Reference number(s)
1914-A, 1915-A

Specialty Guideline Management Follitropins

Hereafter, follitropin will be used to describe all products.

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Follistim AQ	follitropin beta
Gonal-F	follitropin alfa

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[1-5]

Follistim AQ is indicated for:

- Induction of ovulation and pregnancy in anovulatory infertile women in whom the cause of infertility is functional and not due to primary ovarian failure
- Pregnancy in normal ovulatory women undergoing controlled ovarian stimulation as part of an in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) cycle
- Induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism (HH) in whom the cause of infertility is not due to primary testicular failure

Gonal-F is indicated for:

- Induction of ovulation and pregnancy in oligio-anovulatory women in whom the cause of infertility is functional and not due to primary ovarian failure

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- Development of multiple follicles in ovulatory women as part of an assisted reproductive technology (ART) cycle
- Induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure

All other indications are considered experimental/investigational and not medically necessary.

Medical Benefit Alignment

Specialty Guideline Management coverage review will be bypassed for drug(s) being requested for a procedure that has been approved under a member's medical benefit plan. Such members will be exempt from the requirements in the coverage criteria. A medical authorization number and confirmation of the approved procedure(s) will be required.

NOTE: Some plans may opt-out of medical benefit alignment. Members receiving coverage under such plans must meet the requirements in the coverage criteria.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Hypogonadotropic Hypogonadism

Chart notes, medical record documentation, or laboratory results to support pretreatment morning serum total testosterone levels, and either follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels.

Coverage Criteria

Follicle Stimulation[1-7]

Authorization of 12 months may be granted for members undergoing ovulation induction or assisted reproductive technology (ART) who meet any of the following criteria:

- Member has completed three or more previous cycles of clomiphene or letrozole.
- Member has a risk factor for poor ovarian response to clomiphene or letrozole.
- Member has a contraindication or exclusion to clomiphene or letrozole.
- Member is 37 years of age or older.

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Hypogonadotropic Hypogonadism[1,2,8-12]

Authorization of 12 months may be granted for treatment of hypogonadotropic hypogonadism in members who meet all of the following criteria:

- Member will be using the requested medication for the induction of spermatogenesis.
- Member has at least two confirmed low pretreatment serum total testosterone levels based on the reference laboratory range or current practice guidelines, taken in the morning on separate days.
- Member has low or low to normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

References

1. Follistim AQ Cartridge [package insert]. Jersey City, NJ: Organon USA LLC.; February 2026.
2. Gonal-f Multi-Dose [package insert]. Boston, MA: EMD Serono, Inc.; March 2025.
3. Gonal-f RFF [package insert]. Boston, MA: EMD Serono, Inc.; November 2023.
4. Gonal-f RFF Redi-ject [package insert]. Boston, MA: EMD Serono, Inc.; April 2025.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 05/14/2026).
6. Practice Committee of the American Society for Reproductive Medicine. Evidence-based treatments for couples with unexplained infertility: a guideline. Fertil Steril. 2020;113(2):305-322.
7. American College of Obstetricians and Gynecologists Committee on Gynecologic Practice and Practice Committee. Female age-related fertility decline. Committee Opinion No. 589. Fertil Steril. 2014;101(3):633-634.
8. Petak SM, Nankin HR, Spark RF, Swerdloff RS, Rodriguez-Rigau LJ. 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;8:439-456.
9. Schlegel PN, Sigman M, Collura B, et al. Diagnosis and treatment of infertility in men: AUA/ASRM guideline part I. Fertil Steril. 2021;115(1):54-61.
10. Schlegel PN, Sigman M, Collura B, et al. Diagnosis and treatment of infertility in men: AUA/ASRM guideline part II. Fertil Steril. 2021;115(1):62-69.
11. Bhasin S, Brito JP, Cunningham GR, et al Testosterone Therapy in Men With Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018;103(5):1715-1744.

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12. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and management of testosterone deficiency: AUA guideline. J Urol. 2018;200(2):423-432.

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