

INFERTILITY/ ASSISTED REPRODUCTIVE TECHNOLOGY SERVICES

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Overview

The General Laws of Massachusetts require health plans in Massachusetts to provide coverage for medically necessary expenses of diagnosis and treatment of infertility. Under authority issued under the General Laws of Massachusetts, the Division of Insurance defines the scope of coverage and required infertility services in the Code of Massachusetts Regulations 211 CMR 37.00.

http://www.mass.gov/doi/Legal_Hearings/211_37.pdf

Infertility services and infertility drugs require preauthorization.

Definitions

Assisted reproductive technology (ART) services include, but are not limited to: intra-uterine insemination (IUI), in-vitro fertilization (IVF), gamete intra-fallopian transfer (GIFT), zygote intra-fallopian transfer (ZIFT), intra-cytoplasmic sperm injection (ICSI), assisted hatching (AH), frozen embryo transfer (FET), donor oocyte.¹

Infertility – the condition of a presumably healthy (i.e., presumably fertile) individual who is unable to conceive or produce conception during a period of one year, or for a period of six months in women over 40 years of age.²

Infertility for women with male partners – the inability to conceive after one year of unprotected intercourse with exposure to sperm or, for women over 40 years of age, the inability to conceive after six months of unprotected intercourse with exposure to sperm

Infertility for women without male partners – the inability to conceive after six (6) intrauterine insemination cycles performed by a qualified specialist that do not result in conception.

Infertility services – may include, but are not limited to, assisted reproductive technology services, labs to assess infertility, office visits for infertility consultation, hysterosalpingograms, ultrasounds ordered by and/or performed at an infertility specialist's office to assess success of infertility treatment, infertility drugs, and other services to assess and/or treat infertility.

Male factor infertility - the inability to produce conception with documented abnormal semen analysis

Medically necessary infertility treatment – For a member with a documented inability to conceive or produce viable conception after a one-year period of exposure to sperm (or after a 6-month period of exposure to sperm for a woman over 40 years of age), and in whom fertility would naturally be expected, such treatment that is likely (>5% probability) to result in a livebirth, based on clinical history and response to previous cycles.

General Clinical Coverage Criteria

¹ Although FCHP considers IUI to be a form of ART, IUI cycles will not count towards the 6-cycle limit. However, requests for IUI must still meet FCHP's General Medical Necessity Criteria (para IV.A.).

² In accordance with the Office of Patient Protection of the MA DPH, "unable to conceive during a one year period" presumes that the insured would be expected to conceive naturally absent a medical problem (i.e., that the insured is of normal reproductive age).

1. Members must meet the general medical necessity criteria (see *Covered Services-General Medical Necessity Criteria* below) for any and all infertility services, including donor egg treatment.
2. Six-Cycle Limit: FCHP covers a maximum of six (6) medicated ART cycles (including donor egg cycle).
 - a. The following guidelines regarding cycle limits are subject to individual consideration based on the member's specific clinical facts and unique medical circumstances.
 - b. For members <40 years-old with at least a one-year history of exposure to sperm who have unexplained infertility and a normal day 3 FSH, these six cycles must follow the failure of 3 medicated IUI cycles.
 - c. For members ≥40 years-old with at least a six-month history of exposure to sperm who have a normal Clomiphene Citrate Challenge Test (CCCT), these six cycles must follow the failure of 2 medicated IUI cycles.
 - d. FCHP may authorize fewer than 6 cycles if medically appropriate and if additional cycles are not likely to result in a livebirth.
 - e. The 6-cycle limit applies even when previous cycles were not covered by FCHP.
 - f. Previous ART cycles resulting in a livebirth do not count towards the 6-cycle limit.
 - g. Un-medicated (i.e., no gonadotropins) thaw cycles do not count towards the 6-cycle limit.
 - h. If the first IVF cycle in a series using the member's own eggs is cancelled, it will not count towards the 6-cycle limit.
 - i. Members who have unsuccessfully undergone IVF cycles and in whom further IVF cycles would not meet FCHP medical necessity criteria will not be covered for subsequent IUI cycles in the absence of an intervening livebirth.
 - j. Members who have undergone donor egg cycles will not be covered for subsequent IVF cycles with their own eggs.
 - k. Members with previous livebirths achieved through ART procedures do not automatically qualify for coverage of the same ART service during subsequent attempts to achieve pregnancy. FCHP medical directors will take into account the individual facts of each case in determining if such requests meet FCHP medical necessity criteria.

