

ART / Infertility Drugs / Gender Dysphoria

Bravelle (urofollitropin), Cetrotide (cetorelix), Clomid, Clomiphene Powder, Serophene (clomiphene citrate), Crinone, Endometrin, Progesterone in Oil, Progesterone Powder, Prometrium (progesterone), Follistim AQ (follitropin beta), Gonal-F, Gonal F RFF (follitropin alfa), Ganirelix (ganirelix), Eligard, Lupron Depot (leuprolide), Leuprolide powder, Menopur (menotropins)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Assisted Reproductive Technologies (ART) represent a group of non-coital manipulations and processes that manipulate ova and/or sperm to achieve a pregnancy. The most well-known examples are ovulation induction, intrauterine insemination and in-vitro fertilization. ART and infertility drugs used in conjunction with ART procedures or erectile or sexual dysfunction, weight loss, performance enhancement and anti-aging are not covered benefits. The diagnosis of hypogonadotropic hypogonadism is an off label indication for these medications.

A variety of drugs are used to manipulate the hypothalamic-pituitary-gonadal axis in order to induce ovulation in females known as controlled ovarian hyperstimulation (COH). Some of these pharmacologic agents are used for additional clinical care indications.

Drugs Included in Infertility Drugs / ART Criteria

- Antagon (ganirelix) – inhibition of premature LH surges in women undergoing COH
- Bravelle (urofollitropin) – ovulation induction and multiple follicle development during ART
- Clomid (clomiphene citrate) – ovulation induction
- Clomiphene Powder – ovulation induction
- Crinone (progesterone) – progesterone supplementation during ART
- Eligard (leuprolide) – inhibition of premature LH surges in women undergoing COH
- Endometrin (progesterone) – progesterone supplementation during ART
- Follistim AQ (follitropin beta) – ovulation induction and multiple follicle development during ART
- Gonal-F (follitropin alfa) – ovulation induction, and multiple follicle development during ART
- Gonal-F RFF (follitropin alfa) – ovulation induction and multiple follicle development during ART
- HCG powder (human chorionic gonadotropin)- ovulation induction, spermatogenesis induction- separate policy
- Leuprolide powder - inhibition of premature LH surges in women undergoing COH
- Lupron Depot (leuprolide) – inhibition of premature LH surges in women undergoing COH

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- Menopur (menotropins) – multiple follicle development during ART
- Novarel (chorionic gonadotropin) – ovulation induction – separate policy
- Ovidrel (choriogonadotropin) – ovulation induction and stimulation of final follicle maturation and early luteinization for ART – separate policy
- Pregnyl (chorionic gonadotropin) – ovulation induction – separate policy
- Progesterone in oil (progesterone) – progesterone supplementation during ART
- Progesterone powder (progesterone) – progesterone supplementation during ART
- Prometrium (progesterone) – progesterone supplementation during ART
- Serophene (clomiphene citrate) – ovulation induction

Drugs Excluded from Infertility Drugs / ART Criteria

- Arimidex (anastrozole) – limited use in ART and used to treat breast cancer
- Aromasin (exemestane) – limited use in ART and used to treat breast cancer
- Femara (letrozole) – limited use in ART and used to treat breast cancer
- Tamoxifen – limited use in ART and used to treat breast cancer

Regulatory Status

The drugs addressed by this policy are FDA-approved for use in one or more of a variety of different conditions.

Summary

Assisted Reproductive Technology (ART), weight loss, performance enhancement, anti-aging and erectile or sexual dysfunction are not covered benefits. The diagnosis of hypogonadotropic hypogonadism is an off label indication for these medications and is not a covered diagnosis. The primary pharmacologic treatments used to induce ovulation in coital reproduction and for controlled ovarian hyperstimulation (COH) in ART are generally the same. (1-2)

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of drugs used for ART and GD while maintaining optimal therapeutic outcomes.

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References

1. Smith S, Pfeifer SM, Collins JA. Diagnosis and management of female infertility. *JAMA*. 2003; 290(13):1767-1770.
2. Homburg R. Ovulation induction. *Expert Opin Pharmacother*. 2003; 4(11):1995-2004.
3. Hembree, WC, Cohen-Kettenis, P, et al. Endocrine Treatment of Transsexual Persons: AAn Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*.. 2009; 94(9):3132-3154.