

Prior Authorization DRUG Guidelines

Gonal F

(follitropin alfa)

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

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Follitropin alfa is a human FSH preparation of recombinant DNA origin used to treat infertility in both men and women. Follitropins stimulate ovarian follicular growth in women who do not have primary ovarian failure and stimulate spermatogenesis in men with hypogonadotropic hypogonadism. FSH is required for normal follicular growth, maturation, gonadal steroid production, and spermatogenesis.

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

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]

Dosing:

Ovulation induction: SubQ: Initial: 75 units daily for 14 days in the first cycle; incremental dose adjustments of up to 37.5 units may be considered after 14 days based on ovarian response; further dose increases of the same magnitude can be made, if necessary, every 7 days (maximum dose: 300 units daily). Treatment should be continued until follicular growth and/or serum estradiol levels indicate an adequate ovarian response. If response to follitropin is appropriate, human chorionic gonadotropin (hCG) is given 1 day following the last dose to induce final oocyte maturation and ovulation. Follow current clinical practice to reduce the risk of ovarian hyperstimulation syndrome. In general, therapy should not exceed 35 days. Approve Gonal F for one year or until conception.

Spermatogenesis induction: SubQ: Therapy should begin with hCG pretreatment until serum testosterone is in normal range, then initiate follitropin alfa at 150 units 3 times weekly with hCG 3 times weekly; continue with lowest dose needed to induce spermatogenesis (maximum dose: 300 units 3 times weekly); may be given for up to 18 months.

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/2020/020097s0511bl.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>
4. Shmorgun D, Claman P. No-268-The diagnosis and management of ovarian hyperstimulation syndrome. J Obstet Gynaecol Can. 2017;39(11):e479-e486.
5. Gonal-f for injection (follitropin alfa) [prescribing information]. Rockland, MA: EMD Serono, Inc; February 2020
6. Petak SM, Nankin HR, Spark RF, Swerdloff RS, Rodriguez-Rigau LJ; American Association of Clinical Endocrinologists. 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(6):440-456.
7. Corbett S, Shmorgun D, Claman P, et al; Reproductive Endocrinology Infertility Committee. The prevention of ovarian hyperstimulation syndrome. J Obstet Gynaecol Can. 2014;36(11):1024-1033.

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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
5/2/23	N/A	Howard Taekman, MD; Robert Sterling, MD	New
2/13/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Replaced definition of Gonal F with Follitropin Alfa. Dosing information added.