Medical Necessity Guidelines:
Infertility Services – Massachusetts Products

Effective: May 20, 2020

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	**Yes ☒ No ☐**

Applies to:
COMMERCIAL Products
☒ Tufts Health Plan Commercial products; Fax: 617.972.9409
☐ Tufts Health Freedom Plan products; Fax: 617.972.9409
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

TUFTS HEALTH 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 Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

SENIOR Products
- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List
- Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List

Note: While you may not be the provider responsible for obtaining prior authorization as a condition of payment you will need to make sure that prior authorization has been obtained.

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OVERVIEW

These Medical Necessity Guidelines include the coverage criteria for all infertility services covered by Tufts Health Plan policies issued under a Massachusetts license.

CLINICAL COVERAGE CRITERIA

I. Infertility Services

A. Definition of Infertility

As per (M.G.L.c. 175, section 47H and 211 C.M.R 37.09)

"Infertility shall mean the condition of an individual who is unable to conceive or produce conception during a period of 1 year if the female is age 35 or younger or during a period of 6 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 1 year or 6 month period, as applicable."

Assisted Reproductive Technology (ART), for the purposes of this document, 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/blasts
- Cryopreservation of sperm

B. Eligibility Requirements for Infertility Services

All employees of Massachusetts-based fully-insured employer groups are covered for Infertility Services, according to this guideline, regardless of their state of residence.

In addition, a Member must meet all of the following applicable minimum eligibility requirements to be covered:

1. The Member has been diagnosed with infertility, the condition of a presumably healthy individual who has been unable to conceive or produce conception during a period of one year or six months as defined in infertility definition above. The Practice Committee and Board of Directors of the American Society for Reproductive Medicine stated in 1993 that infertility is a disease. Their statement goes on to define a disease as "any deviation from or interruption of the normal structure or function of any part, organ or system, or combination thereof, of the body that is manifested by a characteristic set of symptoms or signs, and whose etiology, pathology, and prognosis may be known or unknown." [1]
2. For females, the Member must be premenopausal and reasonably expect fertility as a naturel state, or the Member must be menopausal and experiencing menopause at a premature age.[2] Factors to be considered in making the diagnosis of infertility may include, but are not limited to, age, hormone levels, medical history[3] and a Member's body mass index (BMI.)
3. Tufts Health Plan must receive documentation indicating that the Member has been unable to conceive or produce conception during a period of one year or 12 menstrual

cycles of exposure to sperm for Members ≤ age 35; or 6 cycles for women > age 35 , as a result of infertility.
4. The infertile Member must be the recipient of the intended infertility services.
5. Coverage for infertility treatment is based on the Member's individual medical history and should demonstrate > 5% chance of a birth outcome.[5]
6. ART procedures must be performed by one of Tufts Health Plan's contracting ART providers in order for ART procedures to be covered for HMO and EPO Members. POS and PPO Members must also go to a Tufts Health Plan ART contracting ART provider for coverage at the Authorized/In-network level of benefits.
7. Coverage of Medications: Injectable/non-injectable medications (not experimental) must be given in conjunction with covered infertility procedures in accordance with Tufts Health Plan eligibility requirements, and the Member must be in a plan that includes prescription drug coverage (Pharmacy Medical Necessity Guideline for Infertility Medications).
8. Preimplantation genetic diagnosis (PGD) may be covered when specific criteria are met. Refer to Tufts Health Plan Preimplantation Genetic Diagnosis Medical Necessity Guideline.

C. General Limitations of Infertility Services

Tufts Health Plan does not cover the following:

1. Any assisted reproductive technology (ART) procedure or related treatments that Tufts Health Plan deems experimental or investigative based on the scientific body of evidence with input from the American Society of Reproductive Medicine, the American College of Obstetrics and Gynecology, or another infertility expert recognized by the Massachusetts Division of Insurance.[6]
2. Infertility treatment, when infertility is the result of a non-reversed voluntary sterilization.[7]
3. Infertility services for individuals who have not met the definition of infertility, or the likelihood of a 'success' (defined as a live birth rate) is less than 5%.[5]
4. Infertility treatment for women with age-related infertility and/or who do not demonstrate infertility as a disease state.
   Note: Any elevation in FSH level after the age of 40 is considered age-related infertility and therefore infertility services are not covered.
5. Infertility treatment when the infertile Member is not the recipient of said services (e.g., donor egg in conjunction with gestational carrier or transfer of embryo to a gestational carrier) and drugs that are directly related to a stimulated ART cycle for anonymous or designated donors unless the ART service is prior authorized, and the Member is the sole recipient of the donor's eggs.
6. ART/Infertility services when clinical documentation indicates a Member or Member's partner is using or abusing substances that are known to negatively affect fertility potential, ART outcome, or fetal development (e.g. marijuana, opiates, cocaine, alcohol, tobacco). Results of serum or urine drug screening may be requested before infertility services are authorized.
7. Gonadotropin usage greater than 600 IU/day (8 amps/day) as there is no proven medical necessity or efficacy to support utilization beyond this amount.
8. Intrauterine insemination (IUI) or ART in the absence of male factor infertility or the absence of a male partner, until the female meets the definition of infertility and coverage criteria for said services.
9. The cost of donor sperm, IUI, ART, and related services, if the male partner has a history of prior vasectomy with no subsequent vasectomy reversal procedure. [7]
10. The cost of donor sperm, if the infertile Member does not have a male partner with a diagnosis of male factor infertility.
11. Services or drugs directly related to non-covered services. (Specifically, there is no coverage of ART procedures or drugs when related to, or in conjunction with a non-covered benefit, or when the procedure is outside the scope of the Clinical Coverage Guidelines.)
12. Infertility services for women who are not Rubella immune.
13. Infertility services for women who are actively smoking cigarettes and/or are using nicotine containing products such as gum, patches or electronic cigarettes.[8]
14. Anti-Mullerian hormone (AMH) testing for ovarian reserve is considered experimental.
15. Uterine embryo lavage using Previvo catheter device is considered experimental.

