive estradiol production).

hCG – Human chorionic gonadotropin; IM – intramuscularly; SC – subcutaneously; * The dosage regimen used in any particular patient will depend upon the indication for the use, the age and weight of the patient, and the physician's preference. The regimens listed have been advocated by various authorities; TIW – Three times per week; ART – Assisted reproductive technology.

Coverage Policy

Coverage of treatment services for infertility varies across plans. Please refer to the related coverage policy (0089 Infertility Services).

The use of human chorionic gonadotropin (hCG) for indications other than infertility are addressed in a separate coverage policy (Human Chorionic Gonadotripin for Non-Fertility Uses IP0327)

Policy Statement
Injectable fertility medications are specifically excluded under most benefit plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage.

Prior Authorization is required for benefit coverage of chorionic gonadotropins. In the clinical criteria, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: males are defined as individuals with the biological traits of a male, regardless of the individual's gender identity or gender expression; females are defined as individuals with the biological traits of a female, regardless of the individual's gender identity or gender expression. All approvals are provided for the duration noted below.

Chorionic Gonadotropins are considered medically necessary when ONE of the following is met (I or II):

I. Chorionic Gonadotropin, Novarel (chorionic gonadotropin) intramuscular injection [urine-derived], Pregnyl (chorionic gonadotropin) intramuscular injection [urine derived]. Approve for 1 year if the patient meets the following (1):

FDA-Approved Indications

1. **Infertility.** Patient meets the following (A, B, or C):
   - **A.** *Females undergoing infertility treatment, use is for ovulation induction or to trigger final oocyte maturation; OR
   - **B.** *Females undergoing fertility preservation, use is for ovulation induction or to trigger final oocyte maturation; OR
   - **C.** *Males, use is for the treatment of hypogonadotropic hypogonadism.

II. Ovidrel (choriogonadotropin alfa injection). Approve for 1 year if the patient meets the following (1):

FDA-Approved Indications

1. **Infertility.** Patient meets the following (A or B):
   - **A.** *Females undergoing infertility treatment, use is for ovulation induction or to trigger final oocyte maturation; OR

B. *Females undergoing fertility preservation, use is for ovulation induction or to trigger final oocyte maturation.

*Refer to the Policy Statement.

Conditions Not Covered

Chorionic gonadotropins for any other use is considered not medically necessary. Criteria will be updated as newly published data are available.

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J0725	Injection, chorionic gonadotropin, per 1,000 USP units
J3490†	Unclassified drugs

†**Note:** May be considered for coverage when used to report Ovidrel

References

1. Pregnyl® intramuscular injection [prescribing information]. Jersey City, NJ: Organon; March 2025.
2. Novarel® intramuscular injection [prescribing information]. Parsippany, NJ: Ferring; May 2023.
3. Chorionic gonadotropin intramuscular injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; February 2025.
4. Ovidrel® subcutaneous injection [prescribing information]. Rockland, MA: EMD Serono; June 2018.

Revision Details

Summary of Changes	Review Date	Effective Date
New policy. **Coding Information:** **Added** J0725 & J3490	5/14/2026	7/15/2026

The policy effective date is in force until updated or retired.