

Medical Policy

Assisted Reproductive Services/Infertility Services

Policy Number: 029

| | *Commercial and Qualified Health Plans | MassHealth | Medicare Advantage |
|----------------------------------|--|------------|--------------------|
| Authorization required | X | | X |
| No notification or authorization | | | |
| Not covered | | X | |

*Not all commercial plans cover this service, please check plan’s benefit package to verify coverage.

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Overview

The purpose of this document is to describe the clinical coverage criteria that Mass General Brigham Health Plan utilizes to determine medical appropriateness for assisted reproductive services including infertility services. This document does not address the coverage or criteria for the treatment of the underlying medical condition causing the infertility.

Infertility is the condition of an individual who is unable to conceive or produce conception during a period of one year if the member is younger than 35 or during a period of six months if the member is 35 years of age or older. 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 the member attempted to conceive prior to achieving that

pregnancy shall be included in the calculation of 1 year or 6-month period as applicable (M.G.L. Chapter. 175, section 47H and 211 CMR 37.09).

Mass General Brigham Health Plan only provides coverage for IVF medications if the IVF or medicated IUI services have been approved.

Coverage Guidelines

Mass General Brigham Health Plan covers medically necessary expenses for the non-experimental treatment of infertility to the same extent that benefits are provided for other medically necessary services and prescription medications when the member's plan includes infertility treatment.

The infertility treatment requested must be non-experimental, recognized as the community standard of practice in Massachusetts, and meet the criteria established by the American Society for Reproductive Medicine, the American College of Obstetrics and Gynecology, or the Society of Assisted Reproductive Technology.

Treatment should include thorough review of clinical history, lab values including sexually transmitted infection (STI) testing, uterine and fallopian tube anatomy (as appropriate) and documentation of immunity to varicella, rubella, and measles. Services must be authorized by Mass General Brigham Health Plan and delivered in accordance with medical necessity determinations.

Mass General Brigham Health Plan does not provide coverage for the treatment of infertility for MassHealth members, and members of certain Custom Plans. To determine if a Custom Plan covers infertility services, please refer to the *Schedule of Benefits* for the given plan. Infertility treatment will be listed under either "services your plan does NOT cover" or "Other Covered Services."

Covered Services/Procedures

Covered services and procedures include, but are not limited to:

1. [Artificial Insemination \(AI\)/Intrauterine insemination \(IUI\);](#)
2. [Conversion from IUI to In Vitro Fertilization \(IVF\);](#)
3. [In Vitro Fertilization \(IVF\);](#)
4. [Frozen embryo transfer \(FET\);](#)
5. [Single embryo transfer \(SET\);](#)
6. [Intra-Cytoplasmic Sperm Injection \(ICSI\);](#)
7. [Donor Egg for Infertility;](#)
8. [Donor Sperm or Therapeutic Donor Insemination \(TDI\) Services for Infertility;](#)
9. [Donor Egg/Sperm When There is a Risk of Transmitting a Genetic Disorder for a serious genetic condition;](#)
10. [Microsurgical Epididymal Sperm Aspiration \(MESA\); and Percutaneous epididymal sperm aspiration \(PESA\);](#)
11. [Testicular Sperm Extraction;](#)
12. [Cryopreservation of Embryos/Eggs;](#)
13. [Cryopreservation of Sperm;](#)
14. Sperm, egg and/or inseminated egg procurement and processing, and banking of sperm, eggs, or embryos when they will be used by the member, to the extent such costs are not covered by the donor's insurer, if any;
15. Assisted Hatching; and
16. Ovulation kits: Coverage provided with prescription for up to 3 kits to support authorized AI/IUI.



General Eligibility Coverage Criteria for treatment of infertility

Mass General Brigham Health Plan covers medically necessary assisted reproductive services when a member meets criteria for the service-specific assisted reproductive service that is requested. Certain services, as specified below, also require that the member meet general eligibility criteria for treatment of infertility, which are as follows:

1. The member must otherwise be an individual with whom fertility would be expected.
2. The member has ovaries and infertility, as demonstrated by one of the following:
 - a. The member has regularly attempted to conceive with a partner who has testes/sperm, but has been unable to conceive or produce conception during a one-year period, or for members ≥ 35 years of age for a period of six months (inclusive of time attempting to conceive a pregnancy that results in a miscarriage), or
 - b. For members with uteri/ovaries but without exposure to sperm, the member has been unable to conceive despite completion of six AI/IUI cycles performed by a qualified specialist using donor sperm with normal semen analysis parameters, or for members ≥ 35 years of age completion of three AI/IUI cycles, or
 - c. The member has oligo-ovulation or anovulation treated with medication for at least 6 months, or for members ≥ 35 years of age at least 3 months, or
 - d. The member has one of the following causes of infertility:
 - I. tubal factor infertility, such as bilateral Fallopian tube obstruction, or
 - II. stage 3 or 4 endometriosis, or
 - III. partner with severe male factor infertility, as defined in 7b, below.
3. Ovarian Reserve Assessment Criteria:
 - a. Members with ovaries < 40 years old should have ovarian reserve submitted by menstrual history and results from day 3 Follicle Stimulating Hormone (FSH) and Estradiol levels obtained within 2 years.
 - b. Members with ovaries ≥ 40 years of age must demonstrate adequate ovarian reserve evidenced by menstrual history and results from any of the following:
 - I. Clomiphene Citrate Challenge Test (CCCT) within the past 6 months by showing a Day 3 FSH level < 15 mIU/ml, Day 3 Estradiol Level < 80 pg/mL, and Day 10 FSH level < 15 mIU/ml; or
 - II. A CCCT within the parameters above performed within the past 12 months, and a Day 3 FSH level < 15 mIU/ml and Day 3 Estradiol Level < 80 pg/mL performed within the past 6 months; or
 - III. AMH level > 1.0 mg/mL or antral follicle count > 6 within the past 12 months, and Day 3 FSH < 15 mIU/mL within the past 6 months.
 - c. A member with FSH ≥ 15 mIU/ml at any time after her 40th birthday is ineligible for IVF, donor egg, or ICSI.
4. Anatomy Assessment:
 - a. With any AI/IUI request, tubal patency and adequate uterine contours must be demonstrated by either a hysterosalpingogram, or laparoscopy/hysteroscopy performed within the past 2 years.
 - b. With any IVF, FET, or donor egg request, adequate uterine cavity evaluation must be documented by either one of the tests above or by sonohysterogram or hysteroscopy performed within the past 2 years.
5. If the member or partner was a smoker/vaper within the last year, there must be documentation of urine or serum negative cotinine levels within a month of requested service.
6. A semen analysis within the past year must be submitted if partnered and applicable.