16. Cryopreservation, storage, and thawing of reproductive tissue (ovarian/testicular), CPT codes 0058T, 89335, 89344, and 89354 are considered experimental.

D. General Information

To be considered for eligibility for Infertility treatment approval and cycle initiation, the following must be completed:

1. Evaluation of the Female

a. The following evaluation is required:
   1) Thyroid stimulating hormone (TSH)
   2) Rubella status (all non-immune Members must be vaccinated and wait one month thereafter before seeking approval for ART)
   3) Urine or serum Cotinine level (for a Member who has quit smoking within a year)
   4) Follicle Stimulating Hormone (FSH) and Estradiol (E2) test annually on cycle day 3 for women < age 40
   5) Clomiphene Citrate Challenge Test (CCCT), with the day 3 FSH test repeated every 6 months for any woman $\geq$ 40 years of age. (If a woman has a history of an abnormal CCCT, plans to use donor egg and is under age 40, this test does not need to be repeated.)

b. Uterine cavity evaluation
   1) A uterine cavity evaluation must occur within one year prior to the initial ART cycle.
   2) Interim uterine cavity follow-up evaluation (HSG, HSC or SHG) is required every two years.
   3) A uterine cavity evaluation is needed following a pregnancy that results in an antenatal, intrapartum, or postpartum complication.

2. Evaluation of the Male

a. The following evaluation is required for all males:
   1) Semen analysis (within one year)
   2) Urine or serum Cotinine level for a partner who has quit smoking within a year

b. The following is required for males found to have abnormal semen analysis with severe male factor infertility (TMS < 10 mil or $\leq$ 1% normal forms) requesting coverage for donor sperm or ART:
   1) Evaluation by an urologist
   2) Two semen analyses, including volume
   3) FSH and testosterone levels
   4) Karyotyping and Y chromosome microdeletion (YCMD) for nonobstructive azospermia and for all S/A < 3 mil sperm/cc
   5) Cystic fibrosis screening for male with obstructive azospermia-Congenital Absence of the Vas deference (CAVD) Karyotyping

3. Members with History of a Sterilization Procedure

Tufts Health Plan may cover medically necessary infertility services for Members who have had a prior voluntary sterilization procedure when:

a. There is documentation confirming the existence of established infertility independent of the sterilization procedure and/or reversal of sterilization procedure and either;
   1) Documentation of a successful reversal of tubal ligation as evidenced by a normal hysterosalpingogram demonstrating unilateral or bilateral tubal spill; or
   2) Documentation of a successful reversal of vasectomy as evidenced by two normal semen analyses.

   Note: These semen analyses must be obtained within three months of the planned infertility services.

E. Insemination Cycles: Intra-cervical (AI), Intra-uterine (IUI) Without Medication

1. Natural IUI, defined as IUI without medication, for a woman with or without a confirmed diagnosis of infertility, **may be covered when the Member has documented acceptable ovarian reserve as defined by:**
   a. For women < 40 years of age, documentation of acceptable ovarian reserve is not required

b. For women 40 and 41 years of age: FSH level which is < 15mIU/mIU/ml on Cycle day 3 and the day 3 Estradiol level in < 80 pg/mL
c. For women ≥ age 42 years of age: FSH level which is < 12 mIU/ml on Cycle day 3 and the 3 day Estradiol level < 80 pg/mL

AND the Member must meet one of the following:

a. The woman has a history of more than one LEEP or conization procedures that is considered a factor in the woman's infertility.
b. The woman has a diagnosis of vaginismus.
c. There is male factor infertility.

Note: For women without the diagnosis of infertility there will be a cycle limit of 12 cycles for Members ≤ age 35; or 6 cycles for Members > age 35.

