Infertility

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit	Comments
Cetrotide	N/A	N/A
Clomiphene Citrate	N/A	N/A
Crinone 8%	1 applicator per day	In women with partial or complete ovarian failure who require progesterone replacement, 2 applicators per day may be approved. Override criteria only apply to benefits with fertility coverage.
Eligard (leuprolide acetate) 7.5mg	1 per 4 weeks	N/A
Eligard (leuprolide acetate) 22.5mg	1 per 12 weeks	N/A
Eligard (leuprolide acetate) 30mg	1 per 16 weeks	N/A
Eligard (leuprolide acetate) 45mg	1 per 24 weeks	N/A
Endometrin	N/A	N/A
Follistim AQ (non-preferred follicle stimulating hormone agent)	N/A	N/A
Ganirelix	N/A	N/A
Gonal-F (preferred follicle stimulating hormone agent)	N/A	N/A
Gonal-F RFF (preferred follicle stimulating hormone agent)	N/A	N/A
Leuprolide acetate (immediate release)	N/A	See note below
Lupron Depot (1 month) (leuprolide acetate) 3.75mg	1 per 4 weeks	See note below
Lupron Depot (1 month) (leuprolide acetate) 7.5mg	1 per 4 weeks	See note below

Lupron Depot (3 month) (leuprolide acetate) 11.25mg and 22.5mg	1 kit per 12 weeks	See note below
Lupron Depot (4 month) (leuprolide acetate) 30mg	1 per 16 weeks	See note below
Lupron Depot (6 month) (leuprolide acetate) 45mg	1 per 24 weeks	See note below
Menopur	N/A	N/A
Novarel	N/A	N/A
Ovidrel	N/A	N/A
Pregnyl	N/A	N/A

********Note:*** **For Eligard, Leuprolide acetate (immediate release), or Lupron Depot request other than infertility please see the separate clinical criteria document (GnRH Clinical Criteria) detailing that specific approval criteria*****

Clomiphene Citrate

Requests for clomiphene citrate may be approved for 6 cycles of therapy for ovulation induction in an individual if the following criteria are met:

I. Individual has a diagnosis of normogonadotropin anovulatory dysfunction including polycystic ovary syndrome; **OR**
II. Individual has a diagnosis of unexplained infertility of short duration with normal levels of luteal progesterone and a normal hysterosalpingogram; **OR**
III. Individual has a diagnosis of Stage I or II endometriosis.

Requests for clomiphene citrate may not be approved for any of the following:

I. Primary ovarian failure or tubal occlusion; **OR**
II. Hypogonadotropic anovulatory disorders or hypopituitarianism; **OR**
III. Received greater than 6 cycles of therapy.

Injectable Follicle Stimulating Hormones (Follistim AQ, Gonal-f, Gonal-f-RFF, or Menopur (menotropins) for Ovarian Stimulation Alone or with Intrauterine Insemination

Requests for Follistim AQ, Gonal-f, Gonal-f-RFF, or Menopur may be approved for a maximum of 3 cycles, with or without intrauterine insemination in an infertile* individual if the following criteria are met:

I. Individual has a diagnosis of hypogonadotropin anovulatory disorders or hypopituitarianism (these individuals will not respond to follicle stimulating hormone alone, but will require additional therapy with an luteinizing hormone containing product such as human chorionic gonadotropin or will use a mixed follicle stimulating hormone/luteinizing hormone product like Menopur); **OR**
II. Individual has a diagnosis of normogonadotropion anovulatory disorders (including polycystic ovary syndrome) or those with unexplained infertility* who have not ovulated or conceived after a prior trial of 3 cycles of clomiphene.

Requests for ovarian induction with Follicle Stimulating Hormones or Menopur (menotropins) may not be approved for the following**:**

I. Individual is receiving more than 3 ovulatory cycles of therapy; **OR**
II. Individual has a diagnosis of tubal occlusion or primary ovarian failure.

