

Infertility

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Exceptions	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Infertility is the condition of an individual who is unable to conceive or produce conception during a period of one year if the female is age 35 or younger or during a period of six months if the female is over age 35. For the purposes of meeting the criteria of infertility in this section, if a person conceives but is unable to carry that pregnancy to live birth, the period of time she attempted to conceive prior to achieving that pregnancy shall be included in the calculation of 1 year or 6-month period as applicable.

Mass General Brigham Health Plan only provides coverage for IVF medications (e.g. Bravelle, Cetrotide, Follistim AQ, Gonal-F RFF, Menopur, Novarel, Ovidrel, and Pregnyl) if the IVF or medicated IUI services have been approved.

FDA Indications

Cetrotide and Ganirelix are indicated for:

1. The inhibition of premature luteinizing hormone (LH) surges in women undergoing controlled ovarian stimulation.

Menopur is indicated for:

1. Development of multiple follicles and pregnancy in ovulatory women as part of an assisted reproductive technology cycle.

Novarel and Pregnyl are indicated for:

1. Prepubertal cryptorchidism not due to anatomic obstruction
2. Selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males
3. Induction of ovulation and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure, and who has been appropriately pretreated with human menopausal gonadotropins

Ovidrel is indicated for:

1. Induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been appropriately pretreated with follicle stimulating hormones as part of an assisted reproductive technology (ART) program such as in vitro fertilization and embryo transfer
2. Induction of ovulation and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure

Coverage Guidelines

Leuprolide*

Authorization may be granted for the inhibition of premature LH surge in members undergoing ovulation induction or assisted reproductive technology (ART).

Cetrotide & Ganirelix acetate*

Authorization may be granted for the inhibition of premature LH surges in members with infertility.

Novarel, Pregnyl, Ovidrel, chorionic gonadotropin (hCG)*

Authorization may be granted to members requiring induction of oocyte maturation and/or release with infertility prescribed hCG

Gonal-F, Follistim AQ, and Bravelle

Authorization may be granted for ovulation induction or follicle stimulation as part of an assisted reproductive technology (ART) program when ANY of the following criteria is met, and documentation is provided:

1. Member has completed three or more previous cycles of clomiphene.
2. Member has a risk factor for poor ovarian response to clomiphene.
3. Member has contraindication or exclusion to clomiphene.
4. Member is 37 years of age or older.
5. Follistim AQ and Bravelle only:
 - a. Member is intolerant to, had a confirmed adverse event, or has a contraindication to Gonal-F or any of its drug components.

Please Note: Gonal-F is the preferred Follitropins product.

Menopur*

Authorization may be granted for follicle stimulation in members with infertility prescribed menotropins who meet any of the following criteria:

1. Member has completed three or more previous cycles of clomiphene, or
2. Member has a risk factor for poor ovarian response to clomiphene, or
3. Member has a contraindication or exclusion to clomiphene, or
4. Member is 37 years of age or older

* Prior authorization requirements will be bypassed for drug(s) being requested for a procedure that has been approved under a member's medical benefit plan. A medical authorization number and confirmation of the approved procedure(s) will be required.

Continuation of Therapy



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

Limitations

1. Approvals will be granted for 12 months.

References

1. Bakas P, Konidaris S, Liapis A, et al. Role of gonadotropin-releasing hormone antagonist in the management of subfertile couples with intrauterine insemination and controlled ovarian stimulation. *Fertil Steril*. 2011;95:2024-2028.
2. Leuprolide acetate [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; January 2017.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, CO. Available at: <http://www.micromedexsolutions.com> Accessed May 24, 2018.
4. Urman B, Yakin K. Ovulatory disorders and infertility. *J Reprod Med*. 2006;51(4):267-282.
5. National Collaborating Centre for Women's and Children's Health. Fertility: assessment and treatment for people with fertility problems (Clinical guideline no. 156). National Institute for Health and Clinical Excellence (NICE); 2013.
6. Bravelle (urofollitropin) [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals; February 2014
7. Cetrotide (cetorelix acetate) [prescribing information]. Rockland, MA: EMD Serono, Inc; May 2018..
8. Ganirelix acetate injection [prescribing information]. Whitehouse Station, NJ: Merck & Co; May 2018
9. Gonal-f RFF Redi-ject (follitropin alfa) [prescribing information]. Rockland, MA: EMD Serono Inc; November 2019
10. Menopur (menotropin) [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals; April 2017
11. Novarel (chorionic gonadotropin) [prescribing information]. Parsippany, NJ: Ferring Pharmaceutical Inc; May 2018.
12. Ovidrel (choriogonadotropin alfa) [prescribing information]. Rockland, MA: Serono; June 2018.
13. Pregnyl [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2015.
14. Clinical Consult. CVS Caremark Clinical Program Review: Reproductive Endocrinology and Contraceptive Clinical Programs; September 2011.
15. Nosarka S, Kruger T, Siebert I, et al. Luteal phase support in in vitro fertilization: meta-analysis of randomized trials. *Gynecol Obstet Invest*. 2005;60:67-74.
16. American Association of Clinical Endocrinologists. Medical guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients – 2002 Update. *Endocr Pract*. 2002;8:439-456.

Review History

N/A.

