

Effective: November 1, 2024

Prior Authorization Required If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request to the FAX numbers below.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Notification Required IF <u>REQUIRED</u> , concurrent review may apply	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

Applies to:

Commercial Products

- ☒ Harvard Pilgrim Health Care Commercial products; Fax 800-232-0816
- ☒ Tufts Health Plan Commercial products; Fax 617-972-9409
- CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

- ☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 888-415-9055
- ☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 888-415-9055
- ☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 857-304-6404
- ☐ Tufts Health One Care – A dual-eligible product; Fax 857-304-6304

Senior Products

- ☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 866-874-0857
- ☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0965
- ☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0965
- ☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0965

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

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Overview

These Medical Necessity Guidelines include the clinical coverage criteria for all assisted reproductive technology/infertility services covered by the Plan for Massachusetts-based commercial products and employer groups in accordance with the applicable plan documents.

General Information

Assisted reproductive technology/infertility services are considered to be medically necessary for all members (male, female, and other gender identities) when criteria in this policy are met. For the purposes of this guideline, the term biological female refers to an individual having ovaries and a uterus and includes other gender identities. The term biological male refers to an individual having sperm and/or testes and includes other gender identities.

This medical necessity guideline is meant to be inclusive of people of all gender identities, sexual orientation, and relationships, intending to support equitable access to assistive reproductive services in accordance with plan covered benefits.

This medical necessity guideline is administered in accordance with M.G.L.c. 175, section 47H and 211 C.M.R 37.09, which states “Infertility shall mean the condition of an individual who is unable to conceive or produce conception during a period of one year if the female is age 35 or younger or during a period of six months if the female is over the age of 35. For purposes of meeting the criteria for 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 the one year or six-month period, as applicable.”¹

Assisted Reproductive Technology (ART) services, for the purposes of this guideline, include, but are not limited to:

- In vitro fertilization (IVF) and/or embryo transfer (ET)
- Frozen embryo transfer (FET)
- Gamete intra-fallopian transfer (GIFT)
- Donor oocyte (DO/IVF)
- Donor embryo/frozen embryo transfer (DE/FET)
- Intracytoplasmic sperm injection (ICSI)
- Assisted hatching (AH)
- Cryopreservation of embryos/sperm/eggs

ART/Infertility services will be covered when criteria are met, during the time when fertility is naturally expected. Additionally, there must be a 5%, or greater, chance of live birth as demonstrated by the treating provider.^{2,3}

Clinical Guideline Coverage Criteria

ART/Infertility Services

Eligibility Requirements

The Member must meet **ALL** of the following:

1. The member must be the recipient of the intended services;
2. Coverage for assisted reproductive technology/infertility treatment is based on the member's individual medical history and should demonstrate > 5% chance of live birth, using the members own eggs
3. The member must expect fertility as a natural state or must be experiencing menopause at a premature age. Hormone levels and medical history, among other factors, may be considered in this evaluation. Members who are unable to achieve a viable birth outcome using their own eggs/embryos,(unless criteria is met for donor egg) and are experiencing a normal and expected physiological decline in fertility (not consistent with a disease process) are not covered for infertility services.

In addition, the member must meet **ONE** of the following requirements to demonstrate infertility:

1. The Member has been diagnosed with infertility, the condition of a presumably healthy individual who has been unable to conceive or produce conception with exposure to sperm (e.g., at home insemination, sexual intercourse) during a period of six months, if the biological female is over the age of 35, and a period of one year if the biological female is age 35 or younger, as represented in the medical record; **or**
2. The member may also demonstrate infertility by **ONE** or more of the following:
 - a. An otherwise healthy member, who has completed four cycles of intrauterine inseminations (IUIs) with or without medication and has not been able to conceive ⁴; **or**
 - b. A member with an ovulation disorder who has been:
 - i. Treated with medication, with or without IUI for up to four cycles and has been unable to conceive ⁴; **or**
 - c. A member with **ONE** of the following documented conditions (including but not limited to):
 - i. Tubal factor infertility; **or**
 - ii. Adnexal adhesive disease; **or**
 - iii. Endometriosis (class III or IV)⁵; **or**
 - iv. Member's partner has male factor infertility as defined in this policy