F. Insemination Cycles: Intra-cervical (AI), Intra-uterine (IUI) With Medication (e.g., Gonadotropins, Letrozole and/ or Clomiphene Citrate)

Tufts Health Plan may authorize coverage of intra-cervical, intra-uterine insemination cycles with medication when the following criteria are met:

1. Members must have a diagnosis of infertility and meet the infertility coverage criteria within this document. Members age 40 and over must also demonstrate acceptable ovarian reserve as defined by:
   a. For women 40 and 41 years of age: FSH level which is < 15mIU/mIU/ml on Cycle day 3 and the day 3 Estradiol level is < 80 pg/mL
   b. For women ≥ age 42 years of age: FSH level which is < 12 mIU/ml on Cycle day 3 and the 3 day Estradiol level < 80 pg/mL

Note:

- There is a limit of two (2) medicated IUI cycles per Member, with the following exception: For Member's with a successful medicated IUI cycle resulting in a live birth, two additional cycles may be authorized when and if the Member choses to try to conceive again as long as the Member continues to meet the definition of female infertility. This limit shall include cycles completed before Tufts Health Plan membership.
- Females ≥ 44 years of age will not be covered for IUI, gonadotropins or ART using their own eggs even with a normal Clomiphene Citrate Challenge Test (CCCT), as the chance of a birth outcome is < 5%. These Members should discuss alternative intervention with their provider.
- Women who have been denied ART services are generally not appropriate candidates for medicated IUI cycles. Exceptions based upon an individual's medical history will be considered.

G. ART Clinical Coverage Criteria

Please Note: Authorization for IVF cycles is considered on a case-by-case basis depending upon the Member's individual history (e.g., age, previous pregnancies with or without ART, length of time attempting pregnancy, ovarian reserve, results of previous IVF cycles, male factor) and the probability of a 5 % or greater chance of a live birth as a result of the requested cycle. Please note that current clinical evidence suggests that the chance of a live birth after 6 consecutive unsuccessful IVF cycles (including incomplete cycles and the use of donor eggs, but not including frozen embryo transfers) in women age 40 and over is typically less than 5%. (Smith, et al., 2015)

1. In Vitro Fertilization (IVF)

Note: If approved for IVF, members will be approved for one fresh cycle **or** one freeze-all cycle per request.

a. ART, as outlined in this medical necessity guideline, is a covered benefit for females who demonstrate infertility as a disease[1,] and/or whom fertility is otherwise expected as a natural state (e.g., women < age 40 with an abnormal FSH level or CCCT).

Note: The day 3 FSH test needs to be repeated every 6 months for any woman ≥ 40 years of age.

For IVF for preimplantation genetic diagnosis, refer to Tufts Health Plan Preimplantation Genetic Diagnosis Medical Necessity Guideline.

b. Single Embryo Transfer (SET)
   1) For the first two IVF cycles ever for members <35 years of age, coverage will only be provided for Single Embryo Transfer (SET), when at least two good-quality embryos are available at the time of transfer. If coverage of the second SET cycle is requested, authorization will not be given for a single fresh embryo transfer, as only a single frozen embryo transfer will be covered unless a frozen embryo is not available.

   2) For the first IVF cycle ever for members 35 through 37 years of age, coverage will only be provided for Single Embryo Transfer (SET), when at least two good-quality embryos are available at the time of transfer.

      If a live birth results from this cycle, then **one additional SET cycle will be required** if more IVF cycles are requested for women ages 35-37 at the time of the request, when at least two good-quality embryos are available at the time of transfer. If a frozen embryo is available for transfer then a FET cycle only will be approved.

c. Age related infertility is not a covered benefit, and is demonstrated by an abnormal CCCT in women age 40 and over. This is defined by:

   Cycle Day 3 FSH level ≥15 mIU/ml and/or the day 3 Estradiol Level ≥ 80 pg/mL (for women age 40 and 41).[9, 10]

   Cycle Day 3 FSH level ≥12 mIU/ml and/or the day 3 Estradiol level ≥80 pg/mL (for women age ≥42).

   ART using a woman's own eggs continues to be the treatment of choice for women > age 40 and < age 44 when the following outcome is achieved for each previous ART cycle initiated:

   1) At least 3 embryos on day 3, each of which are at least 6-8 cells, or at least one blastocyst on day 5 of average grade (Gardner 3BB or better),
      and
   2) Reasonable quality (grade B or its equivalent) are available for transfer per cycle (including up to fair fragmentation <25%-50%).

d. Female Members > age 44 requesting to use their own eggs will not be covered for infertility treatment and/or related services regardless of FSH levels or previous cycle response as the birth outcome is < 5%. The Member's individual medical history will be considered in making coverage decisions, and will be based upon a 5% expected chance of a birth outcome using one's own eggs and a current history of infertility as a disease state verses an expected state associated with the menopausal transition.

Note: Members who meet the criteria for in vitro fertilization outlined above who also 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.

2. Donor Egg Coverage Criteria

a. Donor egg/Donor Embryo/ART treatment may be covered if Infertility is a disease[1] and the women's fertility is expected as a natural state[12, 13] when one of the following criteria are met:

   1) Premature menopause or premature ovarian failure (onset prior to age 40 with an FSH ≥15 mIU/ml on Cycle day 3). Women 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.