- a. A normal fertility threshold based on WHO 6th edition 2021 (i.e., semen volume 1.5 ml, sperm concentration 15 million/ml, sperm total 40 million, 40% motility, and 4% normal morphology by Kruger classification or morphology of 30% by WHO 6th edition classification).
 - b. Severe male factor infertility is defined with the following parameters documented on 2 semen analyses showing:
 - I. < 10 million total motile sperm/ejaculate (pre-wash specimen); or
 - II. < 3 million total motile sperm (post-wash specimen); or
 - III. ≤ 2% normal forms (Strict Kruger Morphology); or
 - c. If the sample is abnormal, a second sample within the past year must be obtained, and if it remains abnormal, an evaluation and treatment of reversible causes is recommended including smoking cessation for at least 3 months, if applicable. Mass General Brigham Health Plan requires a Urology consult for cases of severe male factor infertility.
 - d. If the partner has undergone a vasectomy reversal, two semen analyses in the past 3 months must be submitted to demonstrate continued success of the reversal and normal fertility threshold, in addition to meeting the service-specific criteria for individuals who have had a reversal of prior sterilization.
7. With any infertility treatment request, documentation of all prior treatment and cycle details, including pre- and post-wash semen analyses, must be submitted.
 8. There is a > 5% probability that infertility treatment being requested will result in a live birth using the member's own eggs based on clinical history including: pregnancy history, menopausal status, diagnosis, BMI, semen analysis and response to previous cycles and infertility treatments, or the member must meet criteria for donor egg.
 9. Mass General Brigham Health Plan does not cover infertility services for age-related decline, even if the member also has a medical-related cause of infertility. Members with uteri/ovaries ≥44 years of age are generally not eligible for infertility services. Based on published research by the CDC, a woman ≥ 44 years of age utilizing their own eggs have a ≤ 5% probability that in vitro fertilization will result in a live birth. Individual medical history is considered in any determination, but the age of the member with uterus/ovaries is the most important factor affecting the live birth probability.

SERVICE-SPECIFIC INFERTILITY COVERAGE FOR MEMBERS WITH UTERI and OVARIES

Artificial Insemination (AI)/Intrauterine Insemination (IUI)

Mass General Brigham Health Plan covers AI/IUI for members <44 years of age without a diagnosis of infertility who have ovulatory cycles but no exposure to sperm, unless otherwise specified in the Member Handbook or Schedule of Benefits.

Additionally, the Plan covers medically necessary AI/IUI and associated medications for treatment of infertility when [General Eligibility Coverage Criteria](#) 1-9 are met, and there is documentation of the following:

1. At least one patent Fallopian tube, normal ovary, and uterine cavity evaluation;
2. Spontaneous ovulation or adequate ovarian reserve testing;
3. Any one of the following:
 - a. Unexplained infertility
 - b. Anovulation in the absence of primary ovarian insufficiency/premature ovarian failure
 - c. Mild to moderate endometriosis
 - d. Cervical factors
 - e. Mild to moderate male factor infertility (i.e., with abnormal semen analysis but at least a sperm concentration of 10 mil/ml; total sperm count 20 million; motility of 20%; morphology 2% by strict Kruger classification or morphology 20% by WHO 6th edition classification; total motile sperm of at least 10 million; and total motile sperm of at least 5 million on a washed sample if performed);



- f. Medically necessary use of frozen sperm with normal fertility threshold parameters.

Conversion from IUI to In Vitro Fertilization (IVF)

Mass General Brigham Health Plan covers medically necessary conversion from IUI to IVF due to inadvertent ovarian hyperstimulation when the IUI cycle met IUI criteria, and all of the following are met:

1. Current IUI cycle has resulted in estradiol level of greater than or equal to 800 pg/ml.
2. Current IUI cycle has resulted in production of at least 5 follicles greater than 13 mm in diameter.

