Applicable Drugs: Cetrotide (cetrorelix), Follistim AQ (follitropin beta), Fryemadel (ganirelix acetate), Gonal-f RFF (follitropin alfa), leuprolide acetate, human chorionic gonadotropin - hCG, Menopur (menotropins), Novarel (human chorionic gonadotropin - hCG), Ovidrel (choriogonadotropin alfa), Pregnyl (human chorionic gonadotropin – hCG)

Date of Origin: 12/29/2025

Date Last Reviewed / Revised: 1/28/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I - VII are met)

I. Documented diagnosis of A or B and additional criteria below:

A. Infertility defined as: i, ii, or iii:

i. Inability to achieve a successful pregnancy based on a patient's medical, sexual, and reproductive history, age, physical findings, diagnostic testing, or any combination of those factors.

ii. Need for medical intervention to achieve a successful pregnancy either as an individual or with a partner.

iii. Failure to achieve a pregnancy in patients without any known etiology for either partner, despite having regular, unprotected intercourse after 1 or 2:

1. 12 months or more when the female partner is under 35 years of age.
2. 6 months or more when the female partner is 35 years of age or older.

B. Fertility preservation is defined as i. or ii. below:

i. Documentation of planned gonadotoxic therapy (eg, exposure to cytotoxic agents, invasive surgery, prolonged hormonal ovarian suppression, etc)

ii. Documentation of diagnosis of gender dysphoria/incongruence and starting puberty suppression therapy or gender-affirming hormonal therapy

II. Documentation of infertility assessment and pertinent testing results (eg, sperm sample analysis, ovarian reserve testing, hysterosalpingogram, transvaginal ultrasound or sonohysterography) showing that other causative factors for infertility have been treated or excluded (when applicable).

III. Documentation of treatment plan for the use of requested injectable fertility medications listed in Table 1 for the treatment of the following conditions and applicable procedures (A through E):

A. Ovulation induction in female to treat infertility attributed to such conditions as ovulatory dysfunction due to polycystic ovarian disease (PCOS) or diminished ovarian reserve etc, minimal to mild endometriosis, unilateral tubal factor infertility, or unexplained infertility (not due to primary ovarian insufficiency/failure or tubal occlusion) in combination with timed intercourse or intrauterine insemination (IUI).

B. Controlled ovarian stimulation (COS) in female in combination with assisted reproductive technology (ART), such as in-vitro fertilization (IVF), intracytoplasmic sperm injection (ISCI), to treat infertility due to conditions such as diminished ovarian reserve, endometriosis, unexplained infertility, uterine factor infertility, male factor infertility, tubal factor infertility, ovulatory dysfunction, etc.

C. Fertility preservation in conjunction with ART.

D. Male hypogonadotropic hypogonadism (HH) (not due to primary testicular failure) with documentation of i and ii:

i. Low morning serum testosterone level (<300 ng/mL)

ii. Oligospermia (< 10 million sperm/mL)

E. Male prepubertal cryptorchism (not due to anatomical obstruction).

IV. Prescribed by or in consultation with reproductive specialist, endocrinologist, obstetrician/gynecology provider, or urologist.

V. Medication coverage limitations are dependent on plan benefit design.

VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VII. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Documented ovarian failure when a couple is attempting conception with their own gametes.
- Documented prior failed OI or COS in combination ART cycles due to poor ovarian response (eg, estradiol level < 100 pg/mL, production of no follicles ≥ 15 mm in diameter, etc) or low-quality oocytes or embryos.

OTHER CRITERIA

Table 1. Injectable fertility medications (gonadotropins, GnRH agonists, and GnRH antagonists) with indications, drug-specific criteria, exclusions, dosing, how supplied, and quantity limits.

Drug Class		
Drug Name(s) - Brand Name(s) (generic name)		
Indication(s) and Drug Specific Criteria	Dosing	How Supplied/Quantity limits
Gonadotropins		
Human chorionic gonadotropin, Novarel, Pregnyl (hCG)[a]		
Female Indication(s): • Ovulatory trigger in OI protocols in combination with timed intercourse or IUI and OS protocols in ART[b] Male Indication(s): • Induction of spermatogenesis in HH[b] • Prepubertal cryptorchidism[b] Exclusion: • Concomitant use of testosterone in HH	Ovulatory trigger in OI and COS protocols: • 5000 to 10,000 U IM one day following the last dose of gonadotropins after adequate follicular development[c] Spermatogenesis in HH: • 500 to 1000 U IM 3 times a week for 3 weeks, then the same dose twice a week for 3 weeks[c] -OR- • 4000 U IM 3 times weekly for 6 to 9 months, then 2000 U 3 times weekly for an additional 3 months[c] Prepubertal cryptorchidism (usually initiated between 4 and 9 yo): • 4000 U 3 times weekly for 3 weeks[c] • 5000 U every second day for 4 injections[c] • 15 injections of 500 to 1000 U over a period of 6 weeks[c]	How Supplied: • Human chorionic gonadotropin: 10,000 U hCG per 10 mL MDV • Novarel: • 5,000 U hCG per vial Pregnyl: 10,000 U hCG per 10 mL MDV Quantity/DS limits: • HH or prepubertal cryptorchidism: Quantity sufficient for 28 days supply • OI and COS: One 10mL vial per cycle. Lifetime quantity limit of 3 vials per 3 cycles of OI with timed intercourse or IUI or COS with ART. Note: if OI with letrozole or clomiphene with IUI was not successful in the treatment of unexplained infertility in a pr otocol where hCG was used as a trigger, may approve 3 additional vials for 3 cycles of COS with ART (lifetime limit of 6 vials)

