POLICY Document for GONAL-F (follitropin alfa)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
FOLLICLE STIMULATING HORMONE (FSH) PRODUCTS

PREFERRED PRODUCT: GONAL-F

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the follicle stimulating hormone (FSH) products specified in this policy. Coverage for targeted product is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Targeted Follicle Stimulating Hormone Products

	Products
Preferred*	• **Gonal-f** (follitropin alfa)
Targeted	• **Follistim AQ** (follitropin beta)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for Follistim AQ is provided when the following criteria is met:

A. Member has had a documented inadequate response, contraindication, or intolerable adverse event to Gonal-f.

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Section 2: Clinical Criteria

Specialty Guideline Management Follitropins

Hereafter, follitropin will be used to describe all products.

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Follistim AQ	follitropin beta
Gonal-F	follitropin alfa

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.

FDA-approved Indications

- Follistim AQ is Indicated for:
  - Induction of ovulation and pregnancy in anovulatory infertile women in whom the cause of infertility is functional and not due to primary ovarian failure.
  - Pregnancy in normal ovulatory women undergoing controlled ovarian stimulation as part of an in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) cycle.
  - Induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism (HH) in whom the cause of infertility is not due to primary testicular failure.
- Gonal-f is indicated for:
  - Induction of ovulation and pregnancy in oligio-anovulatory women in whom the cause of infertility is functional and not due to primary ovarian failure.
  - Development of multiple follicles in ovulatory women as part of an Assisted Reproductive Technology (ART) cycle.
  - Induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.

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

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 the coverage criteria section. 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 the coverage criteria section.

Documentation

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

Coverage Criteria

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:

- Member has completed three or more previous cycles of clomiphene or letrozole
- Member has a risk factor for poor ovarian response to clomiphene or letrozole
- Member has a contraindication or exclusion to clomiphene or letrozole
- Member is 37 years of age or older

Hypogonadotropic Hypogonadism

Authorization of 12 months may be granted for treatment of hypogonadotropic hypogonadism in members who meet both of the following criteria:

- Member has low pretreatment testosterone levels
- Member has low or low to normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

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REFERENCES:

SECTION 1

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2. Gonal-f RFF [package insert]. Rockland, MA: EMD Serono, Inc.; November 2023.
3. Gonal-f RFF Redi-ject [package insert]. Rockland, MA: EMD Serono, Inc.; May 2024.
4. Follistim AQ Cartridge [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2020.

SECTION 2

1. Follistim AQ Cartridge [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; March 2023.
2. Gonal-f Multi-Dose [package insert]. Rockland, MA: EMD Serono, Inc.; December 2023.
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