

Medical Policy Assisted Reproductive Services/Fertility Services

Policy Number: 089

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

^{*}Not all commercial plans cover this service, please check plan's benefit package to verify coverage.

Contents

Overview	
Coverage Guidelines	
Covered Services/Procedures	2
General Eligibility Coverage Criteria	
SERVICE-SPECIFIC COVERAGE	
Artificial Insemination (AI)/Intrauterine Insemination (IUI)	3
Conversion from IUI to In Vitro Fertilization (IVF)	4
In vitro fertilization (IVF, with preimplantation genetic testing or for GIC plans only)	4
Frozen Embryo Transfer (FET)	
Donor Eggs (GIC plans only)	6
Donor sperm	
Cryopreservation of Eggs/Embryos	6
Assisted Reproductive Technology (ART) when using a Surrogate/Gestational Carrier	6
Intra-Cytoplasmic Sperm Injection (ICSI)	7
Cryopreservation of Sperm	7
Donor Egg/Sperm Services When There is a Risk of Transmitting a Genetic Disorder	7
Exclusions	
MassHealth Variation	9
Medicare Variation	9
Definitions	
Relevant Regulation	
Related Policies	
Codes	
Effective date	
References	

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 for members without a diagnosis of infertility. Members with diagnoses of infertility or who will be undergoing a procedure or treatment likely to result in infertility should refer to the Mass General Brigham Health Plan Assisted Reproductive Services/Infertility Services Medical Policy.



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

Coverage Guidelines

For members who do not have a diagnosis of infertility as defined in the Mass General Brigham Health Plan Assisted Reproductive Services/Infertility Services Medical Policy, selected assisted reproductive services may be covered as described in the plan's Schedule of Benefits or in the Member Handbook. Such assisted reproductive services are subject to requirements as described in this policy, including:

- The 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 assisted reproductive services for MassHealth members and members of certain Custom Plans. To determine to what extent a Custom Plan covers assisted reproductive services, please refer to the *Member Handbook* or to the *Schedule of Benefits*.

Covered Services/Procedures

For members for whom Mass General Brigham Health Plan has authorized preimplantation genetic testing (see <u>Mass General Brigham Health Plan Preimplantation Genetic Testing Medical Policy</u>), covered assisted reproductive services may include, but are not limited to:

- 1. In Vitro Fertilization (IVF);
- 2. Frozen embryo transfer (FET);
- 3. Single embryo transfer (SET);
- 4. Intra-Cytoplasmic Sperm Injection (ICSI);
- 5. Donor Egg;
- 6. Donor Sperm;
- 7. Cryopreservation of Embryos/Eggs;
- 8. Cryopreservation of Sperm;
- 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;
- 10. Assisted Hatching.

If members of Commercial and Medicare Advantage plans do not have a diagnosis of infertility and do not meet authorization requirements for preimplantation genetic testing, their schedule of benefits will confirm which assisted reproductive services may be covered. These may include, but are not limited to:

- 1. Artificial Insemination (AI)/Intrauterine insemination (IUI);
- 2. Conversion from IUI to In Vitro Fertilization (IVF);
- 3. Donor sperm for use in IUI;

For members of a Group Insurance Commission (GIC) plan who do not have a diagnosis of infertility and who do not meet authorization requirements for preimplantation genetic testing, covered assisted reproductive services may include, but are not limited to:



- 1. Artificial insemination (AI)/Intrauterine Insemination (IUI);
- 2. Conversion from IUI to In Vitro Fertilization (IVF);
- 3. IVF or reciprocal IVF;
- 4. Intra-Cytoplasmic Sperm Injection (ICSI);
- 5. <u>Donor Egg for members who do not have a partner that can produce fertilizable eggs;</u>
- 6. Donor Sperm for members who do not have a partner that can produce sperm;
- 7. Cryopreservation of Embryos/Eggs;
- 8. Cryopreservation of Sperm;
- 9. 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; and
- 10. Assisted Hatching IVF
- 11. Donor sperm for use in IUI
- 12. Donor sperm used for purposes of IUI, In-Vitro Fertilization (IVF), and reciprocal IVF services

General Eligibility Coverage Criteria

Mass General Brigham Health Plan covers 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, which are as follows:

- The member must be an individual in whom fertility would be expected. If infertility is identified, refer
 to the <u>Mass General Brigham Health Plan Assisted Reproductive Services/Infertility Services Medical
 Policy</u>.
- 2. There must be a greater than 5% probability that the treatment being requested will result in a live birth based on clinical history including: pregnancy history, menopausal status, diagnosis, BMI, semen analysis and response to previous cycles and fertility treatments.
- 3. With any request for assisted reproductive services, documentation of all prior treatment and cycle details, including pre- and post-wash semen analyses where applicable, must be submitted.
- 4. The member must be the recipient of the requested service.
- 5. Mass General Brigham Health Plan does not cover fertility services for age-related decline, even if there is a medical-related cause. Members with uteri/ovaries at least 44 years of age are generally not eligible for fertility services. Based on published research by the CDC, a woman at least 44 years of age utilizing her own eggs has 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 COVERAGE

Artificial Insemination (AI)/Intrauterine Insemination (IUI)

Mass General Brigham Health Plan covers Al/IUI for members with ovaries/uteri who meet general eligibility criteria, when their Member Handbook or Schedule of Benefits confirms donor sperm is a covered service. The following tests are required:

- Tubal patency and adequate uterine contours must be demonstrated by either a hysterosalpingogram, sonohysterogram, or laparoscopy/hysteroscopy performed within the past 2 years.
- 2. Adequate ovarian reserve must be demonstrated by one of the following:



- a. Members with ovaries less than 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 at least 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.
- 3. 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.

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 both 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, with preimplantation genetic testing or for GIC plans only)

Mass General Brigham Health Plan covers IVF for members with ovaries/uteri who meet general eligibility criteria who have received Health Plan authorization for preimplantation genetic testing. Additionally, Mass General Brigham Health Plan covers IVF or reciprocal IVF for members with ovaries/uteri who meet general eligibility criteria who are members of GIC plans.

The following are required for authorization of IVF:

- 1. Tubal patency and adequate uterine contours must be demonstrated by either a hysterosalpingogram, sonohysterogram, or laparoscopy/hysteroscopy performed within the past 2 years. This requirement is waived for the egg donor in a reciprocal IVF procedure.
- 2. Adequate ovarian reserve must be demonstrated by one of the following:
 - a. Members with ovaries less than 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 at least 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</p>



- 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.
- 3. 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.
- 4. 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. 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.
 - c. 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.
- 5. 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.
- 6. No more than one IVF cycle may be approved at a time.
- 7. Single Embryo Transfer (SET)
 - a. Mass General Brigham Health Plan requires SET for the first two IVF cycles for members less than 35 years of age.
 - b. Mass General Brigham Health Plan requires SET for the first IVF cycle for members aged 35 to 37.
 - c. Mass General Brigham Health Plan does not require SET for a member over the age of 37.

Frozen Embryo Transfer (FET)

Mass General Brigham Health Plan covers FET when <u>general eligibility criteria</u> are met and when all of the following criteria are met:

- 1. The request is not related to gestational carrier services (unless specified in Member Handbook), and
- 2. Tubal patency and adequate uterine contours must be demonstrated by either a hysterosalpingogram, sonohysterogram, or laparoscopy/hysteroscopy performed within the past 2 years; and
- 3. Frozen embryos are available from a prior IVF cycle and one of the following:



- a. the IVF or donor egg cycle was approved by Mass General Brigham Health Plan; or
- the recipient of the embryo met General Eligibility criteria 1-9 in the Mass General Brigham
 Health Plan Assisted Reproductive Services/Infertility Services Medical Policy (either at the time of freezing or at the time of the request for FET), or
- c. the embryos were subjected to preimplantation genetic testing and the recipient of the embryo met criteria for authorization of preimplantation genetic testing (see Mass General Brigham Health Plan Preimplantation Genetic Testing Medical Policy), or
- d. the recipient of the embryo is enrolled in a GIC plan.

Donor Eggs (GIC plans only)

Mass General Brigham Health Plan covers donor eggs for GIC members with testes who do not have a partner who can produce fertilizable eggs. A semen analysis must be performed within one year. If the semen analysis shows severe male factor infertility, the member may also be eligible for donor sperm; see Mass General Brigham Health Plan Assisted Reproductive Services/Infertility Services Medical Policy.

Donor sperm

Mass General Brigham Health Plan covers donor sperm for members with ovaries/uteri when criteria for authorization of IUI or IVF are met and their schedule of benefits confirms this is a covered service. One vial of donor sperm is authorized per IUI or IVF cycle.

Cryopreservation of Eggs/Embryos

Mass General Brigham Health Plan covers cryopreservation and up to two years' storage 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.

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 in Mass General Brigham Health Plan

Assisted Reproductive Services/Infertility Services Medical Policy, 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 for members with ovaries (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.



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. Total failed fertilization or near total failed fertilization (less than 50%) of mature eggs on a prior IVF cycle with standard insemination.
- 2. Need for coverage of preimplantation genetic testing (PGT). Please refer to <u>Mass General Brigham</u>
 Health Plan Medical Policy for Preimplantation Genetic Testing. For these cases, there is no need to document a second semen analysis or Urology consult.
- 3. Need to fertilize cryopreserved eggs.
- 4. 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.

Cryopreservation of Sperm

Mass General Brigham Health Plan covers cryopreservation and up to two years' storage for a member who 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 a Mass General Brigham Health Plan-authorized fertility procedure. The member must have a confirmed diagnosis that requires that sperm be obtained in advance and cryopreserved for ongoing fertility treatment.

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

Mass General Brigham Health Plan covers **donor egg** or **donor sperm** services in order to reduce the risk of transmitting a genetic disorder when:

- 1. Mass General Brigham Health Plan has authorized PGT-SR or PGT-M (see Mass General Brigham Health Plan Preimplantation Genetic Testing Medical Policy), and
- 2. Mass General Brigham Health Plan has authorized IVF.

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.

Exclusions

Mass General Brigham Health Plan does not cover assisted reproductive services for:

- 1. Members who do not have a fertility benefit;
- 2. Members who are menopausal or perimenopausal or who are not naturally expected to be fertile;
- 3. Services requested for the convenience, lifestyle, or personal preference of the member in the absence of medical necessity (except as described in the Member Handbook);
- 4. Fertility treatment with ≤5% chance of success for a live birth;
- 5. Reversal of voluntary sterilization;



- 6. Donor sperm in the absence of a male partner; please check plan benefit documents to confirm coverage.
- 7. Fertility services (including but not limited to consultations, labs, radiology studies, infertility drugs, ART cycles, MESA, TESE and other services to assess and/or treat a member or a member's partner) requested as a result of a prior voluntary sterilization or unsuccessful sterilization reversal procedure;
- 8. Monitoring of non-authorized IUI cycles;
- 9. Storage of cryopreserved embryos, sperm, and eggs exceeding 2 years;
- 10. Cryopreservation and/or storage of testicular tissue;
- 11. Fertility services when normal embryos have been or will be discarded because of elective gender selection;
- 12. Embryonic research;
- 13. IUI, IVF, or ICSI when using donor sperm that is not of normal quality;
- 14. Non-medical fees related to sperm procurement, (e.g., fee to a sperm donor for donation of sperm to a sperm bank);
- 15. Fertility medications for anonymous donor;
- 16. 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;
- 17. 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;
- 18. Egg harvesting or other treatment incidental to an operative procedure required for an unrelated cause;
- 19. 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;
- 20. Surrogacy/Gestational Carrier Services unless those outlined above;
- 21. 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;
- 22. Assisted reproductive services when an individual or couple is using illicit substances or misusing 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 assisted reproductive services are authorized;
- 23. Assisted reproductive services for a member who smokes or has not abstained from smoking for at least 3 months;
- 24. Assisted reproductive services when a partner smokes or has not abstained from smoking for at least 3 months;
- 25. 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;



- 26. Use of donor egg with gestational carrier even when the gestational carrier is a Mass General Brigham Health Plan member;
- 27. Investigational experimental procedures or treatment not based on scientific body of evidence;
- 28. Coverage of fertility medications if the IVF or medicated IUI services are not approved;
- 29. Assisted reproductive services when the 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 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

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

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

<u>Clomiphene Challenge Test (CCCT)</u>: 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.

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

<u>Cycle</u>: 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.

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

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

<u>Infertility</u>: 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.

<u>Intrauterine Insemination (IUI)</u>: 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.

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

<u>Single embryo transfer (SET)</u>: 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.

Related Policies

- Assisted Reproductive Services/Infertility Services Medical Policy
- Preimplantation Genetic Testing Medical Policy

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
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

July 2025: Effective date.

References

Massachusetts Regulations 211 CMR 37.00: Infertility Benefits.

M.G.L. Chapter 175 Section 47H.

Agency for Healthcare Research and Quality. Effectiveness of Assisted Reproductive Technology. Evidence Report/technology Assessment Number 167. May 2008. Accessed May 11, 2016.

American College of Obstetricians and Gynecologists Committee on Gynecologic Practice and Practice Committee. Female age-related fertility decline. Committee Opinion No. 589. Fertil Steril. 2014 Mar;101(3):633-4. doi: 10.1016/j.fertnstert.2013.12.032. PMID: 24559617. Reaffirmed 2020.

American Society for Reproductive Medicine (ASRM), American College of Obstetricians and Gynecologists (ACOG). ASRM and ACOB Committee on Gynecologic Practice. Pre-pregnancy Counseling. Committee Opinion Number 762. Fertil Steril. 2019 Jan;111(1):32-42. Accessed at: https://www.fertstert.org/article/S0015-0282(18)32252-0/pdf

American Society for Reproductive Medicine (ASRM), Society of Reproductive Biologists and Technologists (SRBT), Society for Assisted Reproductive Technology (SART). Practice Committees of ASRM, SRBT, and SART. In vitro maturation: a committee opinion. Fertil Steril. 2021 Feb;115(2):298-304. doi: 10.1016/j.fertnstert.2020.11.018. Epub 2020 Dec 24. PMID: 33358333



American Society for Reproductive Medicine (ASRM). Practice Committee of ASRM. Role of tubal surgery in the era of assisted reproductive technology: a committee opinion. Fertil Steril. 2021 May;115(5):1143-50. doi: 10.1016/j.fertnstert.2021.01.051. Epub 2021 Feb 26. PMID: 33642065

American Society for Reproductive Medicine. "Reproductive Aging in Women" Fact Sheet. Revised 2012 Accessed 2014

American Society for Reproductive Medicine. The Practice Committee. Aging and infertility in women: a committee opinion. Fertility and Sterility. July 2002; 78(1):215-219.

American Urological Association (AUA), American Society for Reproductive Medicine (ASRM). Schlegel PN, Sigman M, Collura B, et al. Diagnosis and treatment of infertility in men: AUA/ASRM guideline part I. Fertil Steril. 2021 Jan;115(1):54-61. doi: 10.1016/j.fertnstert.2020.11.015. Epub 2020 Dec 9. PMID: 33309062.

Anderson, Kirsty, Vicki Nisenblat, and Rob Norman. "Lifestyle factors in people seeking infertility treatment—a review." *Australian and New Zealand journal of obstetrics and Gynecology*. 2010; 50: 8-20.

Armstrong, Sarah, and Valentine Akande. "What is the best treatment option for infertile women aged 40 and over?" *Journal of assisted reproduction and genetics*. 2013; 30: 667-671.

Boulet, Sheree L., et al. "Trends in Use of and Reproductive Outcomes Associated with Intracytoplasmic Sperm Injection." *JAMA* 2015; 313: 255-263.

Centers for Disease Control and Prevention, American Society for Reproductive Medicine, Society for Assisted Reproductive Technology. 2010 Assisted Reproductive Technology National Summary Report. Atlanta: U.S. Department of Health and Human Services; 2012.

Centers for Disease Control and Prevention, American Society for Reproductive Medicine, Society for Assisted Reproductive Technology. 2015 Assisted Reproductive Technology National Summary Report. Atlanta (GA): US Dept of Health and Human Services; 2017

CMS Medicare Benefit Policy Manual, Chapter 15, Covered Medical and Other Health Services. Section 20.1 – Physician Expense for Surgery, Childbirth, and Treatment for Infertility.

Consensus Report of Massachusetts IVF Programs including: Bay State Medical Center, Springfield, MA, Boston IVF, Waltham, MA, Brigham & Women's Hospital, Boston, MA, Fertility Centers of New England, Reading, MA, Massachusetts General Hospital, Boston, MA and Reproductive Science Center, Lexington, MA, 2010

Cooper TG, Noonan E, von Eckardstein S, et al. World Health Organization reference values for human semen characteristics. Human reproduction update. 2010; 16: 231-245.

Corsan, G., et al. "Ovulation induction combined with intrauterine insemination in women 40 years of age and older: is it worthwhile?" *Human reproduction*. 1996; 11:1109-1112.

Division of Insurance Infertility benefits, 211 CMR 37.00: M.G.L.chs. 175, 176A, 176B, 176D and 176G: St. 1987, c. 394, accessed 2008, 2009, 2010, 2011, 2012, 2013, 2014, and 2018.

Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Division of Applied Public Health Training Epidemiology Program Office, Assisted Reproductive Technology Surveillance -- United States, Surveillance Summaries, 4/30, 2004 / 53(SS01); 1-20

Dovey, Serena, Rita M. Sneeringer, and Alan S. Penzias. "Clomiphene citrate and intrauterine insemination: analysis of more than 4100 cycles." *Fertility and Sterility*. 2008; 90: 2281-2286.



Eijkemans MJ, van Poppel F, Habbema DF, Smith KR, Leridon H, te Velde ER. Too old to have children? Lessons from natural fertility populations. Hum Reprod. 2014 Jun;29(6):1304-12. doi: 10.1093/humrep/deu056. Epub 2014 Mar 27. PMID: 24676403; PMCID: PMC4389129.

Ethics Committee of the American Society for Reproductive Medicine. "Fertility treatment when the prognosis is very poor or futile." *Fertility and Sterility. 2009;* 92: 1194.

Ethics Committee of American Society for Reproductive Medicine. Fertility treatment when the prognosis is very poor or futile: a committee opinion. Fertil Steril. 2012 Jul;98(1): e6-9. doi: 10.1016/j.fertnstert.2012.03.045. Epub 2012 Apr 25. PMID: 22537382

Ethics Committee of the American Society for Reproductive Medicine. Fertility treatment when the prognosis is very poor or futile: an Ethics Committee opinion. Fertil Steril. 2019 Apr;111(4):659-663.

Haebe, Jeffrey, et al. "Success of intrauterine insemination in women aged 40–42 years." *Fertility and Sterility*. 2002; 78: 29-33.