   2) Previously failed IVF in a woman with acceptable ovarian reserve between age 40-42 as defined by:

a) FSH level which is < 15 mIU/ml on Cycle day 3 and the day 3 Estradiol level is < 80 pg/mL (for women age 40-41).
b) FSH level which is < 12 mIU/ml on Cycle day 3, and the day 3 Estradiol level is < 80 pg/mL (for women 42 up to the 43 birthday).

b. Women age 43 or older, who are unable to achieve a viable birth outcome using their own eggs/embryos, are experiencing normal and expected age-related decline in fertility, and therefore are not covered for infertility services. These changes are no longer consistent with a disease process.
c. Anonymous or designated donors must be ≤ 35 years of age, or between ages 36 and 39 with normal ovarian reserve as demonstrated by a normal CCCT. (Cycle Day 3 level is < 12 mIU/ml, and the day 3 Estradiol level is < 80 pg/ml).
d. Women age 40 or older are not generally appropriate candidates to donate oocytes/embryos.

Note: Use of donor egg with a gestational carrier is not covered, as the member is not treated in this situation.

3. Frozen Embryo Transfers (FET)

a. Members seeking coverage for FET must meet the definition of infertility and expect fertility as a natural state.
b. Cryopreserved embryos **must** be used prior to authorization for additional fresh ART cycles under the following circumstances:
   1) Maternal age ≤ 37 years old and undergoing 2nd SET cycle, only a single FET will be covered unless a frozen embryo is not available (see section G.1.b.)
   2) Maternal age < 35 years old and 3 cryopreserved embryos of a similar developmental stage are available for transfer.
   3) Maternal age ≥ 35, and 4 cryopreserved embryos of a similar developmental stage are available for transfer.

Note: It is recognized that some women 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.

4. Intra-Cytoplasmic Sperm Injection (ICSI)

a. ICSI may be approved for coverage if a severe male factor exists. Severe male factor is defined as meeting one of the following:
   1) <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 2 weeks apart, **or**
   2) ≤ 1% normal forms (Strict Kruger Morphology), **or**
   3) Poor (< 50%) or failed fertilization in a current or previous cycle

b. ICSI may be authorized for Members authorized, by Tufts Health Plan, for the coverage of preimplantation genetic diagnosis (PGD). Refer to Tufts Health Plan Preimplantation Genetic Diagnosis Medical Necessity Guideline.

II. Donor Sperm or Therapeutic Donor Insemination (TDI) Services

Tufts Health Plan provides coverage for donor sperm or TDI/IUI services that are provided to Tufts Health Plan Members who have partners diagnosed with severe male factor infertility based on the results of the semen analysis:

1. <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 2 weeks apart, **or**
2. ≤ 1% normal forms (Strict Kruger Morphology), **or**
3. Poor (< 50%) or failed fertilization in a current or previous cycle

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. If approved by an Authorized Reviewer, Tufts Health Plan may initially authorize up to three donor sperm /IUI cycles.

After the authorization end date, or completion of the authorized cycles, the Member must go through a new prospective review approval process for coverage of additional cycles.

III. In-Vitro Fertilization Due to Inadvertent Ovarian Hyperstimulation During Preparation for a Stimulated Intrauterine Insemination Cycle

A. Definition

Assisted Reproductive Technologies (ART) 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 into a woman's 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, the only safe alternative to cancellation of the cycle is to convert it to IVF.

B. 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 has a diagnosis of infertility and is eligible for coverage of medically necessary infertility treatments as defined by the Tufts Health Plan Clinical Coverage Guidelines.
   b. Member must be < age 40 with an infertility diagnosis, with an Estradiol level greater then 1000, with at least 3 or more follicles >16mm or 4-8 follicles that are greater than or equal to 14mm and/or a large number of smaller follicles **on day the decision is made to convert.**
   c. For Members > age 40, 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.14
2. Members must receive IVF services at a Tufts Health Plan contracted ART contracting ART providers.

IV. Sperm, Oocytes, or Embryo Cryopreservation

A. Clinical Coverage Criteria for Cryopreservation

1. Tufts Health Plan may authorize, with prior authorization, coverage for the harvest, procurement, and storage of sperm, oocytes, or embryos for Members who have no prior history of sterilization, and said storage is in association with ongoing infertility care (Infertility treatment within 90 days of the cryopreservation) when **one** of the following is met:
   a. Male partner has been diagnosed with a medical condition, not a result of previous voluntary sterilization, which requires that sperm be obtained directly from testicular biopsy tissue.
   b. Male partner has a medical or psychological condition (e.g., situational anxiety), which may interfere with the ability to produce a sperm sample on the day of an infertility procedure, not a result of previous voluntary sterilization. The Member must have a confirmed diagnosis that requires that sperm be obtained in advance and cryopreserved for future infertility treatment.
   c. Female Member is receiving authorized IVF treatment and has embryos which should not be transferred into the uterus during the current IVF cycle due to:
      1) The high probability of an adverse impact on the woman’s health and well-being (e.g., severe hyperstimulation syndrome).
      2) Single embryo transfer requirements or the high risk of multiple gestations from the transfer of an excessive number of available embryos.
2. Tufts Health Plan may prior authorize coverage for the harvest, procurement, and short-term storage (<90 days) of sperm, oocytes, or embryos for Members who have no prior history of sterilization, in the presence or absence of ongoing infertility care, when the Member requires medical treatment that may render them sterile. Examples of such treatment include, but are not limited to, chemotherapy and/or radiation therapy for cancer and medically necessary gender confirming treatment. A letter of medical necessity from the treating physician is required. Coverage for this indication is limited to one cycle.