Intrauterine Insemination

Members seeking Intrauterine Insemination (IUI) service must meet **ONE** of the following:

1. History of more than one Loop electrosurgical excision procedure (LEEP) for conization procedure that is considered a factor in the member's infertility
2. Diagnosis of vaginismus
3. The member or partner has met the eligibility requirements for ART services

In addition, Members seeking (IUI) services, the member must submit clinical evidence demonstrating ALL of the following:

1. Eligibility for ART services
2. Ovarian Reserve Testing-Cycle Day 3 (within one year)
 - a. Follicle Stimulating Hormone (FSH) level ≤ 15 mIU/ml**AND**
 - b. Estradiol (E2) level ≤ 100 pg/mL**OR**
 - c. Anti-Mullerian Hormone (AMH) (documentation is required with reason why FSH/E2 cannot be performed)⁶
3. Thyroid Stimulating Hormone (TSH) completed:
 - a. <35 years within two years
 - b. ≥ 35 years within one year
4. Rubella Status (all non-immune members must be vaccinated and wait one month thereafter before seeking approval for ART)⁷
5. Uterine cavity evaluation¹⁰
 - a. A uterine cavity evaluation (e.g., Hysterosalpingogram (HSG), Hysterosalpingo-Contrast Sonography (HyCoSy) within one year prior to the initial ART cycle
 - b. Uterine cavity follow-up evaluation is required every two years
 - c. A uterine cavity evaluation is needed following a pregnancy that resulted in an antenatal, intrapartum, or postpartum complications

Limitation: Cycle or treatment limitations may apply based on the plan. Please refer to the member's benefit document for any applicable benefit coverage limitations

In Vitro Fertilization

Members seeking In Vitro Fertilization (IVF) services, the member must submit clinical demonstrating ALL of the following:

1. Eligibility requirements for ART services
2. Thyroid Stimulating Hormone (TSH) completed:
 - a. <35 years within two years
 - b. ≥35 years within one year
3. Rubella Status (all non-immune members must be vaccinated and wait one month thereafter before seeking approval for ART)⁷
4. Urine or Serum Cotinine level (for a member who has quit smoking within one year)⁸
5. Ovarian Reserve Testing
 - a. For members ≥40 years of age
 - i. Clomiphene Citrate Challenge Test (CCCT) should occur every 12 months with an interval Cycle Day 3 test at six months. Anti-Mullerian (AMH) testing may be considered when documentation indicates a contraindication to CCCT ⁹
 - a. Cycle Day 3
 - FSH level ≤15 mIU/ml
 - AND**
 - Estradiol (E2) level ≤100 pg/mL
 - b. Cycle Day 10
 - FSH level ≤ 15 mIU/ml
 - ii. Interval Cycle Testing-Day 3 labs (6 months after CCCT)
 - a. FSH level ≤ 15 mIU/ml
 - AND**
 - b. Estradiol (E2) level ≤ 100 pg/mL
 - iii. Anti-Mullerian Hormone ¹⁸
 - a. Performed every six months If CCCT contraindicated
 - b. AMH greater than 0.3 ng/ml
 - b. For members < 40 years of age
 - i. Cycle Day 3 Ovarian Reserve Testing with FSH and E2 should occur every 12 months. Anti-Mullerian (AMH) testing may be considered when documentation indicates a contraindication to FSH and E2 testing.
 - a. Cycle Day 3
 - FSH level ≤15 mIU/ml
 - AND**
 - Estradiol (E2) level ≤100 pg/mL
 - OR**
 - b. Anti-Mullerian Hormone ¹⁸
 - Performed every 12 months if ovarian reserve testing contraindicated
 - AMH greater than 0.3 ng/ml
6. Uterine cavity evaluation¹⁰
 - a. A uterine cavity evaluation (e.g., Hysterosalpingogram (HSG), Hysteroscopy (HSC), Sonohysterography (SHG), or Hysterosalpingo-Contrast Sonography (HyCoSy) within one year prior to the initial ART cycle
 - b. Uterine cavity follow-up evaluation is required every two years
 - c. A uterine cavity evaluation is needed following a pregnancy that resulted in an antenatal, intrapartum, or postpartum complications

Limitations:

- Cycle or treatment limitations may apply based on the plan. Please refer to the member's benefit document for any applicable benefit coverage limitations

In-Vitro Fertilization (IVF) Services

Authorization for IVF cycles are considered on a case-by-case basis based upon the member's probability of a 5% or greater chance of live birth related to requested cycle and individual medical history. Medical history may include age, previous pregnancies with or without ART, length of time attempting pregnancy, ovarian reserve, results of previous IVF cycles and

male factor infertility. If approved for IVF, members will be approved for one fresh cycle or one freeze-all cycle per request.

1. ART/infertility services, as outlined in this medical necessity guideline, is a covered benefit for member who demonstrate infertility as defined above and for whom fertility is otherwise expected as a natural state (e.g., biological female < age 40 with an abnormal CCCT or AMH)

Note: For biological females over the age 40, There must be no evidence of significant diminished ovarian reserve as evidenced by abnormal lab values within the past six months

2. ART/infertility services using a biological female's own eggs continues to be the treatment of choice for biological female > age 40 and < age 44 when the following outcome is achieved for each previous ART cycle initiated:
 - a. At least three embryos on Day 3, each of which are at least six to eight cells, or at least one on Day 5 of average grade (Gardner 3BB or better)¹⁴
AND
 - b. Reasonable quality (grade B or its equivalent) is available for transfer per cycle (including up to fair fragmentation <25%-50%)
3. For IVF for preimplantation genetic diagnosis, refer to applicable Preimplantation Genetic Diagnosis Medical Necessity Guideline or applicable AIM criteria

Note: Members who have a documented medical contraindication to pregnancy, are using their own eggs, and are self-paying for a gestational carrier, may be authorized for ovarian stimulation, egg retrieval, and fertilization. Embryo transfer to the gestational carrier would not be covered.

In-Vitro Fertilization (IVF) due to Inadvertent Ovarian Hyperstimulation:

ART/Infertility services include a wide range of treatments and procedures to assist infertile individuals in achieving successful reproduction. One of these procedures includes intrauterine insemination (IUI), in which washed sperm is deposited directly the uterine cavity in an effort to achieve successful fertilization. Preparation for this procedure can include pre- treatment with various pharmacologic agents (including, but not limited to gonadotropins, clomiphene citrate, GnRH agonists and antagonists) to produce controlled ovarian hyperstimulation. When the use of these agents results in Ovarian Hyperstimulation Syndrome (OHSS), the only safe alternative to cancellation of the cycle is to convert it to IVF.¹⁵

Clinical Coverage Criteria

1. Coverage for IVF services due to inadvertent ovarian hyperstimulation during preparation for a stimulated intrauterine insemination cycle may be approved when **ALL** of the following are met:
 - a. The Member must be < age 40 with an infertility diagnosis, with an Estradiol level > 1000, with at least three or more follicles >16mm or four to eight follicles that are ≥ 14mm and/or a large number of smaller follicles on day the decision is made to convert; **and**
 - b. For members ≥40 years, it is not medically necessary to convert an IUI cycle to IVF due to ovarian hyperstimulation unless E2 is > 2000 and therefore coverage will be based on prior cycle response and individual history

Donor Egg

Donor Egg and/or Donor embryo transfer may be covered for members when they meet **ONE** of the following criteria:

1. Infertility is demonstrated pursuant to the criteria above
 - a. Premature menopause or premature ovarian failure (onset prior to age 40 with an FSH ≥15 mIU/ml on Cycle Day 3). Members with abnormal FSH levels after age 40 are not eligible for donor egg coverage regardless of evidence of abnormal FSH levels prior to age 40; **or**
 - i. Previously failed IVF in members with acceptable ovarian reserve between age 40-42 as noted under the in Vitro Fertilization section

Note: Anonymous or designated donors must be ≤ 35 years of age, or between ages 36 and 39 with normal ovarian reserve as noted above in ART requirements. Individuals aged 40 or older are not generally appropriate candidates to donate oocytes/embryos

The Plan does not cover the transfer of the embryo if the member is using a gestational carrier. The Plan does not cover surrogacy services.

Single Embryo/Frozen Embryo Transfer

Single Embryo Transfer (SET)

1. For the first two IVF cycles ever for members <35 years of age:
 - a. Coverage for the initial SET will be provided, when there are at least two good-quality embryos available at the time of transfer
 - b. If coverage for a second SET cycle is requested, authorization will not be given for a single fresh embryo transfer, unless a frozen embryo is not available for transfer
2. For the first IVF cycles ever for members 35 through 37 years of age:
 - a. Coverage will be provided for SET, when at least two good quality embryos are available at the time of transfer^{16,17,18}

If a live birth results from this cycle, then one additional SET cycle will be approved, when there are at least two good-quality embryos available at the time of transfer. If only a frozen embryo is available for transfer, then a Frozen Embryo Transfer cycle will be approved.

Frozen Embryo Transfer (FET)

1. Members seeking coverage for FET must demonstrate infertility and expect fertility as a natural state
2. Cryopreserved embryos must be used prior to authorization for additional fresh ART cycles under the following circumstances:
 - a. Members aged ≤ 37 years old and undergoing 2nd SET cycle, only a single FET will be covered unless a frozen embryo is not available (see section for SET)
 - b. Members aged < 35 years old and three cryopreserved embryos of a similar developmental stage are available for transfer
 - c. Members aged > 35, and four cryopreserved embryos of a similar developmental stage are available for transfer

Note: It is recognized that some members may elect to do a FET cycle regardless of the number of available embryos before proceeding to another fresh cycle. Such requests will be approved as long as the member continues to be eligible for coverage of infertility treatment.

Intra-Cytoplasmic Sperm Injections (ICSI)¹⁹

ICSI may be approved for coverage for **ONE** of the following:

1. Male factor infertility as defined by:
 - a. <10 million total motile sperm/ejaculate (pre-wash specimen) or < 3 million total motile sperm (post-wash specimen) on two separate semen analysis performed at least two weeks apart¹¹, OR
 - b. ≤1% normal forms pre or post wash on two separate semen analyses (Strict Kruger Morphology¹²), OR
 - c. < 40% fertilization (for mature eggs) on an IVF cycle with drop insemination
2. Use of frozen eggs
3. ICSI may be authorized for members authorized, for the coverage of preimplantation genetic diagnosis (PGD)

Assisted Hatching (AH)²⁰

The Plan considers assisted hatching as reasonable and medically necessary when part of an IVF or FET procedure when documentation confirms **ONE** of the following:

1. Prior failed transfer using quality embryos
2. Need for assisted hatching in prior ART cycles
3. Member is >35
4. Use of frozen embryos

ART Services for Biological Males

For biological males ~~members~~ seeking donor sperm or ART services, the member must submit documentation meet the following:

1. Semen analysis performed within one year
 - a. Abnormal semen analysis confirming male factor infertility as defined by:
 - i. <10 million total motile sperm/ejaculate (pre-wash specimen) or <3 million total motile sperm (post-wash specimen) on two separate semen analysis performed at least two weeks apart; ¹¹ OR
 - ii. ≤1% normal forms (Strict Kruger Morphology) ¹² AND;
 - b. Evaluation by a urologist
 - c. Two semen analyses, including volume
 - d. FSH and testosterone levels (within six months)
 - e. Karyotyping and Y chromosome microdeletion (YCMD) for nonobstructive azoospermia and for all S/A <3 mil sperm/cc
 - f. Cystic fibrosis screening for obstructive azoospermia – Congenital Absence of the Vas Deferens (CAVD) Karyotyping

Gamete and Zygote Intrafallopian Transfer (GIFT&ZIFT)

The plan considers GIFT/ZIFT to be medically necessary when the member meets the IVF criteria above

Donor Sperm

Coverage for donor sperm is provided to members undergoing infertility/ART services when criteria is met:

1. Male factor infertility as defined by:
 - a. <10 million total motile sperm/ejaculate (pre-wash specimen) or < 3 million total motile sperm (post-wash specimen) on two separate semen analysis performed at least two weeks apart¹¹, OR
 - b. ≤1% normal forms pre or post wash on two separate semen analyses (Strict Kruger Morphology¹²), OR
 - c. < 40% fertilization (for mature eggs) on an IVF cycle with drop insemination
 - d. Significant genetic defect in the biological male, electing donor sperm over genetic testing

In addition, coverage decisions regarding donor sperm services will be based upon the following information: member's past medical/infertility history, including, but not limited to past infertility interventions.

Microsurgical Epididymal Sperm Aspiration (MESA)

The Plan considers Microsurgical Epididymal Sperm Aspiration (MESA) as medically necessary for members with sperm with a documented congenital absence or obstruction, or traumatic obstruction, of the vas deferens, excluding obstruction resulting from prior sterilization or sterilization reversal procedures. ^{21,22}

Testicular Sperm Extraction (TESE)

The Plan considers testicular sperm extraction (TESE) or micro-TESE as medically necessary when documentation confirms members with testicles/sperm has documented non-obstructive azoospermia or have failed a prior MESA procedure. ^{21,22}

For Members with a History of a Sterilization Procedure Reversal

The Plan considers coverage of ART/Infertility services after successful reversal of prior sterilization as medically necessary for members who have undergone a previous sterilization procedure (e.g., tubal ligation or vasectomy) and subsequent surgical reversal, only when there is clinical documentation confirming **ALL** the following:

1. The Member meets all applicable medical necessity criteria for infertility treatment in this policy, and the member has undergone a successful reversal procedure
 - a. The Member's infertility is independent of the previous sterilization procedure, and the successful reversal procedure has been followed by appropriate attempts of natural conception
2. There is documentation of **one** of the following:
 - a. For members with testicles/sperm, two consecutive semen analyses within three months of the request for infertility services demonstrating a normal fertility threshold (as noted in Guidelines below) and continued success of the reversal
 - b. Documentation of a successful reversal of tubal ligation as evidenced by a normal hysterosalpingogram demonstrating unilateral or bilateral tubal spill

Cryopreservation

Clinical Coverage Criteria for Cryopreservation of Sperm, Oocyte, or Embryos²³

The Plan may authorize, with prior authorization, coverage for the harvest, procurement, and storage of sperm, oocytes, or embryos and said storage for up to 24 months in association with ongoing infertility care when or documentation confirms

ONE of the following is met:

1. When a member is undergoing medical treatment that may result in infertility (e.g., chemotherapy, radiation, gender affirming services)
2. When there is a high probability of an adverse impact on the member's health and well-being (e.g., severe hyperstimulation syndrome)
3. Single embryo transfer requirements or the high risk of multiple gestations from the transfer of an excessive number of available embryos
4. When eggs cannot be fertilized during an authorized IVF cycle due to lack of sperm or sperm of poor quality on the day of egg procurement
5. When a member has been diagnosed with a medical condition (excluding prior sterilization procedure) which requires that sperm be obtained directly from testicular tissue (including MESA or TESE)

Clinical Coverage Criteria for Cryopreservation of Reproductive Tissue²⁴

The Plan may authorize, with prior authorization, coverage for the storage of ovarian and testicular tissue for up to 24 months in members undergoing gonadotoxic treatment (e.g., chemotherapy, radiation)

Limitations

The Plan considers Services for fertility and infertility/assisted reproductive technology, for all other indications, not medically necessary and therefore not covered. In addition, the plan does not cover services for **any** of the following:

1. Services for individuals who do not have with a likelihood of 'success' (defined as a live birth rate less than 5%)
2. ART/Infertility services for members with age-related infertility and/or who do not demonstrate infertility
3. Infertility treatment when infertility is the result of a non-reversed voluntary sterilization
4. Treatment and related expenses not otherwise outlined above when the member is not the recipient of said services (e.g., gestational carrier or transfer of embryo to a gestational carrier, donor egg recruitment, or surrogacy related expenses) and drugs that are directly related to a stimulated ART cycle for anonymous or designated donor unless the ART service is prior authorized, and the Member is the sole recipient of the donor's eggs
5. Sperm cryopreservation as a routine procedure for sperm backup in the absence of a confirmed physical or psychological diagnosis requiring cryopreservation
6. ART/Fertility services (including but not limited to consultations, labs, radiology studies, infertility drugs, ART cycles, 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 unless there is documentation that criteria (above) are met
7. Treatments requested solely for the convenience, lifestyle, personal or religious preference of the member in the absence of medical necessity
8. ART/Fertility services in cases in which normal embryos have been or will be discarded because of gender selection
9. Infertility services for biological females who are not Rubella immune
10. ART/fertility services when clinical documentation indicates a member or member's partner has active or uncontrolled alcohol use disorder or substance use disorder. Results of serum or urine drug screening may be requested before ART services are authorized
11. ART/Infertility services for biological females who are actively smoking cigarettes and/or are using nicotine containing products such as gum, patches, or electronic cigarettes
12. Treatment to reverse voluntary sterilization, or MESA/TESE, for a member who has undergone prior sterilization
13. Charges for the storage of eggs, sperm or embryos that remain in storage after the completion of approved fertility service beyond the authorization period described above
14. Compensation for the recruitment of egg donors including but not limited to testing, screenings, services fees, and charges
15. Chromosome studies of donor (sperm or egg)
16. ICSI for any IVF cycle involving use of donor sperm
17. Services or drugs directly related to non-covered services (when the procedure is outside the scope of the Clinical Coverage Guidelines)
18. Members aged 43 or older, who are unable to achieve a viable birth outcome using their own eggs/embryos and are experiencing normal and expected age-related decline in fertility, are not covered for infertility services Members aged 40 or older are not appropriate candidates to donate oocytes/embryos

Administrative Process

1. The member must have a diagnosis of infertility and be eligible for coverage of medically necessary services as defined by these guidelines.
2. The member must receive infertility services at a Plan OB/GYN, or infertility specialist as required by the member's benefit document.
3. The member must receive ART services at a Plan contracting ART Center as required by the member's benefit document.
4. The Provider must complete the applicable prior authorization forms when requesting services.
5. The Provider must complete the Infertility Treatment Summary Form when requesting services.
6. Authorized services may be approved for up to one year for biological females < 40 years old and up to six months for biological females ≥ 40 years old.
7. If a request or clinical need for treatment such as FSH/IUI OR a conversion from IUI to IVF due to inadvertent ovarian hyperstimulation occurs outside of the Plan's normal business hours, the Member's physician should make the treatment decision based on their clinical judgment at the time. The physician must contact the Plan on the next business day. Retrospective coverage may be approved if the medical necessity guidelines and eligibility requirements are met.
8. After the authorization period ends, the member must go through a new prospective review process for coverage of any additional cycles.

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

Code	Description
58321	Artificial insemination; intra-cervical
58322	Artificial insemination; intra-uterine
58970	Follicle puncture for oocyte retrieval, any method
58974	Embryo transfer, intrauterine
58976	Gamete, zygote, or embryo intrafallopian transfer, any method
76948	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation
89250	Culture of oocyte(s)/embryo(s), less than 4 days;
89251	Culture of oocyte(s)/embryo(s), less than 4 days; with co-culture of oocyte(s)/embryos
89253	Assisted embryo hatching, micro techniques (any method)
89254	Oocyte identification from follicular fluid
89255	Preparation of embryo for transfer (any method)
89258	Cryopreservation; embryo(s)
89259	Cryopreservation; sperm
89268	Insemination of oocytes
89272	Extended culture of oocyte(s)/embryo(s), 4-7 days
89280	Assisted oocyte fertilization, micro technique; less than or equal to 10 oocytes
89281	Assisted oocyte fertilization, micro technique; greater than 10 oocytes
89290	Biopsy, oocyte polar body or embryo blastomere, micro technique (for pre-implantation genetic diagnosis); less than or equal to 5 embryos
89335	Cryopreservation, reproductive tissue, testicular
89337	Cryopreservation, mature oocyte(s)
89342	Storage (per year); embryo(s)
89343	Storage (per year); sperm/semen
89344	Storage (per year); reproductive tissue, testicular/ovarian
89346	Storage (per year); oocyte(s)

Code	Description
58321	Artificial insemination; intra-cervical
89352	Thawing of cryopreserved; embryo(s)
89354	Thawing of cryopreserved; reproductive tissue, testicular/ovarian
89356	Thawing of cryopreserved; oocytes, each aliquot
89398	Unlisted reproductive medicine laboratory procedure
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
S4028	Microsurgical epididymal sperm aspiration (MESA)
S4037	Cryopreserved embryo transfer, case rate

References:

1. Massachusetts General Law Chapter 175 § 47H: Infertility, Pregnancy-Related Benefits: <https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47H>.
2. Fertility treatment when the prognosis is very poor or futile: a committee opinion. ASRM. Fertil Steril_ 2012; 98:e6–e9. Accessed at https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/ethics-committee-opinions/fertility_treatment_when_the_prognosis_is_very_poor_or_futile.pdf, on September 14, 2022
3. Luke B, Brown MB, Wantman E, et al. A prediction model for live birth and multiple births within the first three cycles of assisted reproductive technology. Fertil Steril. 2014;102(3):744-752. doi:10.1016/j.fertnstert.2014.05.020
4. Starosta A, Gordon CE, Hornstein MD. Predictive factors for intrauterine insemination outcomes: a review. Fertil Res Pract. 2020;6(1):23. Published 2020 Dec 11. doi:10.1186/s40738-020-00092-1
5. Cai H, Xie J, Shi J, Wang H. Efficacy of intrauterine insemination in women with endometrioma-associated subfertility: analysis using propensity score matching. BMC Pregnancy Childbirth. 2022;22(1):12. Published 2022 Jan 4. doi:10.1186/s12884-021-04342-y
6. Harris BS, Acharya KS, Weber JM, Truong T, Eaton JL. Can high antimüllerian hormone mitigate some of the age-related decline in live birth rates? The association between antimüllerian hormone and live birth among women over 40 undergoing in vitro fertilization. F S Rep. 2021 Sep 8;2(4):440-447. doi: 10.1016/j.xfre.2021.08.009. PMID: 34934985; PMCID: PMC8655414
7. Pregnancy and Rubella. Center for Disease Control and Prevention. <https://www.cdc.gov/rubella/pregnancy.html>. Published 2022. Accessed September 19, 2022.
8. Practice Committee of the American Society for Reproductive Medicine. Electronic address: asrm@asrm.org; Practice Committee of the American Society for Reproductive Medicine. Smoking and infertility: a committee opinion. Fertil Steril. 2018;110(4):611-618. doi:10.1016/j.fertnstert.2018.06.016
9. Practice Committee of the American Society for Reproductive Medicine. Aging and infertility in women: a committee opinion. Fertil Steril. 2002 Jul;78(1):215-9. doi: 10.1016/s0015-0282(02)03212-0. PMID: 12095531.
10. Gu P, Yang X, Zhao X, Xu D. The value of transvaginal 4-dimensional hysterosalpingo-contrast sonography in predicting the necessity of assisted reproductive technology for women with tubal factor infertility. Quant Imaging Med Surg. 2021;11(8):3698-3714. doi:10.21037/qims-20-1193

