

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

SPECIALTY GUIDELINE MANAGEMENT

FOLLISTIM AQ (follitropin beta injection) GONAL-F (follitropin alfa injection)

*Hereafter, follitropin will be used to describe all products

POLICY

I. 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.

A. FDA-Approved Indications

Follistim AQ is indicated for:

1. Induction of ovulation and pregnancy in anovulatory infertile women in whom the cause of infertility is functional and not due to primary ovarian failure
2. Development of multiple follicles in ovulatory women participating in an assisted reproductive technology (ART) program
3. Pregnancy in normal ovulatory women undergoing controlled ovarian stimulation as part of an in vitro fertilization or intracytoplasmic sperm injection cycle
4. Induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure

Gonal-f is indicated for:

1. Induction of ovulation and pregnancy in the anovulatory infertile patient in whom the cause of infertility is functional and not due to primary ovarian failure.
2. Development of multiple follicles in the ovulatory patient participating in an ART program.
3. Induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.

B. Compendial Uses

Hypogonadotropic hypogonadism in males

All other indications are considered experimental/investigational and are not a covered benefit.

II. 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 Sections III and IV. 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 Sections III and IV.

III. CRITERIA FOR INITIAL APPROVAL

A. Follicle stimulation

Authorization of 12 months may be granted for members with infertility prescribed follitropin who meet any of the following criteria:

1. Member has completed three or more previous cycles of clomiphene, or

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2. Member has a risk factor for poor ovarian response to clomiphene, or
3. Member has a contraindication or exclusion to clomiphene, or
4. Member is 37 years of age or older

B. Hypogonadotropic hypogonadism

Authorization of 12 months may be granted for members prescribed follitropin for hypogonadotropic hypogonadism who meet both of the following criteria:

1. Low pretreatment testosterone levels
2. Low or low-normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. REFERENCES

1. Follistim AQ [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; December 2013.
2. Follistim AQ Cartridge [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; December 2014.
3. Gonal-f Multi-Dose [package insert]. Rockland, MA: EMD Serono, Inc.; December 2012.
4. Gonal-f RFF [package insert]. Rockland, MA: EMD Serono, Inc.; October 2013.
5. Gonal-f RFF Redi-ject [package insert]. Rockland, MA: EMD Serono, Inc.; January 2014.
6. DRUGDEX System (electronic version). Truven Health Analytics, Greenwood Village, CO. Available at: <http://www.micromedexsolutions.com>. Accessed May 22, 2017.
7. Practice Committee of the American Society of Reproductive Medicine. Use of clomiphene citrate in infertile women: a committee opinion. *Fertil & Steril*. 2013;100:341-348.
8. 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.