

Reference number
2047-H

SPECIALTY QUANTITY LIMIT PROGRAM

FOLLITROPINS

I. PROGRAM DESCRIPTION

The initial limit is designed to allow a quantity sufficient for the most common uses of the medication. The recommended dosing parameters for all FDA-approved indications fall within the standard limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request.

II. COVERED QUANTITIES

Medication	Standard Limit	FDA-recommended dosing
Follitropin Beta (Follistim AQ) 75 unit vial	60 vials per 28 days	Ovulation induction: starting dose of 75 IU daily for at least 7 days, increased by 25 to 50 IU at weekly intervals until adequate ovarian response. Maximum daily dose of 300 IU. Assisted reproductive technology: starting dose of 150 to 225 IU daily for at least 4 days with subsequent doses adjusted based upon ovarian response. Maximum daily dose of 600 IU. Induction of spermatogenesis: 450 IU per week
Follitropin Beta (Follistim AQ) 300 unit cartridge	15 cartridges per 28 days	Ovulation induction: starting dose of 50 IU daily for at least 7 days, increased by 25 to 50 IU at weekly intervals until adequate ovarian response. Maximum daily dose of 250 IU. Controlled ovarian stimulation as part of an in vitro fertilization or intracytoplasmic sperm injection cycle: starting dose of 200 IU daily for at least 7 days with subsequent doses adjusted up or down based upon ovarian response. Maximum daily dose of 500 IU. Induction of spermatogenesis: 450 IU per week
Follitropin Beta (Follistim AQ) 600 unit cartridge	10 cartridges per 28 days	
Follitropin Beta (Follistim AQ) 900 unit cartridge	7 cartridges per 28 days	
Follitropin Alfa (Gonal-f) 450 units vial	10 vials per 28 days	Ovulation induction: first cycle starting dose of 75 IU daily with incremental adjustment of up to 37.5 IU after 14 days. If necessary, increase dose by same magnitude every 7 days (in general up to 35 days of treatment). The initial dose in
Follitropin Alfa (Gonal-f) 1050 units vial	6 vials per 28 days	

Medication	Standard Limit	FDA-recommended dosing
		<p>subsequent cycles is individualized based on prior response. Maximum daily dose of 300 IU.</p> <p>Assisted reproductive technology: starting dose of 150 IU per day until adequate follicular development (up to 10 days of therapy in most cases). In patients whose endogenous gonadotropin levels are suppressed, starting dose of 225 IU daily. Consider dose adjustment after 5 days based on response (adjust no more frequently than every 3-5 days by no more than 75-150 IU). Maximum daily dose of 450 IU.</p> <p>Hypogonadotropic hypogonadism: 150 IU three times per week. Maximum dose of 300 IU three times per week.</p>
Follitropin Alfa (Gonal-f RFF) 300/0.5ml pen injector	15 cartridges per 28 days	Ovulation induction: first cycle starting dose of 75 IU daily for 14 days. If indicated by the ovarian response after the initial 14 days, adjust dose by up to 37.5 IU every 7 days. Continue until adequate ovarian response (up to 35 days). The initial dose in subsequent cycles is based on prior response. Maximum daily dose of 300 IU.
Follitropin Alfa (Gonal-f RFF) 450/0.75ml pen injector	10 cartridges per 28 days	Ovulation induction: first cycle starting dose of 75 IU daily for 14 days. If indicated by the ovarian response after the initial 14 days, adjust dose by up to 37.5 IU every 7 days. Continue until adequate ovarian response (up to 35 days). The initial dose in subsequent cycles is based on prior response. Maximum daily dose of 300 IU.
Follitropin Alfa (Gonal-f RFF) 900/1.5ml pen injector	7 cartridges per 28 days	<p>Assisted reproductive technology: starting dose of 150 IU per day until adequate follicular development (up to 10 days of therapy in most cases). In patients whose endogenous gonadotropin levels are suppressed, starting dose of 150 IU per day (if under 35 years old) or 225 IU per day (if 35 years old or older). Adjust dose after 5 days based on response (adjust no more frequently than every 3-5 days by no more than 75-150 IU). Maximum daily dose of 450 IU.</p>
Follitropin Alfa (Gonal-f RFF) 75 unit vial	60 vials per 28 days	<p>Ovulation induction: first cycle starting dose of 75 IU daily with incremental adjustment of up to 37.5 IU after 14 days. If necessary, increase dose by same magnitude every 7 days (in general up to 35 days of treatment). The initial dose in subsequent cycles is individualized based on prior response. Maximum daily dose of 300 IU.</p> <p>Assisted reproductive technology: starting dose of 150 IU per day until adequate follicular development (up to 10 days of therapy in most</p>

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Medication	Standard Limit	FDA-recommended dosing
		cases). In patients whose endogenous gonadotropin levels are suppressed, starting dose of 150 IU per day (if under 35 years old) or 225 IU per day (if 35 years old or older). Adjust dose after 5 days based on response (adjust no more frequently than every 3-5 days by no more than 75-150 IU). Maximum daily dose of 450 IU.

III. REFERENCES

1. Follistim AQ [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; December 2013.
2. Follistim AQ Cartridge [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; December 2014.
3. Gonal-f Multi-Dose [package insert]. Rockland, MA: EMD Serono, Inc.; December 2012.
4. Gonal-f RFF [package insert]. Rockland, MA: EMD Serono, Inc.; January 2017.
5. Gonal-f RFF Redi-ject [package insert]. Rockland, MA: EMD Serono, Inc.; January 2017.
6. National Institute for Health and Clinical Excellence clinical guidelines 156. Fertility: Assessment and treatment for people with fertility problems. NICE 02/2013.