B. Limitations

Tufts Health Plan will not cover the following:

1. Long-term sperm, oocyte or embryo storage, defined as greater than 90 days, unless the couple is actively receiving infertility treatment (see above).
2. Coverage beyond 90 days after the last cycle of infertility treatment ends, or if a pregnancy occurs.
3. Sperm cryopreservation as a routine procedure for sperm backup in the absence of a confirmed physical or psychological diagnosis requiring cryopreservation.

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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 Tufts Health Plan OB/GYN or infertility specialist as required by the member's benefit document.
3. The member must receive ART services at a Tufts Health Plan contracting ART Center as required by the member's benefit document.
4. The Provider must complete a Tufts Health Plan Infertility Authorization Form when requesting services.
5. Effective June 15, 2008 the Provider must complete the Tufts Health Plan Infertility Treatment Summary Form when requesting services.
6. Level One reviews that do not meet the guidelines and Level Two reviews will be completed by a Tufts Health Plan Medical Director.
7. Authorized services may be approved for up to one year for women < 40 years old and up to six months for women ≥ 40 years old.
8. 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 Tufts Health Plan's normal business hours, the Member's physician should make the treatment decision based on his/her clinical judgment at the time. The physician must contact Tufts Health Plan on the next business day. Retrospective coverage may be approved if the medical necessity guidelines and eligibility requirements are met.
9. After the authorization period ends, the member must go through a new prospective review process for coverage of any additional cycles.

CODES

The following CPT/HCPCS codes require prior authorization:

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, microtechniques (any method)
89254	Oocyte identification from follicular fluid
89255	Preparation of embryo for transfer (any method)
89258	Cryopreservation; embryo(s)
89259	Cryopreservation; sperm
89272	Extended culture of oocyte(s)/embryo(s), 4-7 days
89280	Assisted oocyte fertilization, microtechnique; less than or equal to 10 oocytes
89281	Assisted oocyte fertilization, microtechnique; greater than 10 oocytes
89290	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); less than or equal to 5 embryos
89291	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); greater than 5 embryos
89337	Cryopreservation, mature oocyte(s)
89342	Storage, (per year); embryo(s)
89343	Storage (per year); sperm
89346	Storage, (per year); oocyte(s)
89352	Thawing of cryopreserved; embryo(s)
89356	Thawing of cyropreserved; oocytes, each aliquot
S4013	Complete cycle, gamete intrafallopian transfer (GIFT), case rate
S4015	Complete in-vitro fertilization cycle, not otherwise specified, case rate
S4016	Frozen in-vitro fertilization cycle, case rate
S4018	Frozen embryo transfer procedure cancelled before transfer, case rate
S4020	In-vitro fertilization procedure cancelled before aspiration, case rate

Code	Description
S4021	In-vitro fertilization procedure cancelled after aspiration, case rate
S4025	Donor services for in-vitro fertilization (sperm or embryo), case rate
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
S4014	Complete cycle, zygote intrafallopian transfer (ZIFT), case rate
S4017	Incomplete cycle, treatment cancelled prior to stimulation, case rate
S4022	Assisted oocyte fertilization, case rate
S4023	Donor egg cycle, incomplete, case rate
S4037	Cryopreserved embryo transfer, case rate

APPROVAL HISTORY

May 29, 2003: New, revised criteria. This guideline replaces the following: Clinical Coverage Criteria Guidelines: Assisted Reproductive Technologies (ART): Benefit and Eligibility Requirements, Donor Sperm (TDI) Services, In-Vitro Fertilization due to Inadvertent Ovarian Hyperstimulation During Preparation for a Stimulated Intrauterine Insemination Cycle and Sperm/Embryo Cryopreservation. Subsequent endorsement date(s) and changes made:

