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. Pregnancy in normal ovulatory women undergoing controlled ovarian stimulation as part of an in vitro fertilization or intracytoplasmic sperm injection (ICSI) cycle
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

Gonal-f is indicated for:

1. Induction of ovulation and pregnancy in oligio-anovulatory women in whom the cause of infertility is functional and not due to primary ovarian failure.
2. Development of multiple follicles in ovulatory women as part of an Assisted Reproductive Technology (ART) cycle.
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.

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

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 IV and V. 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 IV and V.

III. DOCUMENTATION

The following information is necessary to initiate the prior authorization review for hypogonadotropic hypogonadism: testosterone, FSH, and LH levels.

IV. CRITERIA FOR INITIAL APPROVAL

A. Follicle stimulation

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

1. Member has completed three or more previous cycles of clomiphene, or
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 treatment of hypogonadotropic hypogonadism in members 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

V. CONTINUATION OF THERAPY

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

VI. REFERENCES

1. Follistim AQ Cartridge [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2020.
2. Gonal-f Multi-Dose [package insert]. Rockland, MA: EMD Serono, Inc.; December 2020.
3. Gonal-f RFF [package insert]. Rockland, MA: EMD Serono, Inc.; December 2020.
4. Gonal-f RFF Redi-ject [package insert]. Rockland, MA: EMD Serono, Inc.; February 2020.
5. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/ Accessed: May 2, 2022.
6. Practice Committee of the American Society for Reproductive Medicine. Evidence-based treatments for couples with unexplained infertility: a guideline. *Fertil & Steril.* 2019. 113(2):305-322.
7. 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.