Covered Services

General Medical Necessity Criteria

FCHP covers infertility services when all of the following criteria are met:

1. The member has a documented inability to conceive or produce conception after a one year period of exposure to sperm, or for a period of six months in women over 40 years of age.
2. The member is an individual in whom fertility would naturally be expected.
3. Ovarian Reserve Assessment Criteria
 - a. To be covered, women **less than 40 years-old** must submit results from day 3 FSH and Estradiol levels obtained within the past year.
 - b. To be covered, women **≥ 40 years-old** must demonstrate adequate ovarian reserve as evidenced within the past 6 months by:³
 - 1) CCCT with day 3 and day 10 FSH levels <15 mIU/ml and day 3 Estradiol level <80 pg/ml,⁴ and
 - 2) Adequate ovarian response to stimulation if prior medicated cycles were attempted.
4. There is a >5% probability that infertility treatment will result in a livebirth, based on clinical history and response to previous cycles.

Artificial Insemination (AI)/Intrauterine Insemination (IUI)

³ FCHP may require updated CCCTs less frequently than every 6 months based on the recentness and results of prior medicated cycles.

⁴ Note that when a member has had multiple CCCTs, all CCCTs must meet these criteria.

FCHP covers AI or IUI services when any of the following criteria are met:

1. Male factor infertility (such as low sperm count, low motility, low percentage of normal forms, retrograde ejaculation).
2. Cervical factors.
3. Unexplained infertility.
4. Sperm antibodies.
5. Mild endometriosis.
6. Use of stored sperm from male members who, subsequent to active infertility treatment, required sperm banking/storage as a result of medical treatment (e.g., cancer treatment) likely to cause infertility.

In Vitro Fertilization (IVF)

FCHP covers IVF services when any of the following criteria are met:

1. Bilateral fallopian tube absence or bilateral fallopian tube obstruction due to prior tubal disease with failure of conventional therapy.
2. Severe endometriosis after failed surgical and medical therapy.
3. Male factor infertility.
4. Unexplained infertility of one year's duration and failed medicated IUI cycles (see also General Clinical Coverage Criteria paragraphs 2b and 2c).

Conversion from IUI to IVF

FCHP covers conversion to an IVF cycle from the current IUI cycle in women <40 years of age when the current IUI cycle has resulted in an estradiol level of ≥ 800 pg/ml and the production of at least 5 follicles >13 mm in diameter.

Intracytoplasmic Sperm Injection (ICSI)

1. FCHP covers ICSI when any of the following criteria are met:
 - a. Male factor infertility
 - b. Reduced fertilization on a prior IVF cycle (i.e., <50% fertilization rate on a prior IVF cycle)
 - c. Frozen sperm limited in number and quality.
 - d. Obstruction of the male reproductive tract not amenable to repair necessitating MESA or TESE.
2. ICSI is not a covered service when performed solely to accomplish PGD when the PGD is not a covered service (see below under PGD).

Assisted Hatching (AH)

While the routine use of AH in all IVF cycles, particularly in women <40 years of age, is not recommended, a specific subset of patients may benefit from the use of AH. FCHP will take into consideration the number of previously failed cycles, the woman's age, and other relevant clinical information. FCHP covers AH when any of the following criteria are met:

1. 2-3 failed IVF cycles due presumably to failure to implant after embryo transfer
2. Documented prior pregnancy following IVF with assisted hatching.

Microsurgical Epididymal Sperm Aspiration (MESA)

FCHP covers MESA in male members with congenital absence or congenital obstruction of the vas deferens.

Testicular Sperm Extraction (TESE)

FCHP covers TESE in male members with non-obstructive azoospermia.

Donor Egg

FCHP covers donor egg or donor embryo procedures when any of the following criteria are met:

1. Congenital or surgical absence of ovaries.

2. Premature ovarian failure (premature menopause; i.e., typically characterized by amenorrhea, hypoestrogenism, and elevated serum gonadotropin levels in women under 40 years of age)
3. Premature diminished ovarian reserve (defined as FSH \geq 15 in women under 40 years of age)
4. Inadequate ovarian response during an IVF attempt or medicated IUI cycle, or poor embryo quality following a medicated cycle within the prior 6 months.

Gamete intrafallopian transfer (GIFT)/Zygote intrafallopian transfer (ZIFT)

Patients undergoing GIFT or ZIFT must have at least one patent fallopian tube. FCHP covers GIFT or ZIFT if any of the following criteria is met:

1. Severe endometriosis after failed surgical and medical therapy.
2. Male factor infertility.
3. Unexplained infertility of one year's duration and failed medicated IUI cycles (see also General Clinical Coverage Criteria paragraphs 2b and 2c).

