SPECIALTY GUIDELINE MANAGEMENT

Human Chorionic gonadotropin (hCG) and Choriogonadotropin alfa

NOVAREL (chorionic gonadotropin)
PREGNYL (chorionic gonadotropin)
OVIDREL (Choriogonadotropin alfa)

POLICY

A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
- Novarel/Pregnyl
  - Ovulation induction
  - Hypogonadotropic hypogonadism in males
- Ovidrel
  - Ovulation induction
  - Stimulation of final follicular maturation and early luteinization for ART

Compendial Uses
- Novarel/Pregnyl
  - Stimulation of final follicular maturation and early luteinization for ART
  - Luteal phase support
- Ovidrel
  - Hypogonadotropic hypogonadism in males
  - Luteal phase support

All other indications are considered experimental/investigational and are not a covered benefit.

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
- For female members
  - Documentation of assisted reproductive technology (ART) type (e.g., in vitro fertilization (IVF), zygote intra-fallopian transfer (ZIFT), gamete intra-fallopian transfer (GIFT), tubal embryo transfer (TET))

C. EXCLUSIONS
- For male members
  - Uncontrolled thyroid or adrenal dysfunction
  - Uncontrolled organic intracranial lesion, such as a pituitary tumor
  - Prostatic carcinoma or other androgen-dependent neoplasm
- For female members
  - Primary ovarian failure
  - Uncontrolled thyroid or adrenal dysfunction
  - Uncontrolled organic intracranial lesion, such as a pituitary tumor
  - Sex hormone dependent tumors of the reproductive tract and accessory organs
  - Abnormal uterine bleeding of undetermined origin
  - Clinically significant ovarian cysts or enlargement of undetermined origin
  - Pregnancy
D. CRITERIA FOR APPROVAL
1. Hypogonadotropic hypogonadism
   Authorization of 12 months may be granted for male members for the treatment of hypogonadotropic hypogonadism.

2. Prepubertal cryptorchidism
   Authorization of 6 months may be granted for male members for the treatment of prepubertal cryptorchidism.

3. Part of ART program
   Authorization of 12 months may be granted for female members when the following criteria are met:
   i. The members will be pretreated with an appropriate follicle stimulating agent.
   ii. When the therapy is continued during the luteal phase, the therapy will be withheld if there are risk factors or evidence of ovarian hyperstimulation syndrome (OHSS).

4. Ovulation induction
   Authorization of 12 months may be granted for female members when the therapy is continued during the luteal phase, the therapy will be withheld if there are risk factors or evidence of OHSS.

E. CONTINUATION OF THERAPY
   All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

F. DOSAGE AND ADMINISTRATION
   Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

   1. Dosing Limits
      The following dosing limits apply:
      • Ovidrel: 250 mcg per day for all approvable indications
      • Novarel/Pregnyl
         o Hypogonadotropic hypogonadism: 12,000 U per WEEK
         o Prepubertal cryptorchidism: 20,000 U per WEEK
         o Part of ART program/Ovulation induction: 10,000 U per day

REFERENCES