In Vitro Fertilization (IVF) for Infertility

A. Coverage Criteria

Mass General Brigham Health Plan covers medically necessary IVF for treatment of infertility when General Eligibility Coverage Criteria 1-9 are met, with the following conditions:

1. If severe male factor infertility is present, a urology consultation is required.
2. Members with severe premature ovarian failure characterized by age less than 40, amenorrheic for 6 months, and a menopausal FSH level OR primary ovarian insufficiency characterized by irregular menses for greater than 4 months (without another endocrine disorder) and a diagnosis of functional hypogonadotropic hypogonadism/functional hypothalamic amenorrhea are not eligible for IVF using their own eggs but can be considered for donor egg.
Mass General Brigham Health Plan expects that standard medication doses for stimulation be used and that all good quality embryos be frozen for future use. Mass General Brigham Health Plan covers cryopreservation up to two years for the remaining embryos.
3. When there are at least 3 cryopreserved embryos from a member ≤ 37 , or at least 4 from a member ≥ 38 , these must be used prior to any request for further IVF cycles.
4. No more than one IVF cycle may be approved at a time.

B. Single Embryo Transfer (SET)

1. Mass General Brigham Health Plan requires SET for the first two IVF cycles when at least 2 good-quality embryos are available at the time of transfer for members < 35 years of age.
2. Mass General Brigham Health Plan requires SET for the first IVF cycle when at least 2 good-quality embryos are available at the time of transfer for members age 35–37.
3. Mass General Brigham Health Plan does not require SET for a member over the age of 37.

In Vitro Fertilization (IVF) for Member not in Active Infertility Treatment

Mass General Brigham Health Plan covers one cycle of IVF for the purpose of egg retrieval, processing and fertilization and a single cryopreservation of eggs/embryos for up to two years, when there is documentation that a member will be undergoing medical or surgical treatment (e.g., chemotherapy, radiation, gender affirming treatment), that is likely to result in permanent infertility. In this case the member and/or couple do not need to be already receiving Mass General Brigham Health Plan -authorized infertility services. This does not include voluntary sterilization or past voluntary sterilization.

Mass General Brigham Health Plan does not cover these services for age-related decline in fertility. Members \geq age 40 must demonstrate adequate ovarian reserve as per General Eligibility Coverage Criteria 3b and 3c. Members ≥ 44 years of age are not eligible for these services, as per General Eligibility Coverage Criterion 9.

Frozen Embryo Transfer (FET)

Mass General Brigham Health Plan covers medically necessary FET when [General Eligibility Coverage Criteria 4b, 5, and 8 are met, and additionally:](#)

1. The request is not related to gestational carrier services (unless specified in Member Handbook), and



2. If the member is 44 years of age or older, not more than 5 years have elapsed since the creation of the embryo, and
3. One of the following two conditions is met:
 - a. Member has frozen embryos from a prior IVF or Donor Egg Cycle approved by Mass General Brigham Health Plan; or
 - b. Embryos were created while a patient was under an insurer other than Mass General Brigham Health Plan AND member met General Eligibility criteria 1-9 in this policy (either at the time of freezing or at the time of the request for FET).

Donor Egg Services for Infertility

Mass General Brigham Health Plan covers medically necessary donor egg services for treatment of infertility when fertility is naturally to be expected, when the member meets all [General Eligibility Coverage Criteria](#), and one of the following is met:

1. Premature ovarian failure with onset and diagnosis prior to age 40 (with either a Day 3 FSH or a random FSH if menopausal and amenorrheic of > 20 mIU/ml prior to age 40), or
2. Congenital or surgical absence of ovaries, or
3. Has failed IVF due to poor embryo quantity or quality, or
4. IVF is felt to offer ≤5% probability of live birth.

Donor egg services are subject to the following conditions:

1. Treatment of age-related decline in fertility, as defined in General Eligibility Coverage criterion #9, is excluded. Donor egg services are not covered for members ≥44 years of age, or for members ≥40 with inadequate ovarian reserve (see General Eligibility Coverage criterion 3b).
2. Anonymous or designated donors must be ≤ 35 years of age, or between the ages of 36 and 39 with normal ovarian reserve as demonstrated by a normal ovarian reserve criteria as outlined in General Eligibility criteria above. Those who are ≥40 years of age are not generally appropriate candidates to donate oocytes or embryos.
3. When donor egg coverage criteria are met, the cycle is authorized for up to 6 months. If the donor egg procedure is not performed, a new request with updated clinical information must be submitted for authorization.
4. Coverage for the embryo recipient (Mass General Brigham Health Plan member) includes: medications to support implantation if the member has a prescription drug benefit, egg insemination, the embryo transfer procedure, member monitoring, and cryopreservation of remaining embryos up to two years.
5. Coverage for the egg donor is limited to monitoring up to egg retrieval and the egg retrieval procedure, unless the embryo recipient has Mass General Brigham Health Plan prescription drug coverage in which case medications to stimulate the donor's ovaries and to induce ovulation are also covered.

Cryopreservation of Eggs/Embryos

Mass General Brigham Health Plan covers cryopreservation and storage for up to two year's storage when authorized in accordance with this policy and when one of the following criteria is met:

1. The member is receiving Mass General Brigham Health Plan -authorized IVF or Donor Egg services and has embryos which should not be transferred into the uterus during the current cycle due to:
 - a. The high risk of multiple gestations from the transfer of an excessive number of available embryos; or
 - b. The high probability of an adverse impact on the member's health and well-being, e.g., severe hyperstimulation syndrome.
2. The member is receiving Mass General Brigham Health Plan -authorized IVF and there are unfertilized mature eggs due to an unexpected lack of sperm for fertilization; or



3. The member will be undergoing medical or surgical treatment (e.g., chemotherapy, radiation, gender affirmation etc) excluding voluntary sterilization that is likely to result in permanent infertility, and Mass General Brigham Health Plan has authorized IVF for stimulation and retrieval. Cryopreservation of eggs/embryos will be covered for up to two years from the time of the egg retrieval.