Sperm storage/banking

FCHP covers sperm banking/storage for members who were already in active infertility treatment and who meet one of the following criteria:

1. Male member is undergoing medical treatment (e.g., cancer treatment) that is likely to result in infertility.
2. Male member has undergone MESA or TESE.

Prior Voluntary Sterilization

FCHP covers infertility services for members who have undergone previous sterilization procedures (e.g., tubal ligation or vasectomy) with subsequent surgical reversal if their infertility is independent of the sterilization procedure and:

1. in the case of previous vasectomy with vasectomy reversal, there is a normal semen analysis within 6 months of the requested infertility services.
2. in the case of previous tubal ligation with re-anastomosis, post-surgery hysterosalpingogram demonstrates unilateral or bilateral tubal patency.
3. the member meets all other applicable medical necessity criteria under this policy.

Pre-Implantation Genetic Diagnosis (PGD)

FCHP covers PGD with ICSI for fertile and infertile couples when one of the following criteria is met:

1. Both partners are known carriers of a single gene autosomal recessive disorder
2. One partner is a known carrier of a single gene autosomal dominant disorder
3. One partner is a known carrier of a single gene X-linked disorder

FCHP covers PGD with ICSI for members who were already in active infertility treatment for IVF when:

1. One of the partners is known to have a balanced translocation.

FCHP may require laboratory documentation of the results from the partner's(s') genetic test(s).

Elevated Body Mass Index (BMI)

1. Female members with BMI \geq 40 must submit all of the following documentation prior to the initial FCHP approval of an ART cycle (including IUI):

- Nutrition consult
- Maternal fetal medicine (i.e., high risk obstetrics) consult

2. Female members with BMI \geq 35 must submit the following documentation prior to the initial FCHP approval of coverage of an IVF cycle:

Anesthesiology consult

Exclusions

1. Services that are considered experimental or investigational.
2. Services for a member who is not medically infertile.

3. Services for a partner or dependent who is not a member.
4. Services for women who are menopausal, except those women who are experiencing premature menopause.
5. Donor sperm
 - a. in the absence of documented male factor infertility, as evidenced by abnormal semen analysis.
 - b. In men with genetic sperm defects.
6. Chromosome studies of a donor (sperm or egg).
7. Preimplantation genetic diagnosis (PGD) for aneuploidy screening or other indications not listed above under "Covered Services."
8. Gender selection in the absence of a documented X-linked disorder.
9. Treatments requested solely for the convenience, lifestyle, personal or religious preference of the member in the absence of medical necessity.
10. Transportation costs to and from the medical facility
11. Treatment to reverse voluntary sterilization
12. Infertility services that are necessary as a result of a prior voluntary sterilization or unsuccessful sterilization reversal procedure, including, but not limited to consultations, labs, radiology studies, infertility drugs, ART cycles, and other services to assess and/or treat infertility in the member or in the member's partner prior to exposure of the female partner to sperm through either 12 months of attempted natural conception or 6 cycles of IUI.
13. Supplies that may be purchased without a physician's written order, such as ovulation test kits.
14. Services related to achieving pregnancy through a surrogate or gestational carrier.
15. Charges for the storage of donor sperm, eggs or embryo that remain in storage after the completion of an approved series of infertility cycles.
16. Service fees, charges or compensation for the recruitment of egg donors (this exclusion does not include the charges related to the medical procedure of removing an egg for the purpose of donation when the recipient is a member of the Plan).
17. Sperm, egg and/or inseminated egg procurement and processing, and banking of sperm or inseminated eggs, to the extent such costs are covered by the donor's insurer.

Committee Review Dates:

Benefit Committee Review Date(s): 08/1996, 10/1996, 02/1999, 07/2003

Technology Assessment Committee Review Date(s): 06/2003, 06/01/2006, 04/10/07

Technology Assessment Subcommittee review Date(s): 01/2004, 05/23/06, 01/30/07

Approved by: *Signature on file* 01/30/2007
 Dennis A. Batey, MD – Chief Medical Officer Date

IMPORTANT NOTE

Not all services are covered for all products or employer groups. This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy. Medicare and Medicaid policies will only apply to benefits paid for under Medicare or Medicaid rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the following website:

<http://cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp>