



## **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.