Harris, Isiah D., Stacey A. Missmer, and Mark D. Hornstein. "Poor success of gonadotropin-induced controlled ovarian hyperstimulation and intrauterine insemination for older women." *Fertility and Sterility*. 2010; 94: 144-148.

Hayes. Health Technology Assessment. Ovarian Tissue Cryopreservation for Preservation of Fertility in Patients Undergoing Gonadotoxic Cancer Treatment. Dallas, TX: Hayes; 2019 Oct 1. Annual Review 2021 Jan 18.

Kim, Howard H., et al. "Use and outcomes of intracytoplasmic sperm injection for non–male factor infertility." *Fertility and Sterility* 2007; 88: 622-628.

Landersoe SK, Forman JL, Petersen KB, Larsen EC, Nohr B, Hvidman HW, Nielsen HS, Andersen AN. Ovarian reserve markers in women using various hormonal contraceptives. Eur J Contracept Reprod Health Care. 2020 Feb;25(1):65-71. doi: 10.1080/13625187.2019.1702158. Epub 2019 Dec 19. PMID: 31852271.

Luna, Martha, et al. "Should ICSI be recommended routinely in patients with four or fewer oocytes retrieved?" *Journal of assisted reproduction and genetics* 2011; 28: 911-915.

Merviel, Phillipe, et al. "Predictive factors for pregnancy after intrauterine insemination (IUI): An analysis of 1038 cycles and a review of the literature." *Fertility and Sterility*. 2010; 93:79-88.

Moragianni, Vasiliki A., Stephanie-Marie L. Jones, and David A. Ryley. "The effect of body mass index on the outcomes of first assisted reproductive technology cycles." *Fertility and Sterility*. 2012; 98: 102-108.

Myers. "Outcome of donor oocyte cycles in assisted reproduction" JAMA. 2013; 310: 2403-2434

National Center for Chronic Disease Prevention (CDC): Assisted Reproductive Technology (ART): Annual Art Success Rates Reports. http://www.cdc.gov/art/ARTReports.htm.

Peng, Jing, et al. "Microsurgical vasoepididymostomy is an effective treatment for azoospermic patients with epididymal obstruction and prior failure to achieve pregnancy by sperm retrieval with intracytoplasmic sperm injection." *Human Reproduction*. 2014; 29: 1-7.

Petersen, Gitte Lindved, et al. "The influence of female and male body mass index on live births after assisted reproductive technology treatment: a nationwide register-based cohort study." *Fertility and Sterility*. 2013; 99:1654-1662.



Practice Committee of the American Society for Reproductive Medicine. "Aging and infertility in women." *Fertility and Sterility. 2006;* 86: S248.

Practice Committee of the American Society for Reproductive Medicine, and Practice Committee of the Society for Assisted Reproductive Technology. "Criteria for number of embryos to transfer: a committee opinion." *Fertility and Sterility*. 2013; 99: 44-46.

Practice Committee of the American Society for Reproductive Medicine, and Practice Committee of the Society for Assisted Reproductive Technology. "Definitions of infertility and recurrent pregnancy loss: a committee opinion" *Fertility and Sterility* 2020 Mar; 13(3):533-5. doi: 10.1016/j. fertnstert.2019.11.025. Epub 2020 Feb 27. PMID: 32115183.

Practice Committee of the American Society for Reproductive Medicine, and Practice Committee of the Society for Assisted Reproductive Technology. "Diagnostic evaluation of the infertile male: a committee opinion" *Fertility and Sterility.* 2015; 103: e18-e-24

Practice Committee of the American Society for Reproductive Medicine, and Practice Committee of the Society for Assisted Reproductive Technology. "Endometriosis and infertility: a committee opinion" *Fertility and Sterility*. 2012; 98: 591-598

American Society for Reproductive Medicine (ASRM). Practice Committee of ASRM. Evidence-based treatments for couples with unexplained infertility: a guideline. Fertil Steril. 2020 Feb;113(2):305-22. doi: 10.1016/j.fertnstert.2019.10.014. PMID: 32106976.