Assisted Reproductive Technology (ART) when using a Surrogate/Gestational Carrier

Mass General Brigham Health Plan will authorize one cycle of oocyte stimulation, retrieval, and fertilization for members who meet General Eligibility Criteria 1, 3, 5, 6, 7, 8, and 9, and:

1. The member has a clear medical contraindication to pregnancy due to an uncorrectable structural uterine abnormality or a life-threatening condition (documentation required), and
2. The member is using their own oocytes and self-paying for a gestational carrier.

Use of donor egg(s) with a gestational carrier or transfer of embryo(s) to a gestational carrier is not covered (unless specified in the member's handbook) as the member is not physically treated in this instance. Services related to implantation (transfer, pre-pregnancy costs, cryopreservation) and pregnancy-related services for the gestational carrier are not covered.

SERVICE-SPECIFIC INFERTILITY COVERAGE FOR MEMBERS WITH TESTICLES/SPERM

Intra-Cytoplasmic Sperm Injection (ICSI)

Mass General Brigham Health Plan covers medically necessary ICSI when the member meets coverage criteria for IVF, and there is documentation of at least one of the following:

1. Partner has had urology consultation for severe male factor infertility (a Urology consult is required) documented on 2 semen analyses showing:
 - a. < 10 million total motile sperm/ejaculate (pre-wash specimen); or
 - b. < 3 million total motile sperm (post-wash specimen); or
 - c. ≤ 2% normal forms (Strict Kruger Morphology).
2. Total failed fertilization or near total failed fertilization (less than 50%) of mature eggs on a prior IVF cycle with standard insemination.
3. Need for coverage of preimplantation genetic testing (PGT). Please refer to Mass General Brigham Health Plan Medical Policy for Preimplantation Genetic Testing. For these cases, there is no need to document a second semen analysis or Urology consult.
4. Need to fertilize cryopreserved eggs.
5. ICSI is covered on the day of IVF egg retrieval if the post processing semen analysis of non-donor non-frozen sperm on that day meets the ICSI coverage criteria noted immediately above. Retrospective authorizations will be allowed.

Note: ICSI is not authorized for any IVF cycle using donor sperm since it is expected that normal quality donor sperm will be used.

Note: If sperm are to be used from MESA or TESE procedures, sufficient sperm quality and quantity for a successful ICSI and fertilization, and for a > 5% live birth probability must be documented before a request for IVF/ICSI is evaluated and authorized.

Donor Sperm or Therapeutic Donor Insemination (TDI) Services for Infertility

Mass General Brigham Health Plan covers normal quality donor sperm or TDI services for an Mass General Brigham Health Plan member who meets [General Eligibility Coverage Criteria](#) and has a partner diagnosed with moderate to severe male factor infertility as defined in the IVF section above. Coverage is limited to no more than one vial per IUI or IVF cycle.

Note: Please check plan benefit documents to confirm coverage beyond what is stated above.



Microsurgical Epididymal Sperm Aspiration (MESA)

Mass General Brigham Health Plan covers one MESA per lifetime for a member with azoospermia and normal testicular function evidenced by normal testes exam, FSH, and testosterone, and who has either: congenital bilateral absence of vas deferens (CBVAD), stricture of the vas deferens, atrophy/fibrosis of the spermatic cord/vas deferens, or infertility due to extra testicular obstructive causes (excluding that resulting from prior sterilization or sterilization reversal procedures).

Testicular Sperm Extraction (TESE)

Mass General Brigham Health Plan covers one TESE per lifetime for a member with non-obstructive azoospermia that is not due to suppression of sperm production by anabolic steroids, and when the azoospermia is not amenable to other treatment such as hormonal therapy for hypogonadotropic hypogonadism. There must be a Y chromosomal microdeletion assay and karyotype prior to TESE, to eliminate the possibility of genetic traits that would predict the failure of sperm retrieval.

Cryopreservation of Sperm

Mass General Brigham Health Plan covers cryopreservation and storage for up to two year's storage for a member who meets one of the following criteria:

1. The member has been diagnosed with a medical condition, not a result of previous voluntary sterilization, which requires that sperm be obtained directly via an Mass General Brigham Health Plan - authorized MESA or TESE procedure for ongoing infertility treatment.
2. The member has a neurological or psychological condition, not a result of previous voluntary sterilization, which interferes with the ability to produce a sperm sample on the day of an Mass General Brigham Health Plan -authorized infertility procedure. The member must have a confirmed diagnosis that requires that sperm be obtained in advance and cryopreserved for ongoing infertility treatment.
3. The member will be undergoing medical or surgical treatment (e.g., chemotherapy, radiation, gender affirmation) excluding voluntary sterilization that is likely to result in permanent infertility. In this case the member and/or couple do not need to be already receiving Mass General Brigham Health Plan - authorized infertility services. There must be a >5% probability of a future live birth using the member's cryopreserved sperm. Cryopreservation of sperm will be covered for up to two years from the time of the egg retrieval.