- November 14, 2003: Reviewed and updated. Criteria for Intrauterine Insemination Cycle with Gonadotropin Stimulation added to the guideline. Clarifications to the Administrative Process added.
- March 2, 2004: Completed in outline form to help clarify the documentation of ART decisions. Clarification added to Section I. C. 5., Section II. E.b.
- October 18, 2004: Several clarifications were made throughout the document Section I.C.9, 10, 11: to the general limitations, Section I. D. 3.): to announcement that the approval process for prior authorization of gonadotropin medications will change effective 1/1/05, Section II.D.1.f.: uterine cavity evaluation, Section II. D. 2. b.: requirements prior to the ART cycle initiation for women in their 30's, Section II.E.1.a.: ART treatment for women with Advanced Maternal Age, Section II.E.1.c.2)c) and 3)d): requirements specified for women age 43 (up to 44th birthday), Section II.E.2.b.1) and c.: clarification of donor egg treatment requirements, Section IV.B.1.: clarification of services covered during inadvertent ovarian hyperstimulation, Section V. B.1. Additional info re: IUI/FSH treatment for women with advanced maternal age, Section V.C.3.: clarification of gonadotropin usage, Section VI.B. additional info re: sperm or embryo cryopreservation, and Section IX.A. announcement in the Administrative Process that prior authorization will be required for gonadotrophic medication for women $\geq$ age 40 beginning 1/1/05.
- September 16, 2005: Changes were made to the format and content of the complete document.
- July 14, 2006 to be effective August 1, 2006: Section I.A.10: added requirement for prior authorization for all gonadotropin medication prescriptions. Section I.A.11: added requirement for prior authorization of IUI used in conjunction with gonadotropin medication. Section I.C.2: definition of failed vasectomy reversal added. Section I.C.11: added cost of IUI and ART and related services added to cost not covered by Tufts Health Plan when the male partner has a history of prior vasectomy and/or reversal with any one abnormal semen parameter.
- January 1, 2008: Preimplantation Genetic Determination (PGD) removed from exclusions in the plan document. PGD may be authorized in specific circumstances, see Preminplantation Genetic Determination Medical Necessity Guideline for additional information.
- April 7, 2008: For IVF due to inadvertent ovarian hyperstimulation during preparation for a stimulated IUI cycle, for Members < 40, diagnosis of Polycystic Ovarian Syndrome allowed for coverage. And for Members > 40, conversion from IUI to IVF will be allowed if the E2 is greater than 2000.
- April 14, 2008 for June 15, 2008 Effective Date: The Tufts Health Plan Infertility Treatment Summary Form is required when requesting Prior Authorization for Infertility Services.
- November 1, 2008: Infertility Guidelines created two separate policies for Massachusetts, Infertility Guidelines: Massachusetts and Rhode Island, Infertility Guidelines: Rhode Island.
- June 1, 2009: Reviewed and renewed without changes.
- December 17, 2009: Requirement of 1-2 cycles of IUI for women between 40-42 years of age has been deleted.

- January 22, 2010: Reviewed at MSPAC Meeting: Reversal of sterilization sperm parameters changed; interim uterine cavity evaluation changed to every two years; day two embryo transfer coverage language added; re-formatting of document. Effective date July 1, 2010.
- October 2010: Definition of infertility changed as per Massachusetts mandate.
- April 2011: Reviewed my MSPAC. BMI (body mass index) language added Section 1, B points 3, 4 and 5. Section C, point 1 Experimental language reformatted. Section C, point 3 "therapeutic intervention" removed from statement. Treatment Required to ART cycles (FSHI, IUI) section deleted. Assisted Hatching language removed. Elevated FSH language added Section 1, C, point 4. FSH/IUI cycle limit of two and IVF cycle limit of six languages added. IUI conversion to IVF due to hyperstimulation language that stated Member had to go back and complete required IUI cycles deleted. Administrative Process language condensed. Appendix condensed. Glossary deleted.
- July 2011:Reviewed by Medical Affairs, Medical Policy. BMI Criteria added; Reversal of sterilization treatment coverage criteria added; AMH testing limitation added; urology consult for male deleted; cycle limit for IV clarified: this limit shall include ALL ART services; authorization form updated. Effective date October 1, 2011.
- December 19, 2011: Reviewed by the Integrated Medical Policy Advisory Committee on December 14, 2011. The guidelines were changed: Frozen embryo transfer (FET) cycles will not count towards the six-cycle lifetime limit.
- January 18, 2012: Reviewed by the Integrated Medical Policy Advisory Committee (IMPAC), coverage of Insemination Cycles: Intracervical (AI) and Intrauterine (IUI) without Gonadotropins were added to prior authorization. CPT codes for these procedures, 58321 and 58322 were also added. Residency requirements were also updated. These changes will be effective April 1, 2012.
- April 10, 2013: Reviewed by IMPAC, Evaluation by a Reproductive Endocrinologist removed.
- July 10, 2013: Reviewed by IMPAC, Coverage of cryopreservation of oocytes (CPT 89240), with prior authorization, added per MA state mandate; the exclusion of coverage of infertility services for women who use nicotine-containing products was clarified.
- September 11, 2013: Reviewed by IMPAC with changes to the criteria for coverage of Insemination Cycles: Intra-cervical (AI) and Intra-uterine (IUI) With or Without Medication (Gonadotropins or Clomiphene Citrate) Section I. E., for effective date January 1, 2014.
- January 1, 2014: Coding updated, 0059T: cryopreservation: oocyte(s) added to list of codes covered with prior authorization.
- April 11, 2014: Coding updated. 0059T was added for the cryopreservation of oocytes, replacing 89240: unlisted miscellaneous pathology test.
- May 14, 2014: Reviewed by IMPAC, Section I D (2), 'Females With Elevated Body Mass Index', criteria removed.
- June 11, 2014: Reviewed by IMPAC, Section for Natural IUI added, updated the requirement levels of FSH and Estradiol, requirement for 10 day FSH testing removed, coverage of ICSI for PGD added. The effective date for these changes will be October 1, 2014.
- August 28, 2014: Additional wording clarification
- September 17, 2014: Adopted by Tufts Health Plan – Network Health Commercial Plans
- December 31, 2014: Coding updated. Per AMA CPT®, effective December 31, 2014 the following code(s) deleted: 0059T; and effective January 1, 2015 the following code(s) added: 89337.
- January 14, 2015: Age clarified in Sections I. E(b) and I. F(4).
- January 14, 2015: Reviewed by IMPAC. Single Embryo Transfer (SET) criteria added to Section I. 1G(b), for an effective date of April 1, 2015; coding updated, CPT code 89259 (cryopreservation; sperm) added with an effective date of July 1, 2015.
- March 11, 2015: Reviewed by IMPAC, age clarification for documentation of normal ovarian reserve added to sections E. 1. and F. 1.
- March 25, 2015: Clarification of SET requirements added to FET section, G. 3.
- July 23, 2015: Reviewed by IMPAC, limitations added for cryopreservation, storage, and thawing of reproductive tissue (ovarian/testicular). The corresponding CPT codes 0058T, 89335, 89344, and 89354 removed from this guideline as they are considered experimental. Added limitation for Uterine Embryo Lavage using the Previvo catheter device as it is considered experimental.
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- November 16, 2015: Reviewed by IMPAC, updates to sections I.C.5., I.D.2.b. and I.G.1.c and addition of section IV B., "Freeze-All Cycles" , effective April 1, 2016.
- July 20, 2016: Reviewed by IMPAC, renewed without changes

