

POLICY: Chorionic Gonadotropins Benefit Exclusion Overrides Policy

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

EFFECTIVE DATE: 1/1/2021

LAST REVISION DATE: 10/9/2024

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

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

- **Prepubertal cryptorchidism** not due to anatomical obstruction.
- Selected cases of **hypogonadotropic hypogonadism** (hypogonadism secondary to a pituitary deficiency) in males.
- **Induction of ovulation and pregnancy** in anovulatory, infertile patients in whom the cause of anovulation is secondary and not due to primary ovarian failure and who have been appropriately pretreated with human menopausal gonadotropins.

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 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.

Obesity

The prescribing information for Novarel and Pregnyl notes that human chorionic gonadotropin (hCG) has not been demonstrated to be an effective adjunctive therapy in the treatment of obesity.^{1,2} There are no data to suggest that hCG increases weight loss beyond that resulting from caloric restriction. Although preliminary data from several decades ago suggested weight loss and change in body fat distribution when hCG was combined with dietary caloric restriction,^{1,2,5} further evidence did not demonstrate benefit of hCG injections.^{6,7} A meta-analysis of 24 studies (16 controlled trials, 8 uncontrolled) evaluating hCG use for the treatment of obesity concluded that there is no scientific evidence that hCG causes weight loss or redistribution of fat, reduces hunger, or induces a feeling of well-being.⁶

POLICY STATEMENT

This Benefit Exclusion Overrides policy has been developed to authorize coverage of the targeted drugs for all uses, except infertility and obesity, if clinically appropriate. This Benefit Exclusion Overrides policy is not applicable if clients have infertility as a covered benefit. Coverage is also excluded for obesity since clinical data are lacking for this indication and there is a potential for misuse. All approvals are provided for the duration noted below.

CLINICAL REVIEW

If use is for an indication other than infertility or weight loss, a clinical review will be completed to confirm use is for and FDA approved or Compendia supported indications. The following compendia sources will be reviewed for the indication of the requested medication to determine use for a medically accepted indication:

- FDA prescribing information
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - Accepted if the indication is Category 1 or 2A
- Micromedex Drugdex[®] Evaluations
 - Accepted if the indication is Class I, Class IIa, or Class IIb
- American Hospital Formulary Service-Drug Information (AHFS-DI) (accessed via LexiComp)
 - Accepted if the narrative text for the indication is supportive
- Clinical Pharmacology
 - Accepted if the narrative text for the indication is supportive
- Lexi-Drugs
 - Accepted if the indication is listed as “Use: Off-Label” and rated as “Evidence Level A”

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of chorionic gonadotropins is recommended in those who meet the following criteria:

- 1. Medical Indications Other than Infertility and Obesity.** Approve for 1 year if the requested product is being used for an acceptable medical indication per the compendia sources listed above under Clinical Review.

EXCLUSIONS

Coverage of chorionic gonadotropins is not recommended in the following situations.

- 1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Pregnyl[®] intramuscular injection [prescribing information]. Jersey City, NJ: Organon; June 2023.

2. Novarel® intramuscular injection [prescribing information]. Parsippany, NJ: Ferring; May 2023.
3. Chorionic gonadotropin intramuscular injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; February 2016.
4. Ovidrel® subcutaneous injection [prescribing information]. Rockland, MA: EMD Serono; June 2018.
5. Yen M, Ewald MB. Toxicity of weight loss agents. *J Med Toxicol.* 2012;8:145-152.
6. Lijesen GK, Theeuwes I, Assendelft WJJ, et al. The effect of human chorionic gonadotropin (HCG) in the treatment of obesity by means of the Simeons therapy: a criteria-based meta-analysis. *Br J Clin Pharmacol.* 1995;40:237-243.
7. Lovejoy JC, Sasagawa M. An unfortunate resurgence of human chorionic gonadotropin use for weight loss. Commentary. *Int J Obes.* 2012;36:385-386.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/19/2022
Annual Revision	No criteria changes.	11/01/2023
UCare Revision	Updating to a custom UCare policy. No criteria changes.	9/11/2024
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024
Aspirus Revision	Aspirus updated to include assessment for FDA approved or compendia supported indications not otherwise excluded from the benefit prior to approval	10/9/2024