SERVICE-SPECIFIC INFERTILITY COVERAGE – ALL MEMBERS

Donor Egg/Sperm Services When There is a Risk of Transmitting a Genetic Disorder

Mass General Brigham Health Plan covers **donor egg** services for a member who meets IVF criteria for infertility, or covers normal quality **donor sperm** when a member meets General Eligibility Coverage Criteria for infertility in order to prevent a serious genetic condition (serious morbidity and/or mortality in childhood) in offspring when ONE of the following is present:

- Both partners are known carriers of a single autosomal recessive gene (only donor sperm covered); or
- One partner is a known carrier of a single gene autosomal dominant disorder; or
- One partner is a known carrier of a single gene X-linked disorder; or
- One of the partners is known to have a balanced translocation; or
- One of the partners is known to be a carrier of mitochondrial disease

Note: The egg donor is to be between the ages of 21 and 35 years of age with Day 3 FSH < 10 mIU/ml and E < 80 pg/ml OR AMH > 2 ng/mL. Coverage is as listed for Donor Egg Services for Infertility.

Note: Please also see Mass General Brigham Health Plan' medical policy - [Preimplantation Genetic Testing](#).



Individuals with a Sterilization Reversal

Medically necessary infertility services are authorized for members who have undergone successful reversal of previous voluntary sterilization procedures (e.g., vasectomy or tubal ligation) only when:

1. There is documentation of:
 - a. For a **vasectomy reversal**, a semen analysis with a normal fertility threshold (as noted in [General Eligibility Coverage Criteria](#)) to document the success of the reversal, followed by a member-age-applicable period of attempting natural conception, and then two semen analyses within 3 months of the request for infertility services to demonstrate continued success of the reversal.
 - b. For a **tubal ligation reversal**, a post-surgical hysterosalpingogram (HSG) or chromotubation or hystero-salpingo contrast sonography (HyCoSy) demonstrating unilateral or bilateral free spill tubal patency, followed by a member-age-applicable period of attempting natural conception, and then results of an HSG or chromopertubation performed within 3 months of the request for infertility services demonstrating that post-operative scarring and tubal blockage have not occurred, and there have been no ectopic pregnancies since the reversal.
2. The member/couple otherwise meets all [General Infertility Coverage Criteria](#), and
3. The member's need for infertility services is clearly documented to be completely independent of the previous sterilization procedure.

Exclusions

Mass General Brigham Health Plan does not provide coverage for infertility services for any condition/diagnosis/service not covered under this coverage criterion, including but not limited to:

1. Members who do not have an infertility benefit;
2. Coverage for undocumented infertility except for IUI as listed above;
3. Infertility services for members who are menopausal or perimenopausal or who are not naturally expected to be fertile, unless the woman is experiencing menopause at a premature age as noted in criteria above;
4. Services requested for the convenience, lifestyle, or personal preference of the member in the absence of medical necessity;
5. Infertility treatment with ≤5% chance of success for a live birth;
6. Donor sperm in the absence of a male partner; Please check plan benefit documents to confirm coverage.
7. Reversal of voluntary sterilization;
8. Infertility services (including but not limited to consultations, labs, radiology studies, infertility drugs, ART cycles, MESA, TESE and other services to assess and/or treat infertility in a member or a member's partner) requested as a result of a prior voluntary sterilization or unsuccessful sterilization reversal procedure;
9. Testicular Sperm Aspiration (TESA) procedure and all costs related to the procedure including but not limited to pathology screening, and facility and anesthesia charges;
10. Monitoring of non-authorized IUI cycles;
11. Cryopreservation of eggs, embryos, or sperm for convenience;
12. Storage of cryopreserved embryos, sperm, and eggs exceeding 2 years;
13. Cryopreservation and/or storage of testicular tissue;
14. Cryopreservation for the sole purpose of circumventing reproductive aging
15. Infertility services when normal embryos have been or will be discarded because of elective gender selection;
16. Embryonic research;
17. IUI, IVF, or ICSI when using donor sperm that is not of normal quality;



18. Non-medical fees related to sperm procurement, (e.g., fee to a sperm donor for donation of sperm to a sperm bank);
19. Infertility medications for anonymous donor
20. Coverage for donor egg services provided by an IVF center or other organization for use of the donor eggs or created embryos by multiple recipients;
21. Non-medical fees related to donor egg procurement: e.g., fee to a donor for donation of egg(s) to donor egg program, finder fees, broker fees, and legal fees;
22. Egg harvesting or other treatment incidental to an operative procedure required for an unrelated cause;
23. Coverage of donor sperm or the stimulation, retrieval, fertilization, or implantation of donor eggs and/or services when not used by either the member or the member's partner;
24. Surrogacy/Gestational Carrier Services unless those outlined above;
25. 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;
26. Infertility services when an individual or couple is using illicit substances or abusing substances known to negatively interfere with fertility or fetal development (e.g., opiates, cocaine, or alcohol). Results of serum or urine drug screening may be requested before infertility services are authorized;
27. Infertility services for a member who smokes or has not abstained from smoking for at least 3 months;
28. Infertility services when a partner with male factor infertility smokes or has not abstained from smoking for at least 3 months;
29. Services provided to a gestational carrier, including, but not limited to transfer, impending pregnancy costs, or cryopreservation of embryos, whether or not the gestational carrier is a Mass General Brigham Health Plan member;
30. Use of donor egg with gestational carrier even when the gestational carrier is a Mass General Brigham Health Plan member;
31. Investigational experimental procedures or treatment not based on scientific body of evidence;
32. Coverage of Fertility medications if the IVF or medicated IUI services are not approved.
33. Assisted reproductive services when the infertile member is not the intended recipient of the services, unless specified in the member's handbook.