11. Schlegel PN, Sigman M, Collura B, et al. Diagnosis and Treatment of Infertility in Men: AUA/ASRM Guideline Part I. *J Urol*. 2021;205(1):36-43. doi:10.1097/JU.0000000000001521
12. Wald G, Punjani N, Hayden R, Feliciano M, Dudley V, Goldstein M. Assessing the clinical value of the Kruger strict morphology criteria over the World Health Organization fourth edition criteria. *F S Rep*. 2021;2(2):176-180. Published 2021 Apr 19. doi:10.1016/j.xfre.2021.04.003
13. Practice Committee of the American Society for Reproductive Medicine. Diagnostic evaluation of the infertile female: a committee opinion. *Fertil Steril*. 2015;103(6):e44-e50. doi:10.1016/j.fertnstert.2015.03.019
14. Teranishi A, Kuwata A, Fumino T, Hamai H, Shigeta M. A theoretical model for single blastocyst transfer. *J Assist Reprod Genet*. 2009;26(6):327-334. doi:10.1007/s10815-009-9321-y
15. Aboulghar M, Mansour R, Serour G, Abdrazek A, Amin Y, Rhodes C. Controlled ovarian hyperstimulation and intrauterine insemination for treatment of unexplained infertility should be limited to a maximum of three trials. *Fertil Steril*. 2001;75(1):88-91. doi:10.1016/s0015-0282(00)01641-1
16. Luke B, Brown MB, Wantman E, et al. Application of a validated prediction model for in vitro fertilization: comparison of live birth rates and multiple birth rates with 1 embryo transferred over 2 cycles vs 2 embryos in 1 cycle. *Am J Obstet Gynecol*. 2015;212(5):676.e1-676.e6767. doi:10.1016/j.ajog.2015.02.005
17. Practice Committee of American Society for Reproductive Medicine. Multiple gestation associated with infertility therapy: an American Society for Reproductive Medicine Practice Committee opinion. *Fertil Steril*. 2012;97(4):825-834. doi:10.1016/j.fertnstert.2011.11.048
18. Penzias, Bendikson, K., Butts, S., Coutifaris, C., Fossum, G., Falcone, T., Gitlin, S., Gracia, C., Hansen, K., La Barbera, A., Mersereau, J., Odem, R., Paulson, R., Pfeifer, S., Pisarska, M., Rebar, R., Reindollar, R., Rosen, M., Sandlow, J., & Vernon, M. (2017). Guidance on the limits to the number of embryos to transfer: a committee opinion. *Fertility and Sterility*, 107(4), 901–903. <https://doi.org/10.1016/j.fertnstert.2017.02.107>
19. Boulet, SL., Mehta, M., Kissin, DM., et al. Trends in use of and reproductive outcomes associated with intracytoplasmic sperm injection. *JAMA*. 2015; 313(3): 255-263
20. Practice Committee of the American Society for Reproductive Medicine; Practice Committee of the Society for Assisted Reproductive Technology. Role of assisted hatching in in vitro fertilization: a guideline. *Fertil Steril*. 2014;102(2):348-351. doi:10.1016/j.fertnstert.2014.05.034
21. Ramasamy R, Lin K, Gosden LV, Rosenwaks Z, Palermo GD, Schlegel PN. High serum FSH levels in men with nonobstructive azoospermia does not affect success of microdissection testicular sperm extraction. *Fertil Steril*. 2009;92(2):590-593. doi:10.1016/j.fertnstert.2008.07.1703
22. van Wely M, Barbey N, Meissner A, Repping S, Silber SJ. Live birth rates after MESA or TESE in men with obstructive azoospermia: is there a difference?. *Hum Reprod*. 2015;30(4):761-766. doi:10.1093/humrep/dev03
23. Practice Committee of the American Society for Reproductive Medicine. Electronic address: asrm@asrm.org. Evidence-based outcomes after oocyte cryopreservation for donor oocyte in vitro fertilization and planned oocyte cryopreservation: a guideline. *Fertil Steril*. 2021;116(1):36-47. doi:10.1016/j.fertnstert.2021.02.024
24. ASRM Practice Committee. Fertility preservation in patients undergoing gonadotoxic therapy or gonadectomy: a committee opinion. *Fertil Steril* 2019;112(6):1022–33

Approval And Revision History

September 21, 2022: Reviewed and approved by the Medical Policy Approval Committee (MPAC) for an effective date of January 1, 2023.

Subsequent endorsement date(s) and changes made:

- January 27, 2023: Clarified formatting of evaluation requirements for biological males seeking services.
- July 19, 2023: Reviewed by MPAC; criteria for ICSI and assisted hatching clarified; limitations modified for clarity effective September 1, 2023
- November 2023: Unify name changed to OneCare effective January 1, 2024
- December 20, 2023: Review by MPAC, limitations updated effective February 1, 2024
- June 20, 2024: Reviewed by MPAC, format updated, donor egg criteria clarified, code 89272 added to PA for Direct effective October 1, 2024
- September 19, 2024: Reviewed by MPAC, criteria updated to include coverage for cryopreservation and storage of reproductive tissue (ovarian and testicular) when members are undergoing gonadotoxic treatment; Codes 89335, 89344, 89354, and 89398 added to require prior authorization effective November 1, 2024

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better

understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.