- September 14, 2016: Reviewed by IMPAC, update to section I.D.2.b.2.
- December 14, 2016: Reviewed by IMPAC, update to criteria in section I.F.; updates to notes in sections F. and G.
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- September 13, 2017: Reviewed by IMPAC, update to criteria in section IV.B.1.
- October 11, 2017: Reviewed by IMPAC, update to section I.C.8, effective April 1, 2018.
- December 13, 2017: Reviewed by IMPAC, update to criteria in section I.B
- February 14, 2018: Reviewed by IMPAC, update to criteria in section I.G.1.c.
- March 14, 2018: Reviewed by IMPAC. Minor language change in reference to updated coverage of IVF with PGD; update to section I.C.
- September 12, 2018: Reviewed by IMPAC, update to language in section I.C.7 and to criteria in section I.D.2.b., effective 1/1/2019.
- October 2018: Template and disclaimer updated
- November 14, 2018: Reviewed by IMPAC, notes added to sections I.G.1 and I.G.2 regarding coverage when using a gestational carrier.
- March 20, 2019: Reviewed by IMPAC, update to section C.6.; update to note in section G.1.d.; addition of code 89272 to table of codes which require prior authorization, effective May 9, 2019.
- November 20, 2019: Reviewed by IMPAC, note added to section I.G.1., existing note updated in section I.G.1.a., and removal of criteria section for freeze-all cycles from section IV, all effective January 1, 2020.
- December 18, 2019: Reviewed by IMPAC, update to criteria in section I.G.1.c, update to criteria in section I.G.4.a., and update to section IV.A.2, all effective January 1, 2020.
- February 19, 2020: reviewed by IMPAC, update to note in general limitation I.C.4; update to criteria I.G.3.b.2, effective February 19, 2020.
- February 20, 2020: Unify fax number updated
- May 20, 2020: Reviewed by IMPAC, renewed without changes