MassHealth Variation

Mass General Brigham Health Plan uses guidance from MassHealth for coverage determinations for its MassHealth ACO members. **At the time of Mass General Brigham Health Plan's most recent policy review, MassHealth does not cover assisted reproductive services.**

Medicare Variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage determinations. **At the time of Mass General Brigham's most recent review, Medicare had no NCD or LCD for assisted reproductive services.**

Definitions

Artificial Insemination (AI): Placement of semen into the vagina with a syringe rather than through intercourse.

Assisted Hatching (AH): Embryo hatching is initiated in the laboratory by thinning the surrounding membrane around the embryo, enhancing implantation.

Anovulation: Failure to ovulate.



Azoospermia: A lack of sperm in the seminal fluid.

Clomiphene Challenge Test (CCCT): A test to assess ovarian reserve usually used in members with ovaries over 40 years of age. The test measures FSH and estradiol and the FSH response to the oral administration of 100 mg of clomiphene citrate for 5 days of the cycle-on-cycle day 5-9 with FSH measured on cycle Days 3 and 10 and estradiol measured on cycle Day 3.

Cryopreservation: Gametes or Embryos from one cycle are preserved for future use by storing them at very low temperatures.

Cycle: The start of menses followed by ovarian stimulation, egg retrieval, embryo transfer, and pregnancy testing.

Egg Retrieval: The removal of eggs from one or more ovarian follicles.

Embryo Transfer: The transfer of one or more embryos into the uterus or fallopian tube.

Frozen Embryo Transfer (FET): Transfer to the uterus of embryos that have been previously cryopreserved.

Infertility: The condition of an individual who is unable to conceive or produce conception during a period of one year if the member with uterus/ovaries is age 35 or younger or during a period of six months if the member with uterus/ovaries 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 one year or 6-month period as applicable (211 CMR 37.00: M.G.L. chs. 175, 176A, 176B, 176D and 176G; St. 1987, c. 394).

For members without exposure to sperm, infertility is determined by the inability to conceive after six AI/IUI cycles are performed by a qualified specialist using normal quality donor sperm.

Intrauterine Insemination (IUI): A fertility treatment that uses a catheter to place a number of washed sperm directly into a woman's uterine cavity in an effort to achieve pregnancy.

Intra-Cytoplasmic Sperm Injection (ICSI): Injection of sperm into an egg for fertilization.

Single embryo transfer (SET): Transfer of a single embryo at either the cleavage stage (day 2 or 3 after an egg retrieval) or blastocyst stage (day 5 or 6 after an egg retrieval), that is selected from a larger number of available embryos.

Relevant Regulation

Division of Insurance Infertility benefits, 211 CMR 37.00

Infertility (37.03)

The condition of an individual who is unable to conceive or produce conception during a period of one year if the female is younger than age 35 or during a period of six months if the female is age 35 or older. 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 one year or 6-month period as applicable.

Scope of Coverage (37.04)

Insurers shall provide benefits for required infertility procedures, as described in 211 CMR 37.05, which are furnished to an insured, covered spouse and/or other covered dependent.

Insurers shall not be required to provide benefits for services furnished to a spouse or dependent if the spouse or dependent is not otherwise covered by the insurer, except as provided in 211 CMR 37.05(4).

Required Infertility Benefits (37.05)



Subject to any reasonable limitations as described in 211 CMR 37.09, insurers shall provide benefits for all non-experimental infertility procedures including, but not limited to:

- (1) Artificial Insemination (AI) and Intrauterine Insemination (IUI);
- (2) *In Vitro* Fertilization and Embryo Transfer (IVF-ET);
- (3) Gamete Intrafallopian Transfer (GIFT);
- (4) Sperm, egg and/or inseminated egg procurement and processing, and banking of sperm or inseminated eggs, to the extent such costs are not covered by the donor's insurer, if any.
- (5) Intracytoplasmic Sperm Injection (ICSI) for the treatment of male factor infertility;
- (6) Zygote Intrafallopian Transfer (ZIFT);
- (7) Assisted Hatching;
- (8) Cryopreservation of eggs.

Prescription Drugs (37.06)

Insurers shall not impose exclusions, limitations, or other restrictions on coverage for infertility-related drugs that are different from those imposed on any other prescription drugs.

Optional Infertility Benefits (37.07)

No insurer shall be required to provide benefits for:

- (1) Any experimental infertility procedure, until the procedure becomes recognized as non-experimental;
- (2) Surrogacy;
- (3) Reversal of Voluntary Sterilization;

Prohibited Limitations on Coverage (37.08)

- (1) No insurer shall impose deductibles, copayments, coinsurance, benefit maximums, waiting periods, or any other limitations on coverage for required infertility benefits which are different from those imposed upon benefits for services not related to infertility.
- (2) No insurer shall impose pre-existing condition exclusions or pre-existing condition waiting periods on coverage for required infertility benefits. No insurer shall use any prior diagnosis of or prior treatment for infertility as a basis for excluding, limiting, or otherwise restricting the availability of coverage for required infertility benefits.
- (3) No insurer shall impose limitations on coverage based solely on arbitrary factors, including but not limited to number of attempts or dollar amounts.