Injectable Follicle Stimulating Hormones (Follistim AQ, Gonal-f, Gonal-f-RFF, or Menopur (menotropins) for Ovarian Stimulation in Conjunction with In Vitro Fertilization or Intracytoplasmic Sperm Injection

Requests for Follistim AQ, Gonal-f, Gonal-f-RFF, Menopur, Ovidrel (recombinant human chorionic gonadotropin) or Pregnyl, Novarel (urinary derived human chorionic gonadotropins), with Lupron Depot or leuprolide acetate (immediate release) (gonadotropin releasing hormone agonists) or Cetrotide, Ganirelix (gonadotropin releasing hormone antagonists) may be approved for a maximum of 3 cycles of ovarian stimulation in conjunction with in vitro fertilization or intracytoplasmic sperm injection in an infertile* individual or couple if the following criteria are met:

I. The couple has a diagnosis of severe male factor infertility; **OR**
II. The individual has a diagnosis of bilateral tubal occlusion; **OR**
III. The individual has a diagnosis of unexplained infertility that has not responded to ovarian induction therapy.

Injectable Follicle Stimulating Hormones (Follistim AQ, Gonal-f, Gonal-f-RFF, Menopur (menotropins), Pregnyl, Novarel (urinary derived human chorionic gonadotropins)), Lupron Depot, Eligard, leuprolide acetate (immediate release) (gonadotropin releasing hormone agonists), or Cetrotide, Ganirelix (gonadotropin releasing hormone antagonists) for Preservation of Fertility

Requests for Injectable Follicle Stimulating Hormones (Follistim AQ, Gonal-f, Gonal-f-RFF, Menopur (menotropins), Pregnyl, Novarel (urinary derived human chorionic gonadotropins)), Lupron Depot, Eligard, leuprolide acetate (immediate release) (gonadotropin releasing hormone agonists), or Cetrotide, Ganirelix (gonadotropin releasing hormone antagonists) may be approved if the following criteria are met:

I. Individual is using in the preservation of fertility in pre-menopausal women; **AND**
II. One of the following:
    A. Individual has a cancer diagnosis; **AND**
        1. Individual meets one of the following:
            a. Individual will receive chemotherapy for cancer with a curative intent; **OR**
            b. Individual will receive radiation therapy for cancer with a curative intent;

OR

    B. Individual has a diagnosis of gender dysphoria; **AND**
        1. Individual will be starting gender-affirming hormonal therapy; **OR**
        2. Individual is an adolescent who will be starting puberty suppression therapy.

Injectable Follicle Simulating Hormones (Follistim AQ, Gonal-f) for Male Infertility Associated with Hypogonadotropic Hypogonadism

Requests for Follistim AQ or Gonal-F in combination with human chorionic gonadotropins in an infertile* individual may be approved if the following criteria are met:

I. Individual has a diagnosis of hypogonadotropic hypogonadism with onset prior to completion of pubertal development.

Requests for the use of human chorionic gonadotropin alone or in combination with follicle stimulating hormone may be approved if the following criteria are met:

I. Individual is using to maintain spermatogenesis for an infertile individual with post-pubertal acquired hypogonadotropic hypogonadism who have previously had normal sperm production.

Requests for the use of human chorionic gonadotropin alone or in combination with follicle stimulating hormone may be approved if the following criteria are met:

I. Individual is using to maintain spermatogenesis for an infertile individual with partial gonadotropin deficiency.

Progesterone Vaginal Supplementation or Replacement for Infertility Treatment -- Crinone 8% gel, Endometrin vaginal insert

Requests for Crinone 8% gel or Endometrin vaginal insert may be approved if the following criteria are met:

I. Individual is using as part of an Assisted Reproductive Technology treatment; **AND**
II. Individual has a diagnosis of infertility*; **AND**
III. Individual requires progesterone supplementation.

The use of progesterone 4% gel may not be approved as part of an Assisted Reproductive Technology treatment for an infertile individual who requires progesterone supplementation.

*Note: For the purposes of this document, infertility is defined clinically in women and men who cannot achieve a successful pregnancy after 12 months or more of appropriate, timed unprotected intercourse or 6 cycles of therapeutic donor insemination. The diagnosis of male or female infertility requires evaluation of the couple versus a single individual.

Key References:

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    a. Adolescent and Young Adult Oncology. V2.2022. Revised November 22, 2021.
    b. Breast Cancer. V3.2022. Revised May 7, 2022.
    c. Survivorship. V1.2022. Revised March 30, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.