
Prior Authorization DRUG Guidelines

Gonal F
(follitropin alfa)

Effective Date: May 2, 2023

Date Developed: 5/2/23 by H.Tackman, MD

Last Approval Date: 5/2/2023

Gonal F is a follicle-stimulating hormone (FSH) used to treat infertility in both men and women. It is used to stimulate the production of eggs in women and sperm in men. The drug is administered through injection and should be prescribed and monitored by a fertility specialist.

Indication: Treatment of infertility in both men and women

Dosage Form: Injection

Pre-Authorization Criteria:

To ensure appropriate use and monitoring of Gonal F, the following criteria must be met for prior authorization:

1. Female patients:
 - Diagnosis of infertility due to anovulation or poor ovarian reserve
 - Prior authorization request must include a detailed description of the patient's infertility evaluation and treatment plan, including Gonal F dose and duration of treatment.
 - Treatment is performed by a qualified fertility specialist.
 - Documentation of the patient's thyroid and adrenal function
 - Documentation of the patient's prior response to fertility treatments, if applicable
2. Male patients:
 - Diagnosis of infertility due to hypogonadotropic hypogonadism
 - Prior authorization request must include a detailed description of the patient's infertility evaluation and treatment plan, including Gonal F dose and duration of treatment.
 - Treatment is performed by a qualified fertility specialist.
 - Documentation of the patient's prior response to testosterone replacement therapy, if applicable

Approve Gonal F for one year or until conception (for females).

Gonal F is covered under the health plan when the above criteria are met and prior authorization is granted.

NOTE: For purposes of the Plan, infertility is defined as the following:

- 1) Women aged 35 and younger: Failure to conceive after no less than 12 months of unprotected intercourse, or the inability to carry a pregnancy to term. [CHSC 1374.55 (b)]
- 2) Women older than 35: Failure to conceive after no less than 6 months of unprotected intercourse, or the inability to carry a pregnancy to term. [CHSC 1374.55 (b)]

[Ref: VCHCP Medical Policy: Infertility: Treatment of]

References:

1. American Society for Reproductive Medicine (ASRM). (2021). Guidelines: Clinical management of infertility. <https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/clincial-management-of-infertility.pdf>
2. Food and Drug Administration. (2020). Gonal-F (follitropin alfa) injection, for subcutaneous use. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/020097s051lbl.pdf
3. Stanford Health Care. (2021). Prior authorization requirements for medical drugs. <https://stanfordhealthcare.org/medical-clinics/pharmacy-services/prior-authorization-requirements-for-medical-drugs.html>

Revision History:

Date Reviewed/Created: 5/2/23 by H. Taekman, MD

Date Approved by P&T Committee: 5/2/23.

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
5/2/23	N/A	Howard Taekman, MD; Robert Sterling, MD	New