



ART / Infertility / Gender Dysphoria

Cetrotide (cetorelix)
Clomiphene citrate
Clomiphene powder
Crinone/Endometrin/Milprosa*/Progesterone in oil/Progesterone powder/Prometrium (progesterone)
Firmagon (degarelix)
Follistim AQ (follitropin beta)
Fyremadel/Ganirelix (ganirelix)
Gonal-F/Gonal-F RFF (follitropin alfa)
Menopur (menotropins)
Supprelin LA (histrelin)
Synarel (nafarelin)
Trelstar/Triptodur (triptorelin)
Zoladex (goserelin)

*This medication is included in this policy but is not available on the market as of yet

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 for erectile or sexual dysfunction, weight loss, performance (athletic) enhancement and anti-aging are not covered by the Plan. 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)

- Cetrotide (cetorelix)
- Clomiphene citrate
- Clomiphene powder
- Crinone/Endometrin/Milprosa/Progesterone in oil/Progesterone powder/Prometrium (progesterone)
- Firmagon (degarelix)
- Follistim AQ (follitropin beta)
- Fyremadel/Ganirelix (ganirelix)



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- Gonal-F/Gonal-F RFF (follitropin alfa)
- Menopur (menotropins)
- Supprelin LA/Vantas (histrelin)
- Synarel (nafarelin)
- Trelstar/Triptodur (triptorelin)
- Zoladex (goserelin)

Drugs Included in Infertility Drugs (Separate Criteria)

- Camcevi (leuprolide mesylate)
- Eligard/Fensolvi/Leuprolide Acetate/Lupron Depot (leuprolide acetate)
- HCG powder (human chorionic gonadotropin)
- Novarel (chorionic gonadotropin)
- Ovidrel (choriogonadotropin)
- Pregnyl (chorionic gonadotropin)

Drugs Excluded from Infertility Drugs

- 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



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

Summary

Assisted reproductive technologies (ART) represent a group of non-coital manipulations and processes that manipulate ova and/or sperm to achieve a pregnancy. ART and infertility drugs used in conjunction with ART procedures, or for erectile/sexual dysfunction, weight loss, performance (athletic) enhancement or anti-aging are not covered by the Plan.

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

References

1. Esteves, Sandro C, Humaidan, Peter, Roque, Matheus, Agarwal, Ashok. Female fertility and assisted reproductive technology. Panminerval Medica 2019, March; 61 (1): 1-2. doi: 10.23736/S0031-0808.18.03553-X
2. Chehab M, Madala A, Trussell JC. On-label and off-label drugs used in the treatment of male infertility. Fertil Steril. 2015 Mar;103(3):595-604. doi: 10.1016/j.fertnstert.2014.12.122. Epub 2015 Feb 3. PMID: 25660648.



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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.