Permissible Limitations on Coverage (37.09)

Limitations on coverage shall be based on clinical guidelines and the insured's medical history. Clinical guidelines shall be maintained in written form and shall be available to any insured upon request. Standards or guidelines developed by the American Society for Reproductive Medicine, the American College of Obstetrics and Gynecology or the Society for Assisted Reproductive Technology may serve as a basis for these clinical guidelines.

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or payment.

This list of codes applies to commercial and MassHealth plans only.

| Authorized CPT/HCPCS Codes | Code Description |
|----------------------------|--|
| S4011 | In vitro fertilization; including but not limited to identification and incubation of mature oocytes, fertilization with sperm, incubation of embryo(s), and subsequent visualization for determination of development |



| | |
|-------|--|
| S4013 | Complete cycle, gamete intrafallopian transfer (GIFT), case rate |
| S4014 | Complete cycle, zygote intrafallopian transfer (ZIFT), case rate |
| S4015 | Complete in vitro fertilization cycle, not otherwise specified, case rate |
| S4016 | Frozen in vitro fertilization cycle, case rate |
| S4017 | Incomplete cycle, treatment cancelled prior to stimulation, case rate |
| S4018 | Frozen embryo transfer procedure cancelled before transfer, case rate |
| S4020 | In vitro fertilization procedure cancelled before aspiration, case rate |
| S4021 | In vitro fertilization procedure cancelled after aspiration, case rate |
| S4022 | Assisted oocyte fertilization, case rate |
| S4023 | Donor egg cycle, incomplete, case rate |
| S4025 | Donor services for in vitro fertilization (sperm or embryo), case rate |
| S4026 | Procurement of donor sperm from sperm bank |
| S4027 | Storage of previously frozen embryos |
| S4028 | Microsurgical epididymal sperm aspiration (MESA) |
| S4030 | Sperm procurement and cryopreservation services; initial visit |
| S4031 | Sperm procurement and cryopreservation services; subsequent visit |
| S4035 | Stimulated intrauterine insemination (IUI), case rate |
| S4037 | Cryopreserved embryo transfer, case rate |
| S4040 | Monitoring and storage of cryopreserved embryos, per 30 days |
| S4042 | Management of ovulation induction (interpretation of diagnostic tests and studies, nonface-to-face medical management of the patient), per cycle |

Effective Date/Approval History

January 2025: Off-cycle review. Clarified language in 4th exclusion above.

November 2024: Off-cycle review. Clarified Medicare Advantage language. Added MassHealth Variation. Clarified exclusions.

March 2024: Off-cycle review. The following changes were made:

- On Page 3: General Eligibility Criteria
 - Added 2c
 - Redefined and clarified the language around the specific causes of infertility by adding 2d. I, II, III.
 - Under Ovarian Reserve Assessment criteria, added language to specify that time in which AMH testing needs to be done as seen in 3b. III.
 - Age limit applied to item 3c.
- On Page 4 under Subheading Artificial Insemination (AI)/Intrauterine Insemination (IUI), added clarifying language for members <44 years of age.
- On Page 5 Under IVF Coverage Criteria
 - language regarding infertility definition, tubal factor and endometriosis reordered to prior section.



- Removed requirement on six cycle limit of IVF
- Under Frozen Embryo Transfer (FET) language reordered, clarified and added 1. 2. and 3.
- On Page 6 under Donor Egg Services for Infertility; language reordered and clarified without substantive changes to criteria.
- On Page 7 Under ICSI, added language “Partner has had urology consultation” to #1
- On Page 9 under Individuals with a Sterilization Reversal section; added the following language to 1b. “and there have been no ectopic pregnancies since the reversal”.

July 2023: Annual review. The following changes were made:

- On Page 1: Added medicare advantage to table.
- On Page 2: Removed statement that treatment must be provided by a Mass General Brigham Health Plan contracted provider.
- On Page 3:
 - Under 3a. Changed estradiol levels from 1-2 years to 2 years.
 - Under 3b. Added III.
 - Removed Note regarding members unable to tolerate clomiphene.
 - Under 4a. Minor edits. Criteria unchanged
 - Under 5: Added “vaper”
 - Added 6b
- On Page 5: Under IVF Coverage Criteria, #2 and #4 Editorial refinements, intent unchanged.
- On page 6; Under Donor Egg Services, changed age from 42 to 43 years of age. Under Note: changed age from 43 to 44.
- On Page 10; Removed exclusion “cryopreservation and/or storage of ovarian tissue”
- On Page 11: Added Medicare Variation Language

January 2023: Off-cycle review. The following changes were made:

- On Page 9: Under Surrogacy/Gestational Carrier, clarified language regarding transfer of embryo to gestational carrier. Under Service -Specific Infertility Coverage For Members With Testicles/Sperm section, added #5.
- On Page 13: Under Exclusions, added Assisted reproductive services when the infertile member is not the intended recipient.

November 2022: Annual review. The following changes were made:

- Page 1: Changed policy number.
- Page 2: Added language under Coverage Guidelines.
- Page 3: Added language reflective of best practices in STD testing and immunization. Clarified General Eligibility Criteria.
- Page 5: Changed to: “Mass General Brigham Health Plan will require a Urology consult for cases of severe male factor infertility”.
- Page 6: Added ovarian insufficiency language.
- Page 7. Coverage of FET clarified.
- Page 8: Changed egg donor language.
- Page 9: Clarified ICSI and donor sperm language.

