



## Prior Authorization Approval Criteria

### *Gonal-F, Follistim AQ (follitropin)*

<b>Generic name:</b>	follitropin
<b>Brand name:</b>	Gonal-F, Follistim AQ
<b>Medication class:</b>	Fertility
<b>FDA-approved uses:</b>	Indicated for the development of multiple follicles in ovulatory patients participating in Assisted Reproductive Technology (ART) program. Also indicated for the induction of ovulation and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure.
<b>Available dosage forms:</b>	Gonal-F: 75 IU vial, 450 IU MDV, 1050 IU MDV, 300 IU (0.5ml pen), 450 IU (0.75ml pen), 900 IU (1.5ml pen) Follistim AQ: 75 IU (0.5ml vial), 150 IU (0.5ml vial), 300 IU (0.42 ml cartridge), 600 IU (0.78 ml cartridge), 900 IU (1.17ml cartridge)
<b>Usual dose:</b>	Intrauterine Insemination (IUI): 75 to 300 IU per day In Vitro Fertilization (IVF): 225 to 300 IU per day Note: Maximum daily dose from package insert is 450 IU; maximum daily dose used in studies is 600 IU

**Approximate cost:** Gonal-F 2700 IU (3 x 900 IU pens): \$4229  
(based on AWP 2010) Follistim AQ 2700 IU (3 x 900 IU pens): \$3942

**Duration of therapy:** 10-12 days

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must have an authorization for infertility procedures and services.
- Patient is being seen by an infertility specialist.
- The initial amount approved will not exceed\*:
  - Intrauterine Insemination (IUI): 1800 IU for a 10 day cycle
  - In Vitro Fertilization (IVF): 2700 IU for a 10 day cycle
  - Quantities over this limit may be approved if the patient is a poor responder as indicated by poor ovarian reserve:
    - Poor ovarian response in previous cycles (patients who required large doses of medication in the previous cycle but produced less than optimal number of oocytes and/or achieved relatively low estradiol levels.)
  - OR
  - Patient is likely to have a poor response based on pre-cycle assessment of ovarian reserve indicated by high FSH and high estradiol levels (see normal FSH and estradiol levels note below)
- Refills may be approved for more units or length of time, if supported by documentation from the patient's medical records that clearly indicates why there is a need for larger amounts/longer length of therapy :
  - Quantity approved will be on an as needed basis only
  - Follicle development must be less than optimal:
    - Follicle number is below 2
    - or
    - Follicle size is below 18mm
    - or

- Estradiol level is below 200pg/ml per co-dominant follicle
- Request for doses over 600 IU per day or longer than 14 days must be reviewed and approved by a medical director.
- In order to meet criteria for Follistim AQ, in addition to all of the above:
  - Patient must have a documented intolerance to Gonal-F.

**Contraindications:**

In women who exhibit:

- Prior hypersensitivity to recombinant hFSH products
- A high circulating FSH level indicating primary ovarian failure
- Uncontrolled thyroid or adrenal dysfunction
- Tumor of the ovary, breast, uterus, hypothalamus, or pituitary gland
- Pregnancy
- Heavy or irregular vaginal bleeding of undetermined origin
- Ovarian cysts or enlargement not due to polycystic ovary syndrome (PCOS)
- Hypersensitivity reactions to streptomycin or neomycin. Follistim AQ Cartridge may contain traces of these antibiotics and may cause hypersensitivity reactions in susceptible persons.

**Not approved if:**

- Patient does not meet the above stated criteria.
- Patient has any contraindications to the use of Gonal-F or Follistim AQ

**Notes:**

- FSH is often used as a gauge of ovarian reserve. Normal values are 3 – 20 mIU/ml. Pre-cycle level under 6 is excellent, 6-9 is good, 9-10 is fair, 10-13 is diminished, 13+ is very hard to stimulate.
- Normal Estradiol levels are 25 – 75 pg/ml. Pre-cycle levels on the lower end tend to be better for stimulating.

\* Based on an average dosing of 187 IU (IUI) and 262 IU (IVF) and average cycle lasting 10 days

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

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