Practice Committee of the American Society for Reproductive Medicine, and Practice Committee of the Society for Assisted Reproductive Technology. "Female age-related fertility decline" *Fertility and Sterility* 2014; 101:633-634

Practice Committee of the American Society for Reproductive Medicine, and Practice Committee of the Society for Assisted Reproductive Technology. "Intracytoplasmic sperm injection (ICSI) for non-male factor infertility: a committee opinion" *Fertility and Sterility*. 2012:98: 1395-1399

Practice Committee of the American Society for Reproductive Medicine, and Practice Committee of the Society for Assisted Reproductive Technology. "Mature oocyte cryopreservation: a guideline" *Fertility and Sterility*. 2013; 99: 37-43

Practice Committee of the American Society for Reproductive Medicine, and Practice Committee of the Society for Assisted Reproductive Technology. "Obesity and reproduction: a committee bulletin." *Fertility and Sterility*. 2015; 104:1116-26.

Practice Committee of the American Society for Reproductive Medicine, and Practice Committee of the Society for Assisted Reproductive Technology. "Optimizing natural fertility: a committee opinion" *Fertility and Sterility*. 2017; 107: 52-8.

Practice Committee of the American Society for Reproductive Medicine, and Practice Committee of the Society for Assisted Reproductive Technology. "Report on varicolele and infertility: a committee opinion" *Fertility and Sterility* 2014; 102:1556–60

Practice Committee of the American Society for Reproductive Medicine, and Practice Committee of the Society for Assisted Reproductive Technology. "Rescue intracytoplasmic sperm injection: a systematic review" *Fertility and Sterility* 2014; 101:690–8



Practice Committee of the American Society for Reproductive Medicine, and Practice Committee of the Society for Assisted Reproductive Technology. "Role of assisted hatching in in vitro fertilization: a guideline" *Fertility and Sterility* 2014; 102:348–5.

Practice Committee of the American Society for Reproductive Medicine, and Practice Committee of the Society for Assisted Reproductive Technology. "Smoking and infertility: a committee opinion" *Fertility and Sterility*. 2012; 98: 1400-1406

Practice Committee of the American Society for Reproductive Medicine. Practice Committee of the American Society for Reproductive Medicine. Testing and interpreting measures of ovarian reserve: a committee opinion. Fertil Steril. 2020 Dec;114(6):1151-1157. doi: 10.1016/j.fertnstert.2020.09.134. PMID: 33280722.

Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Intracytoplasmic sperm injection (ICSI) for non-male factor indications: a committee opinion. *Fertil Steril*. 2020 Aug;114(2):239-245. doi: 10.1016/j.fertnstert.2020.05.032. Epub 2020 Jul 9. PMID: 32654822.Revelli, Alberto, et al. "Oocyte cryostorage to preserve fertility in oncological patients." Obstetrics and gynecology international volume 2012, Article ID 525896.

Single Embryo Transfer [Internet]. Centers for Disease Control and Prevention. 2017 [cited 2017 Feb 28]; Available from: https://www.cdc.gov/art/patientresources/transfer.html

Steinberg ML, et al. Elective single embryo transfer trends and predictors of a good perinatal outcome—United States, 1999–2010. *Fertility and Sterility* 2013;99(7):1937-1943.

Sunderam, Saswati, et al. "Assisted Reproductive Technology Surveillance—United States, 2010." Morbidity and mortality weekly report. Surveillance summaries (Washington, DC: 2002). 2013; 62: 1-24.

World Health Organization. WHO laboratory manual for the examination of human semen and cervical-mucus interaction, 4th ed. New York: Cambridge University Press. 1999

Wiser, Amir, et al. "Ovarian stimulation and intrauterine insemination in women aged 40 years or more." Reproductive BioMedicine Online. 2012; 24: 170-173.