	• 500 U 3 times weekly for 4 to 6 weeks. If this course of treatment is not successful, another series is begun 1 month later, giving 1000 U per injection[c]	
Ovidrel (choriogonadotropin alfa - rhCG)		
Female Indication(s): • Ovulatory trigger in OI protocols in combination with timed intercourse or IUI and COS protocols in ART[b]	Ovulatory trigger in OI and COS protocols: • 250 µg SC one day following the last dose of follicle stimulating agent after adequate follicular development[c]	How Supplied: • 250 µg per 1 mL pre-filled syringe Quantity/DS limits: • One 1mL syringe per cycle. Lifetime quantity limit of 3 syringes per 3 cycles of OI with timed intercourse or IUI or COS with ART. Note: if OI with letrozole or clomiphene with IUI was not successful in cases of unexplained infertility in a protocol where rhCG was used as a trigger, may approve 3 additional syringes for 3 cycles of COS with ART (lifetime limit of 6 vials).
Menopur[a] [(FSH and LH) menotropins – hMG]		
Female Indication(s): • Ovarian follicular development in OI protocols in combination with timed intercourse or IUI[c] or COS protocols in ART[b] Criteria: • Documented therapeutic failure of clomiphene citrate or letrozole for 3 cycles used for OI in combination with timed intercourse or IUI in oligo- or anovulatory women who	Ovarian follicular development in OI protocols: • Starting dose is usually 37.5 to 75 IU SC daily. Dose is protocol dependent.[d] Ovarian follicular development in COS protocols in ART: • Dose is protocol dependent. Per FDA label, starting dose is 225 IU SC daily for the first cycle. May increase dose	How Supplied: • 75 IU FSH and 75 IU of LH activity per vial Quantity/DS limits: • Quantity sufficient for 1 cycle. Lifetime quantity limit sufficient for 3 cycles of OI with timed intercourse or IUI or COS with ART.

are normogonadadotropic (eg, PCOS etc). • Documented therapeutic failure of clomiphene citrate or letrozole for 3 cycles for OI in combination with IUI for the treatment of unexplained fertility. • Documented prior use of preferred agent for at least 2 IVF cycles within the past 6 months. **Exclusion:** • Menopur in OI protocol with timed intercourse or IUI for the treatment of unexplained infertility. • Letrozole or clomiphene citrate combined with Menopur in OI protocol with IUI for the treatment of unexplained fertility.	after 5 days by no more than 150 IU at each adjustment, up to maximum of 450 IU per day[c]	
Gonal-f RFF Redi-ject (follitropin alpha- rFSH)		
Female Indication(s): • Ovarian follicular development in OI protocols in combination with timed intercourse or IUI[d] or COS protocols in ART[b] Criteria: • Documented therapeutic failure of clomiphene citrate or letrozole for 3 cycles used for OI in combination with timed intercourse or IUI in oligo- or	Ovarian follicular development in OI protocols: • Dose is protocol dependent. Per FDA label, 75 IU SC daily for 14 days for the starting dose of first cycle. May individualize dose after 14 days up to maximum of 300 IU per day[c] Ovarian follicular development in COS protocols in ART:	How Supplied: • 300 IU per 0.48mL prefilled single patient use pen • 450 IU per 0.72mL prefilled single patient use pen • 900 IU per 1.44mL prefilled single patient use pen Quantity/DS limits: • Quantity sufficient for 1 cycle. Lifetime quantity limit sufficient for 3 cycles of OI with timed intercourse or IUI or COS with ART.

