VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

BRAVELLE™; FOLLISTIM® AQ; GONAL-F®; GONAL-F™ RFF (Follitropins)

Effective Date: 7/28/5

Date Developed: 07.14.05 by C. Wilhelmy MD

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Follitropins are Gonadotropin Ovulation Stimulators. Urofollitropin is a preparation of highly purified follicle-stimulating hormone (FSH) extracted from the urine of postmenopausal women. Follitropin alfa and follitropin beta are human FSH preparations of recombinant DNA origin. Follitropins stimulate ovarian follicular growth in women who do not have primary ovarian failure and stimulate spermatogenesis in men with hypogonadotrophic hypogonadism. FSH is required for normal follicular growth, maturation, gonadal steroid production, and spermatogenesis.

Pre-Authorization Criteria:

Urofollitropin (Bravelle™): **NO LONGER AVAILABLE IN U.S.**

Development of multiple follicles with assisted reproductive technologies (ART) in women who have previously received pituitary suppression.

Follitropin alfa (Gonal-f®, Gonal-f RFF); Follitropin beta (Follistim® AQ:

Females: Induction of ovulation in oligo-anovulatory infertile women in whom the cause of infertility is functional and not caused by primary ovarian failure; development of multiple follicles with assisted reproductive technologies (ART, e.g. in vitro fertilization, IVF)

Males: 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 only)

VCHCP requires that these medications be prescribed by an infertility specialist.

Coverage is Not Authorized For Non-FDA approved indications

MONITORING PARAMETERS — Monitor sufficient follicular maturation. This may be directly estimated by sonographic visualization of the ovaries and endometrial lining or measuring serum estradiol levels. The combination of both ultrasonography and measurement of estradiol levels is useful for monitoring for the growth and development of follicles and timing hCG administration.

Spermatogenesis: Monitor serum testosterone levels, sperm coun
DOSING: ADULTS – See Product literature

ADMINISTRATION — See packet insert.

CONTRAINDICATIONS — Hypersensitivity to follitropins or any component of the formulation; high levels of FSH indicating primary gonadal failure (ovarian or testicular); uncontrolled thyroid or adrenal dysfunction; the presence of any cause of infertility other than anovulation; tumor of the ovary, breast, uterus, hypothalamus, testis, or pituitary gland; abnormal vaginal bleeding of undetermined origin; ovarian cysts or enlargement not due to polycystic ovary syndrome; pregnancy

PRECAUTIONS — These medications should only be used by physicians who are thoroughly familiar with infertility problems and their management. To minimize risks, use only at the lowest effective dose. Monitor ovarian response with serum estradiol and vaginal ultrasound on a regular basis.

Multiple pregnancies have been associated with these medications, including triplet and quintuplet gestations. Advise patient of the potential risk of multiple births before starting the treatment.

Follistim® AQ: Contains trace amounts of neomycin and streptomycin. Must be administered using the Follistim Pen™; dose adjustment required when switching from powder for injection to solution for injection due to accuracy of pen device.

PATIENT EDUCATION — Discontinue immediately if possibility of pregnancy. Prior to therapy, inform patients of the following: Duration of treatment and monitoring required; possible adverse reactions; risk of multiple births.

References:

1. Gonal-f RFF Redi-ject for subcutaneous injection (follitropin alfa) [prescribing

information]. Rockland, MA: EMD Serono Inc; May 2024

2. Petak SM, Nankin HR, Spark RF, Swerdloff RS, Rodriguez-Rigau LJ; American Association of Clinical Endocrinologists. 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(6):440-456.

3. Shmorgun D, Claman P. No-268-The diagnosis and management of ovarian hyperstimulation syndrome. J Obstet Gynaecol Can. 2017;39(11):e479-e486. doi:10.1016/j.jogc.2017

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1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/1/18	No	Catherine Sanders, MD; Robert Sterling, MD	Archived – excluded from the Formulary effective 1/1/18
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2/13/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual Review
2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Added **"**Urofollitropin (Bravelle™). NO LONGER AVAILABLE IN U.S." Removed Indications & guidelines sections Updated monitoring parameters, dosing, precaution sections. References updated