SPECIALTY GUIDELINE MANAGEMENT

Follistim AQ (follitropin beta injection)
Bravelle (urofollitropin for injection)
Gonal-F (follitropin alfa for injection)

*Hereafter, follitropin will be used to describe all three products

POLICY
A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Follistim AQ is indicated:
- For induction of ovulation and pregnancy in anovulatory infertile women in whom the cause of infertility is function and not due to primary ovarian failure
- Development of multiple follicles in ovulatory women participating in an assisted reproductive technology (ART) program
- For pregnancy in normal ovulatory women undergoing controlled ovarian stimulation as part of an in vitro fertilization or intracytoplasmic sperm injection cycle
- For 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 induction of ovulation in women who have previously received pituitary suppression
- For development of multiple follicles as part of an assisted reproductive technology cycle in ovulatory women who have previously received pituitary suppression

Gonal-F is indicated:
- For 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
- For the development of multiple follicles in the ovulatory patient participating in an assisted reproductive technology program
- For the 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 are not covered benefits.

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
Ovarian stimulation: Documentation of the type of procedure to be performed

Hypogonadotropic hypogonadism: Testosterone, FSH, and LH levels

C. CRITERIA FOR APPROVAL
1. Ovarian Stimulation For Ovulation Induction Or As Part Of An Assisted Reproductive Technology Procedure
   a. Authorization of 12 months may be granted for female members prescribed follitropin for ovarian stimulation for ovulation induction or as part of an assisted reproductive technology procedure who meet ONE of the following criteria:
      i. The member is 37 years of age or older
      ii. The member has completed three previous cycles of Clomid (clomiphene citrate)
iii. The member has a risk factor for poor ovarian response to Clomid (e.g., previous ovarian surgery, poor ovarian reserve)

iv. The member has a contraindication or exclusion to Clomid (e.g., male factor infertility, previous trial of letrozole, tubal factor infertility)

2. Hypogonadotropic Hypogonadism
   
   a. Authorization of 12 months may be granted for male members prescribed follitropin for hypogonadotropic hypogonadism who meet all of the following criteria:
      i. The member has low testosterone levels
      ii. The member has low or low-normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels

D. CONTINUATION OF THERAPY

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

E. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Ovarian stimulation

- Follistim AQ Cartridge: 7000 IU/month
- Follistim AQ: 8400 IU/month
- Bravelle: 6300 IU/month
- Gonal-F: 6300 IU/month

Hypogonadotropic hypogonadism

- Follistim AQ Cartridge: 450 IU/week
- Follistim AQ: 450 IU/week
- Bravelle: 450 IU/week
- Gonal-F: 900 IU/week

REFERENCES