UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 1040-9
Program	Prior Authorization/Notification
Medication	Novarel® (chorionic gonadotropin) †, Ovidrel® (choriogonadotropin alfa) †, and Pregnyl® (chorionic gonadotropin)*
P&T Approval Date	5/2013, 5/2014, 5/2015, 5/2016, 5/2017, 5/2018, 5/2019, 8/2019, 8/2020
Effective Date	11/1/2020; Oxford only: N/A

1. Background:

The body produces two types of gonadotropins, follicle-stimulating hormone (FSH) and luteinizing hormone (LH), both of which play a role in fertility and human reproduction. After they are produced by the pituitary gland, gonadotropins trigger production of other sex hormones which then promote production of egg and sperm. Produced in pregnant women by the placenta and extracted from the urine, human chorionic gonadotropin (hCG) is similar in chemical structure and function to LH.[1-3]

hCG is routinely used to trigger ovulation in the treatment of infertility, a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse or therapeutic donor insemination.[1-3]

hCG may also be used to treat cryptorchidism in boys because hCG is thought to induce testicular descent in situations when descent would have occurred at puberty. hCG thus may help to predict whether or not orchiopexy will be needed in the future. Although, in some cases, descent following hCG administration is permanent, in most cases the response is temporary. hCG is also used to induce puberty in boys and to treat androgen deficiency in hypogonadotropic hypogonadism. However, the major use of hCG preparations in males is in the initiation and maintenance of spermatogenesis in hypogonadotropic men who desire fertility.[1-3]

Novarel (chorionic gonadotropin)† and Pregnyl (chorionic gonadotropin) are indicated for 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. They are also indicated for prepubertal cryptorchidism not due to anatomic obstruction and selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males.[4,5]

Ovidrel (choriogonadotropin alfa) † is indicated for the 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. It is also indicated for the induction of ovulation and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure.[6]

2. Coverage Criteria:

A. Ovulation Induction

1. Novarel†, Ovidrel†, or **Pregnyl** will be approved based on **all** of the following criteria*:

a. Diagnosis of anovulatory infertility

-AND-

b. Infertility is not due to primary ovarian failure

-AND-

c. For induction of ovulation

-AND-

d. Patient has been pre-treated with a follicular stimulating agent (e.g., gonadotropin, clomiphene citrate, letrozole)

Authorization will be issued for 2 months.

B. Controlled Ovarian Hyperstimulation

1. Novarel†, Ovidrel†, or **Pregnyl** will be approved based on **all** of the following criteria*:

a. Diagnosis of infertility

-AND-

b. For the development of multiple follicles (controlled ovarian hyperstimulation)

-AND-

c. Patient has been or will be pre-treated with a follicular stimulating agent (e.g., gonadotropin, clomiphene citrate, letrozole)

Authorization will be issued for 2 months.

C. Prepubertal Cryptorchidism

1. Novarel†, Ovidrel†, or **Pregnyl** will be approved based on the following criterion*:

a. Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction

Authorization will be issued for 6 weeks.

D. Hypogonadotropic Hypogonadism

1. Initial Authorization

a. **Novarel**†**, Ovidrel**†**,** or **Pregnyl** will be approved based on **all** of the following criteria*:

(1) Diagnosis of hypogonadism secondary to pituitary deficiency

-AND-

(2) Low testosterone (below normal reference level provided by the physician's laboratory)

-AND-

(3) **One** of the following:

(a) Low LH (below normal reference level provided by the physician's laboratory)
(b) Low FSH (below normal reference level provided by the physician's laboratory)

Authorization will be issued for 12 months.

2. Reauthorization

a. Novarel†**, Ovidrel**†**,** or **Pregnyl** will be approved based on the following criterion*:

(1) Documentation of positive clinical response to therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limitations may also be in place.
- Exclusion: †human chorionic gonadotropin (generic), Novarel and Ovidrel are excluded from coverage for the majority of our benefits.

*Infertility is typically excluded from coverage for UnitedHealthcare. Please refer to member's specific benefits for coverage determination.

4. References:

1. World Health Organization web site. http://www.who.int/reproductivehealth/topics/infertility/definitions/en/index.html. Accessed March 30, 2019.
2. American Society for Reproductive Medicine. Definitions of infertility and recurrent pregnancy loss: a committee opinion. Fertil Steril 2013;Jan;99(1):63
3. Petak SM, Nankin HR, Spark RF, Swerdloff RS, Rodriguez-Rigau LJ. 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;8:440-456.
4. Novarel [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; May 2018.
5. Pregnyl [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2015.
6. Ovidrel [package insert]. Rockland, MA: EMD Serono, Inc.; June 2018.

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Change Control	
5/2014	Annual review. No changes to the criteria. References updated.
5/2015	Annual review. No changes to the criteria. Updated background and references.
5/2016	Annual review. No changes to the criteria. Updated references.
5/2017	Annual review. No changes to the criteria. Updated references.
5/2018	Annual review. No changes to the criteria. Updated references.
5/2019	Annual review. No changes to the criteria. Updated references.
8/2019	Indicated that human chorionic gonadotropin (generic), Novarel and Ovidrel are excluded from coverage for the majority of our benefits.
8/2020	Annual review. No changes to the criteria.