Oscar Clinical Guideline: Infertility Injectable Agents (PG119, Ver. 2)

Infertility Injectable Agents

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Fertility problems are possible for both men and women. The cause can be found through physical exam, extensive medical and sexual history. Depending on the cause of infertility, there are different treatment options. Medications are one of the infertility treatment options available for both men and women. Medications can help correct ovulation problems in women and hormone problems in men. When treatment options, including injectable infertility agents, exceed the comfort level of a provider, the member should be referred to a a specialist with expertise in diagnosis and treatment of infertility (e.g., reproductive endocrinologist)

NOTE: Coverage of injectable fertility medications varies depending on a member's benefit policy.

1. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage.
2. Please refer to Oscar's Medical Clinical Guideline Number CG016 - Diagnosis and Treatment of Infertility for medical coverage criteria of infertility diagnostic and treatment services.
3. This Clinical Guideline only applies to members whose plan covers injectable agents listed in Table 1 for infertility treatments.

a. The Plan requires that members be unable to use, or have tried and failed preferred agent(s) first.
b. The use of these agents for other indications (e.g., cancer treatments, gender dysphoria treatments) may also be addressed in separate Clinical Guidelines.

Table 1: Infertility Injectable Agents

Drug	Brand Name	Classification
Follitropin beta	Follistim AQ	Gonadotropins
Follitropin alfa	Gonal-F	
Follitropin alfa	Gonal-f RFF	
Follitropin alfa	Gonal-f RFF Redi-ject Pen	
Chorionic Gonadotropin (Human)	Novarel	
Chorionic Gonadotropin (Recombinant)	Ovidrel	
Chorionic Gonadotropin (Human)	Pregnyl	
Human Chorionic Gonadotropin, HCG		
Menotropins	Menopur	
Leuprolide Acetate		Gonadotropin-Releasing Hormone Agonists
Cetrorelix Acetate	Cetrotide	Gonadotropin Releasing Hormone Receptor Antagonist
Ganirelix Acetate		

Definitions

"Infertility" is a disease or condition characterized by the incapacity to impregnate another person or to conceive, defined by the failure to establish a clinical pregnancy after 12 months of regular, unprotected sexual intercourse or therapeutic donor insemination, or after six (6) months of regular, unprotected sexual intercourse or therapeutic donor insemination for a female 35 years of age or older. Earlier evaluation and treatment may be warranted based on a Member's medical history or physical findings. Infertility may be caused by disease, dysfunction, or malformation.

"**Iatrogenic Infertility**" refers to an impairment of fertility by surgery, radiation, chemotherapy or other medical treatment affecting reproductive organs or processes.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Infertility Injectable Agents** medically necessary when **ALL** of the following criteria are met:

1. The requested medication is prescribed by or in consultation with a specialist with expertise in diagnosis and treatment of infertility (e.g., reproductive endocrinologist); ***AND***
2. **ONE** of the following:
    a. The member is a female and meets **ALL** of the following:
        i. Is 18 years of age or older; ***and***
        ii. The medication is being used for **ONE** of the following FDA approved or compendia supported indications:
            1. induction of ovulation; ***or***
            2. inhibition of premature luteinizing hormone surges; ***or***
            3. multiple follicle development; ***or***
            4. preservation of fertility when a medical treatment will directly or indirectly lead to iatrogenic infertility; ***and***
        iii. For induction of ovulation, has tried and failed or is unable to use clomiphene citrate or comparable estrogen modulators such as letrozole due to **ONE** of the following:
            1. a documented trial and failure, intolerance to, or contraindication; ***or***
            2. risk factor(s) for poor response; ***or***
            3. not clinically appropriate; ***or***
            4. member is 37 years of age or older***; and***
        iv. Clinical chart documentation is submitted showing **ALL** of the following:
            1. complete gynecologic and endocrinologic evaluation and diagnosis of cause of infertility; ***and***
            2. member is currently not pregnant; ***and***
            3. a diagnosis of primary ovarian failure has been excluded; ***and***
            4. the fertility status of the male partner has been evaluated; ***and***
            5. medical conditions preventing pregnancy have been excluded or adequately treated *(medical conditions preventing pregnancy may include blocked fallopian tubes, hyperprolactinemia, thyroid, or adrenal disorders)*; ***OR***
    b. The member is a male and meets **BOTH** of the following:

i. The medication is being used for **ONE** of the following FDA approved or compendia supported indications:
    1. induction of spermatogenesis; ***or***
    2. hypogonadotropic hypogonadism; ***or***
    3. prepubertal cryptorchidism; ***and***
ii. Clinical chart documentation is submitted showing **BOTH** of the following:
    1. complete medical and endocrinologic evaluation and diagnosis of cause of infertility; ***and***
    2. the fertility status of the female partner has been evaluated; ***AND***

3. The use of medication at the requested dosage or quantity, frequency, site of administration, and duration of therapy is supported by Food and Drug Administration (FDA) approved dosing or evidence-based literature.

If the above prior authorization criteria are met, the requested Infertility Injectable Agents will be approved for:

- 3 months for females; ***or***
- 6 months for males

Medical Necessity Criteria for Reauthorization

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

If the above prior authorization criteria are met, the requested Infertility Injectable Agents will be reauthorized for:

- 3 months for females; ***or***
- 6 months for males

Experimental or Investigational / Not Medically Necessary

Infertility Injectable Agents for any other fertility problems is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

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Clinical Guideline Revision / History Information

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