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.

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#### 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:

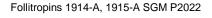
- 1. Low pretreatment testosterone levels
- 2. Low or low-normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels

## 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.



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