APPENDIX A: ENDNOTES

1. Infertility is a disease.** The duration of the failure to conceive should be twelve or more months before an investigation is undertaken unless medical history and physical findings dictate earlier evaluation and treatment.
   **Any deviation from, or interruption of the normal structure or function of any part, organ, or system, or combination thereof, of the body that is manifested by a characteristic set of symptoms or signs, and whose etiology, pathology, and prognosis may be known or unknown: *Dorland's Medical Dictionary* 1988:481). Approved by the Board of Directors of the American Society for Reproductive Medicine (Formerly The American Fertility Society), July 17, 1993.
2. The loss of fertility is the first sign of reproductive aging that precedes the monotropic increase in FSH level and changes in menstrual cycle. Fertility and Sterility 2001; vol. 76 pg. 875. Premature menopause or ovarian failure is a condition associated with loss of menses, decreased estrogens, and increased gonadotropins before the age of 40. Fertility and Sterility 1998; vol. 70 pg. 1.
3. The rise in FSH levels demonstrated in the early follicular phase in women >age 35 is associated with a poor prognosis for future fertility. American Society for Reproductive Medicine. A practice committee report: The menopausal transition. Dec 2001.
4. Normal sperm parameters as defined by the World Health Organization include: concentration of >20million/ml, > 50% motility, > 30% normal forms (WHO) or 14% Kruger criteria.
5. A woman's age is the most important factor affecting the chances of a live birth when her own eggs are used. Success rates decline with each year of age and are particularly low for women 40 or older. Figure 11 shows pregnancy rates, live birth rates, and singleton live birth rates for women 40 or older who used fresh non-donor eggs or embryos. The average chance for pregnancy was 23% for women age 40; the live birth rate for this age was about 16%, and the singleton live birth rate was approximately 13%. All rates dropped steadily with each 1-year increase in age. For women age 43, the live birth rates and the singleton live birth rates were both approximately 6%. For women older than 43, the live birth rates and singleton live birth rates were both about 2%. Women 40 or older generally have much higher success rates using donor eggs Regardless of history of previous live births or miscarriages, women > age 42 have < 5% of a live birth." A Member's individual medical history will be considered in making coverage decisions and will be based upon demonstration of greater than a 5% chance of a birth outcome using one's own eggs and a current history of infertility as a disease state verses an expected state associated with the menopausal transition. National Center for Chronic Disease Prevention

and Health Promotion CDC Reproductive Health Information Source Art Success Rates National Summary and Clinic Fertility Reports 2002.

6. Definition of "Experimental": "A procedure for the treatment of infertility is considered experimental until there is: scientific evidence indicating safety and efficacy, i.e., that the treatment is associated with a higher pregnancy rate than non-treatment of an existing condition; and corroboration of safety and efficacy by at least two appropriately designed, peer-reviewed, published studies by different investigator groups." Approved by the Practice Committee of the American Society for Reproductive Medicine (Formerly The American Fertility Society), March 27, 1993. Approved by the Board of Directors of the American Society for Reproductive Medicine (Formerly The American Fertility Society), May 7, 1993.
7. Infertility treatment secondary to sterilization is an exclusion from coverage and supported as such by the Massachusetts Infertility State Mandate as a non-required benefit. mass.gov/doi/Legal_Hearings/211_37.pdf
8. "The prevalence of infertility is higher, fecundity is lower, and the time to conception is increased in smokers compared to non-smokers." Smoking and Infertility F&S vol. 81 #4, April 2004.
9. Follicle Stimulating Hormone and Estradiol levels are predictors of a poor prognosis in the older women. Typical criteria for normal ovarian reserve are FSH levels of<10 miu/ml and Estradiol level of <80 pg/ml. In consideration of the effect age has on birth outcomes, the following CCCT test results are considered abnormal; (for women $\geq$ ages 40) cycle Days 3 and/or 10 FSH levels $\geq$ 15 mIU/ml and/or the day 3 Estradiol level > 80 pg/ml, (for women age 40 and 41) cycle days 3 and/or 10 FSH levels $\geq$ 12 mIU/ml and/or the day 3 Estradiol level >80 pg/ml (for women age $\geq$ age 42) Aging and Infertility in Women, American Society for Reproductive Medicine Practice Committee Report; Jan 2002.
10. "In a general infertility population, an abnormal CCCT predicts that a successful pregnancy will be achieve about 5% of the time" Aging and Infertility in Women, American Society for Reproductive Medicine, Practice Committee Report; 1/2002.
11. In a multicenter review of initiated IVF cycles in women $\geq$ age 41 the delivery rate was 4.5% and there were no deliveries in women > age 43. "This age related infertility is related to a decline in implantation rates, decreased ovarian responsiveness and an increase in aneuploidy." Fertility and Sterility 2000:74: 471.
12. Oocyte donation is the only non-empirical treatment when the diagnosis is limited to decreased ovarian reserve. Aging and Infertility in Women, American Society for Reproductive Medicine, Practice Committee Report; 1/2002.
13. Women $\geq$ age 40 experience a decline in ovarian responsiveness, a high rate of aneuploidy and a decline in implantation. Rarely, is it medically indicated to convert an IUI to ART cycle due to a risk of ovarian hyperstimulation in this age group.
14. Gonadotropin-induced controlled ovarian hyperstimulation with IUI has limited efficacy for women over the age of 40. In a large retrospective study the results indicate a decline in cycle fecundity with the lowest rate (7%) in women >age 40. Additionally, 87% of all women regardless of age, who conceived did so within the first 3 cycles. Sahakyan, M, Harlow, BL, Hornstein, MD. Influence of age, diagnosis, and cycle number on pregnancy rates with gonadotropin-induced controlled ovarian hyperstimulation and intrauterine insemination. Fertility and Sterility 1999; 72(3): 500-504.
15. Ovulation induction with IUI has limited efficacy for women over the age of 40, yielding a per cycle delivery rate of 5% or less. No viable pregnancies occurred in women > age 43. Corsan G, et al. Ovulation induction combined with intrauterine insemination in women 40 years of age and older: is it worthwhile? Hum Reprod 1996; 11:1109 12.K.

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.

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