Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Gonadotropins and Antigonadotropins**

Effective: June 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) – Approved Indications

Cetrotide (cetrorelix)

- Inhibition of premature luteinizing hormone surges in women undergoing controlled ovarian stimulation

Fyremadel (ganirelix acetate)

- Inhibition of premature luteinizing hormone surges in women undergoing controlled ovarian hyperstimulation

Ganirelix

- Inhibition of premature luteinizing hormone surges in women undergoing controlled ovarian hyperstimulation

Gonal-F (follitropin alfa)

- Induction of ovulation and pregnancy oligoanovulatory women in whom the cause of infertility is functional and not due to primary ovarian failure
- Development of multiple follicles in ovulatory women as part of an Assisted Reproductive Technology cycle
- Induction of spermatogenesis in infertile men with primary and secondary hypogonadotropic hypogonadism for whom the cause of infertility is not due to primary testicular failure

***Note: Gonal-F is the preferred follicle stimulating hormone agonist. Follistim AQ (follitropin beta) is a non-preferred follicle stimulating hormone agent and should be reviewed against Non-Formulary Exceptions coverage criteria*.**

Menopur (menotropins)

- Development of multiple follicles and pregnancy in ovulatory women as part of an Assisted Reproductive Technology cycle

Novarel (chorionic gonadotropin)

- Prepubertal cryptorchidism not due to anatomic obstruction
- Selected cases of hypogonadotropic hypogonadism in males
- 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.

Ovidrel (choriogonadotropin)

- 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.

Pregnyl (chorionic gonadotropin)

- Prepubertal cryptorchidism not due to anatomic obstruction
- Selected cases of hypogonadotropic hypogonadism in males

- 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.

Clinical Guideline Coverage Criteria

Note: *Utilization of gonadotropins and antigonatropins for infertility services is not managed by a Prior Authorization Policy, but rather based on whether an individual's benefit includes infertility coverage. If the individual's benefit includes infertility coverage, the following coverage criteria apply.*

Gonadotropin Therapy for Infertility

The plan may authorize coverage of Cetrotide, cetrorelix acetate, generic chorionic gonadotropin, Fyremadel, Ganirelix, Gonal-F, Menopur, Novarel, Ovidrel, or Pregnyl for Members when **ALL** of the following criteria are met:

1. The patient has been approved for infertility services through a medical authorization with the Plan

Gonadotropin Dispensing Guidelines for Infertility

The plan's Designated Specialty Pharmacies will dispense gonadotropins in accordance with the following Dispensing Guidelines. In cases where a Member requires doses outside of these limits, the prescriber must indicate, to the Specialty Pharmacy, the reason why the dose limit is to be exceeded.

Gonadotropin dosing within any given cycle should remain within the following limits:

- Intrauterine insemination (IUI): 1800 IU per cycle
- In vitro fertilization (IVF): 3600 IU per cycle

Dispensing Guidelines

Procedure	Maximum Number of Gonadotropin Units		
	Initial Fill	Refill	Per Cycle
IUI	1800 IU	N/A	1800 IU
IVF	2700 IU	900 IU	3600 IU

Menotropin Dispensing Guidelines for Infertility

The plan's Designated Specialty Pharmacies will dispense menotropins in accordance with the following Dispensing Guidelines. In cases where a Member requires doses outside of these limits, the prescriber must indicate, to the Specialty Pharmacy, the reason why the dose limit is to be exceeded.

Dispensing Guidelines

Procedure	Maximum Number of Gonadotropin Units	
	Initial Fill	Refill
Menopur	900 IU	900 IU

Note: *Utilization of gonadotropins and antigonatropins for FDA-approved indications unrelated to infertility use is managed by a Prior Authorization Policy with the following coverage criteria.*

Hypogonadotropic Hypogonadism, Prepubertal Cryptorchidism

The plan may authorize coverage of Novarel or Pregnyl for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of **ONE (1)** of the following:
    a. Hypogonadotropic hypogonadism secondary to pituitary deficiency
    b. Prepubertal cryptorchidism secondary to organic dysfunction

AND

2. Prescribed by or in consultation with an endocrinologist or urologist

Limitations

1. For the diagnosis of Infertility, approved medications will be for up to seven (7) months.
2. For the diagnosis of Prepubertal Cryptorchidism, Novarel and Pregnyl will be authorized for six (6) weeks.
3. For the diagnosis of Hypogonadotropic Hypogonadism, Novarel and Pregnyl will be authorized for 12 months.
4. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Point32Health Medical Necessity Guidelines: Assisted Reproductive Technology Services – Massachusetts Products.
2. Point32Health Medical Necessity Guidelines: Assisted Reproductive Technology Services – Rhode Island Products.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- January 10, 2023: Administrative update to add Fyremadel and cetrorelix acetate to guideline and add referenced to Medical Benefit MNG: Assisted Reproductive Technology Services.
- January 9, 2024: No changes
- January 14, 2025: No changes (eff 1/14/25)
- May 12, 2026: Effective June 1, 2026, added indication for Gonal-F: Induction of spermatogenesis in infertile men with primary and secondary hypogonadotropic hypogonadism for whom the cause of infertility is not due to primary testicular failure. Template updated to remove CareLink from the Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.