August 2021: Annual review. The following changes were made:

- Revised policy to reflect organ-specific language.
- Under Covered Services Section:
 - Removed “Gamete Intra-Fallopian Transfer (GIFT)” and “Zygote Intrafallopian Transfer (ZIFT)”;
- Under General Eligibility Coverage Criteria
 - Item 5. Added “measles”
 - Items 6 a. and 6 b. – edited word from “must” to “should”



- Under Single Embryo Transfer (SET) in the 4th note: Removed words “In general”, in the sentence “Mass General Brigham Health Plan covers a maximum of 6 IVF cycles per lifetime, when the member continues to meet criteria.”
- Under “Cryopreservation of Eggs/Embryos” changed storage allowance from one to two years. Clarified this allowance throughout policy where applicable.
- Added Section Heading “Service-specific Infertility Coverage for Members with Uteri and Ovaries”
- Added Section Heading “Service-Specific Infertility Coverage for Members with Testicles/Sperm”
- Added Section Heading “Service-Specific Infertility Coverage – All Members”
- Definitions section updated.

July 2020: Annual review. Policy revised to include:

- Revised Overview section; removed list of the preferred IVF brand medications.
- Revised Covered Services/Procedures to include Percutaneous epididymal sperm aspiration
- General Eligibility Coverage Criteria updated;
 - added azoospermia as a causes of known infertility
 - Under anatomy section:
 - Added hystero-salpingo contrast sonography (HyCoSy)
 - Removed carrying capacity must be demonstrated
 - Revised language regarding hysteroscopy timeline to 2 years
- Revised Individuals with a Sterilization Reversal section to clarify female reversal to include hystero-salpingo contrast sonography (HyCoSy)
- Definitions section updated to include Azoospermia and Percutaneous epididymal sperm aspiration

March 2019: Annual review. Changed name of policy to Assisted Reproductive Services/Infertility Services. Clarified definition of infertility in women without exposure to sperm. Under General Eligibility Coverage Criteria, revised language under #2a to remove “*These AI/IUI cycles with normal quality donor sperm and associated sperm processing and infertility medications are not covered because infertility has not been established until the AI/IUI cycles have been completed...*” Changed language regarding immunity to rubella and varicella, lab testing and BMI. Clarified coverage criteria under Artificial Insemination (AI)/Intrauterine Insemination (IUI) section. Under Intra-Cytoplasmic Sperm Injection (ICSI) section, added language regarding documentation requirements for ICSI with authorized PGT cycle. Under Donor Egg Services for Infertility section, in #2, increased threshold to age 35. Under Donor Egg/Sperm Services When There is a Risk of Transmitting a Genetic Disorder. Increased threshold to age 35. Under Cryopreservation of Eggs/Embryos section, edited language under #3 adding “*or surgical treatment*”. Under Exclusions, edited #1 to include “except for IUI as listed above”, and #3 removed “AI/IUI cycles”. Removed exclusion for IVF only requiring cryopreservation of embryos. Removed requirement of female to meet General Eligibility requirements for TESE and MESA Updated references.

July 2018: Annual review. Added ovulatory dysfunction under General Eligibility Coverage Criteria 2 b. Added second note under General Eligibility Coverage Criteria. Added Hepatitis C to the #6 General Eligibility Coverage Criteria. Added “*documentation of urine or serum negative cotinine levels within a month of requested service*” under # 8 General Eligibility Coverage Criteria. Added unilateral or bilateral in 1.b. under Individuals with a Sterilization Reversal. Added “*and prior IVF cycles that resulted in live birth*” under Single Embryo Transfer (SET) within the fourth note. Added language regarding coverage for gender reassignment under IVF For Member Not in Active Infertility Treatment, Cryopreservation of Eggs/Embryos, and Cryopreservation of Sperm. Added section Surrogacy and Gestational Carrier. Updated references.

July 2017: Removed the restriction “*Infertility services for female member with a BMI ≥40, or has not had a BMI < 40 for the past 3 months*”



April 2017: Added coverage criteria indicating IVF/IUI medications are only covered if the IVF services are covered. Also added criteria for Single Embryo Transfer. Added definition of Single Embryo Transfer. Added exclusion.

November 2016: Annual review.

November 2015: Removed the condition that the intention is to transfer the eggs/embryos back to the member in order to meet IVF for members not in active infertility treatment but are undergoing medical treatment that renders them infertile.

July 2015: Added to general eligibility criteria that partners to be counseled re smoking risks, those with male factor to demonstrate smoking cessation of 3 months; and screening for infectious diseases. Added criteria for TESE; criteria for persons undergoing medical treatment that will render them permanently infertile. Clarified criteria for reversal of sterilization procedure and ICSI as well as made note that Mass General Brigham Health Plan expects with IVF that standard medication does be used and all good quality embryos be frozen.

July 2014: Added "This document does not address treatment of underlying medical condition causing infertility" to overview; reversal of sterilization general eligibility criteria; IUI cycle limit, notes to IVF section regarding premature ovarian failure; cryopreservation up to 1 year and lifetime maximum of 6 cycles; criteria for MESA; exclusions for TESE, illicit substances, BMI > 40 and smoking; and regulation language. Changed: general eligibility criteria: added anatomy assessment, BMI, smoking and semen analysis and donor egg for infertility criteria.

February 2013: Modified definition of infertility, modified general infertility criteria, changed cryopreservation to be up to two years & minor edits for clarification.

January 2012: Added IUI conversion criteria; Amended Benefit Coverage documentation, converted to criteria.

March 2004: Effective date.

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