Cigna National Formulary Coverage Policy

Drug Quantity Management – Per Rx
Chorionic Gonadotropins

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Product Identifer(s)

Effective 1/1/23 to 2/27/23: 109214

Effective 2/28/23: 34552

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. 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.

National Formulary Medical Necessity

Drugs Affected

- Pregnyl® (chorionic gonadotropin injection [urine-derived])
- Novarel® (chorionic gonadotropin injection [urine-derived])
- Chorionic gonadotropin injection [urine-derived])

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of the chorionic gonadotropins. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted below.

Drug Quantity Limits

Product	Strength/Package Size	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Pregnyl® (chorionic gonadotropin injection [urine-derived])	10,000 units/vial	3 vials	9 vials
Novarel® (chorionic gonadotropin injection [urine-derived])	5,000 units/vial	6 vials	18 vials
	10,000 units/vial	3 vials	9 vials
Chorionic gonadotropin injection [urine-derived]	10,000 units/vial	3 vials	9 vials

Based on the dosing and availability above, six 5,000 USP unit vials (30,000 USP units) or three 10,000 USP unit vials (30,000 USP units) would provide a quantity sufficient for 30 days of therapy for most of the recommended dosing regimens for prepubertal cryptorchidism and hypogonadotropic hypogonadism in males and it would also be adequate for the induction of ovulation.

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Pregnyl 10,000 unit vials, Novarel 10,000 unit vials, Chorionic gonadotropin injection 10,000 unit vials

1. If the individual has prepubertal cryptorchidism not due to an anatomical obstruction, approve the requested quantity, not to exceed a total of 4 vials per dispensing at retail and 12 vials per dispensing at home delivery.
2. If the individual has hypogonadotropic hypogonadism (hypogonadism secondary to pituitary deficiency), approve the requested quantity, not to exceed a total of 6 vials per dispensing at retail and 18 vials per dispensing at home delivery.
3. For induction of ovulation and pregnancy, no overrides are recommended.

Novarel 5,000 unit vials

1. If the individual has prepubertal cryptorchidism not due to an anatomical obstruction, approve the requested quantity, not to exceed a total of 8 vials per dispensing at retail and 24 vials per dispensing at home delivery.
2. If the individual has hypogonadotropic hypogonadism (hypogonadism secondary to pituitary deficiency), approve the requested quantity, not to exceed 12 vials at retail and 36 vials per dispensing at home delivery.
3. For induction of ovulation and pregnancy, no overrides are recommended.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Pregnyl, Novarel, and (human) chorionic gonadotropin (hCG) are indicated for the following:[1-3]

- **Prepubertal cryptorchidism** not due to anatomical obstruction. hCG is thought to induce testicular descent in situations when descent would have occurred at puberty. hCG may help predict whether or not orchiopexy will be needed in the future. In most cases, descent following hCG use is temporary, but in some instances, the descent is permanent. hCG therapy is usually initiated in children between the ages of 4 and 9 years.
- Selected cases of **hypogonadotropic hypogonadism in males** (hypogonadism 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 menotropins.

Of note, these hCG products are not indicated for use in assisted reproductive technology (ART)-programs, though they have been consistently used and studied for this indication.

Dosing and Availability

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

Detail	Pregnyl, Novarel, chorionic gonadotropin
Formulation type	Urine-derived
Administration	IM only
Dosing	**Prepubertal cryptorchidism dosing options*:** • 4,000 USP units TIW for 3 weeks. • 5,000 USP units every second day for four 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 2,000 USP units TIW for an additional 3 months. **OI dosing:*** is 5,000 to 10,000 USP units one day following the last dose of menotropins (A dosage of 10,000 USP units is recommended in the labeling for menotropins).
Availability	**Pregnyl:** 10,000 USP units/vial of hCG. **Novarel:** 5,000 USP units/vial, 10,000 USP units/vial of hCG. **Chorionic gonadotropin:** 10,000 USP units/vial of hCG.
Storage	**Pregnyl:** Store at room temperature. Reconstituted solution is stable for 60 days when refrigerated. **Novarel:** Store at room temperature. Use reconstituted product within 30 days when refrigerated. **Chorionic gonadotropin:** Store at room temperature. Reconstituted solution is stable for 60 days when refrigerated.

IM – Intramuscular; * 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 are from the prescribing information; TIW – Three times a week; OI – Ovulation induction; hCG – human chorionic gonadotropin.

Of note, there is another chorionic gonadotropic, Ovidrel® (choriogonadotropin alfa injection [recombinant]), which is also indicated for ovulation induction. Additionally, it is indicated for 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 hormone as part of an ART program. It is not targeted by this quantity management policy.

References

1. Novarel® intramuscular injection [prescribing information]. Parsippany, NJ: Ferring; November 2020.
2. Pregnyl® intramuscular injection [prescribing information]. Whitehouse Station, NJ: Merck; June 2022.
3. Chorionic gonadotropin for intramuscular injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; April 2020.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	09/22/2022