SPECIALTY GUIDELINE MANAGEMENT

FOLLISTIM AQ (follitropin beta injection)
BRAVELLE (urofollitropin for injection)
GONAL-F (follitropin alfa injection)
*Hereafter, follitropin will be used to describe all three 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

Bravelle is indicated for:
1. Induction of ovulation in women who have previously received pituitary suppression
2. Development of multiple follicles as part of an ART cycle in ovulatory women who have previously received pituitary suppression

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. REQUIRED DOCUMENTATION

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

III. CRITERIA FOR INITIAL APPROVAL

A. Ovulation induction or Follicle stimulation as part of an assisted reproductive technology (ART) program

Authorization of 12 months may be granted for members with infertility prescribed follitropin for ovulation induction or follicle stimulation as part of an ART program 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 (eg, poor ovarian reserve, previous ovarian surgery), or
3. Member has a contraindication or exclusion to clomiphene (eg, male factor infertility, tubal factor infertility, previous trial and failure of letrozole), 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 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. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

VI. REFERENCES