anovulatory women who are normogonadadotropic (eg, PCOS etc). • Documented therapeutic failure of clomiphene citrate or letrozole for 3 cycles for OI in combination with IUI for the treatment of unexplained fertility. • Documented prior use of preferred agent for at least 2 IVF cycles within the past 6 months. Exclusion: • Gonal-F in OI protocol with timed intercourse or IUI for the treatment of unexplained infertility. • Letrozole or clomiphene citrate combined with Gonal-F in OI protocol with IUI for the treatment of unexplained fertility	• Dose is protocol dependent. Per FDA label, 150 IU SC daily for the starting dose of first cycle. May adjust after 3-5 days by 75-150 IU at each adjustment up to a maximum of 450 IU per day[c]	
Follistim AQ (follitropin beta - rFSH)		
Female Indication(s): • Ovarian follicular development in OI protocols in combination with timed intercourse or IUI[d] or COS protocols in ART[b] Criteria: • Documented therapeutic failure of clomiphene citrate or letrozole for 3 cycles used for OI in combination with timed intercourse or IUI in oligo- or anovulatory women who	Ovarian follicular development in OI protocols: • Dose is protocol dependent. Per FDA label, starting dose is 50 IU SC daily for 7 days. May adjust dose at weekly intervals by 25-50 IU until follicular growth and/or serum estradiol levels indicate an adequate response[c] Ovarian follicular development in COS protocols in ART	How Supplied: • 300 IU per 0.36 mL prefilled single patient use cartridge • 600 IU per 0.72mL prefilled single patient use cartridge • 900 IU per 0.08mL prefilled single patient use cartridge Quantity/DS limits: • OI and COS: Quantity sufficient for 1 cycle. Lifetime quantity limit sufficient for 3 cycles of OI with timed intercourse or IUI or COS with ART.

are normogonadadotropic (eg, PCOS etc). • Documented therapeutic failure of clomiphene citrate or letrozole for 3 cycles for OI in combination with IUI for the treatment of unexplained fertility. Exclusion: • Follistim AQ in OI protocol with timed intercourse or IUI for the treatment of unexplained infertility. • Letrozole or clomiphene citrate combined with Follistim AQ in OI protocol with IUI for the treatment of unexplained fertility. Male indication(s): • Induction of spermatogenesis in HH[b] Exclusion: • Concomitant use of testosterone in HH	• Dose is protocol dependent. Per FDA label, starting dose is 200 IU SC daily for 7 days. May be increased/decreased at weekly intervals until follicular growth and/or serum estradiol levels indicate an adequate response. Dosage reduction in high responders can be considered from the 6th day of treatment onward[c] Spermatogenesis in HH • After normalization of serum testosterone levels with hCG, administer 450 IU per week (225 international IU twice weekly or 150 IU three times weekly) of rFSH beta SC with the same pre-treatment hCG dose used to normalize testosterone levels[c]	• HH: Quantity sufficient for 28 days
GnRH agonist		
Lupron (leuprolide acetate)		
Female Indication(s): • Pituitary downregulation in IVF protocols to prevent LH surge during COS[d] • Increase FSH/LH release in flare protocol IVF[d] • Ovulatory trigger in short protocol IVF cycles (replaces HCG)[d]	COS in IVF protocols: • Used for various lengths of time and started at various times in cycle-dependent on IVF protocol used. • *Standard dose protocol:* 0.5 mg to 1 mg SC daily[e] Ovulatory trigger:	How Supplied: • 1 mg/0.2 mL supplied as a 2.8 mL MDV Quantity/DS limits: • Quantity sufficient for 1 cycle. Lifetime quantity limit sufficient for 3 total COS with ART cycles.

	• 0.5 mg to 1 mg following last dose of gonadotropins after adequate follicular development[e]	
GnRH antagonists		
Cetrotide (cetrorelix)		
Female Indication(s): • Inhibition of premature LH surge during COS protocols in ART[b]	Pituitary downregulation in COS protocols in ART: • 0.25mg SC daily in morning or evening of cycle day 5 or 6 and continued daily until hCG administration[c]	How Supplied: • 0.25 mg/1 mL kit Quantity/DS limits: • Quantity sufficient for 1 cycle. Lifetime limit of 3 total COS with ART cycles.
Fyremadel (ganirelix acetate)		
Female Indication(s): • Inhibition of premature LH surge during COS protocols in ART[b]	Pituitary downregulation in COS protocols in ART: • 0.25mg SC daily on stimulation starting during the mid to late follicular phase until hCG administration[c]	How Supplied: • 0.25 mg/1 mL kit Quantity/DS limits: • Quantity sufficient for 1 cycle. Lifetime limit of 3 total COS with ART cycles.

Abbreviations: ART, assisted reproductive technology; COS, controlled ovarian stimulation; DS, days supply, FSH, follicle stimulating hormone; GnRH, gonadotropic releasing hormone, hCG, human chorionic gonadotropin; HH, hypogonadotropic hypogonadism; hMG, human menopausal gonadotropin, IM, intramuscular injection; IU, international units; IVF, in vitro fertilization; IUI, intrauterine insemination; LH, luteinizing hormone; OI, ovulation induction; rFSH, recombinant FSH; rHCG, recombinant human chorionic gonadotropin; MDV, multiple-dose vial; PCOS, polycystic ovarian disease; SC, subcutaneous injection, U, USP units.

[a]Human urine derived, [b]FDA approved indication, [c]FDA recommended dosing, [d]Off-label indication, [e]Off label dosing

Quantity / Days Supply Restrictions

- See table 1.

Approval Length

- **Authorization:** 3 months.
- **Re-Authorization:** 3 months with documented adequate response to infertility treatment (eg. ≥1 follicle 15mm in diameter for OI and OS in combination with IUI or ART, testosterone level stabilization, sperm production). See Table 1 for lifetime limits.

Appendix

N/A

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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.