

Medical Necessity Guidelines: Infertility Services – Rhode Island Products

Effective: May 20, 2020

Prior Authorization Required	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request.	
<p>Applies to: COMMERCIAL Products <input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617.972.9409 <input type="checkbox"/> Tufts Health Freedom Plan products; Fax: 617.972.9409 • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</p> <p>TUFTS HEALTH PUBLIC PLANS Products <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055 <input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055 <input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404 <input type="checkbox"/> 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.</p> <p>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</p>	

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.

TABLE OF CONTENTS

OVERVIEW/DEFINITION OF INFERTILITY, ELIGIBILITY LIMITATIONS	2
COVERAGE GUIDELINES	2
I. Infertility Services	2
A. Eligibility Requirements for Infertility Services	2
B. General Limitations of Infertility Services	3
C. General Information.....	3
1. Evaluation of the Female	3
2. Evaluation of the Male	4
3. Members with History of a Sterilization Procedure	4
D. Insemination Cycles: Intra-cervical (AI), Intra-uterine (IUI) Without Medication	4
E. Insemination Cycles: Intra-cervical (AI), Intra-uterine (IUI) With Medication (e.g., Gonadotropins, Letrozole and/ or Clomiphene Citrate)	4
F. ART Clinical Coverage Criteria	5
1. In Vitro Fertilization (IVF).....	5
2. Donor Egg Coverage Criteria.....	6
3. Frozen Embryo Transfers (FET)	6
4. Intra-Cytoplasmic Sperm Injection (ICSI)	6
II. Donor Sperm or Therapeutic Donor Insemination (TDI) Services	7
III. In-Vitro Fertilization Due to Inadvertent Ovarian Hyperstimulation	7
A. Definition	7
B. Clinical Coverage Criteria.....	7
IV. Oocyte, Sperm or Embryo Cryopreservation	7
A. Clinical Coverage Criteria for Cryopreservation.....	7
B. Limitations	8

REFERENCES.....	8
ADMINISTRATIVE PROCESS	10
CODES	10
APPROVAL HISTORY	11
APPENDIX A: ENDNOTES	12
BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION	14

OVERVIEW/DEFINITION OF INFERTILITY, ELIGIBILITY LIMITATIONS

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

CLINICAL COVERAGE CRITERIA

I. Infertility Services

The state of Rhode Island mandates coverage of infertility services in R.I.G.L. Chapter 27-18, Section 27-18-30 and R.I.G.L. Chapter 27-41, Section 27-41-33. In accordance with this law, Tufts Health Plan provides coverage for medically necessary services for the diagnosis and treatment of infertility. Rhode Island General Law Defines infertility as 'the condition of an otherwise presumably healthy individual who is unable to conceive or sustain a pregnancy during the period of one year.'

Rhode Island law also mandates coverage for standard fertility preservation services when a medically necessary medical treatment may directly or indirectly cause iatrogenic infertility. Rhode Island law defines iatrogenic infertility as "an impairment of fertility by surgery, radiation, chemotherapy, or other medical treatment affecting reproductive organs or processes."

Assisted Reproductive Technology (ART) and Advanced Infertility Procedures, for the purposes of this document, includes, but is 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 oocytes
- Cryopreservation of sperm
- Gonadotropin medication (FSH)
- Intrauterine insemination (IUI) used in conjunction with Gonadotropin medication

A. Eligibility Requirements for Infertility Services

The following information about eligibility applies to all services. A Member must meet all of the following applicable minimum eligibility requirements to be covered:

1. The Member has been diagnosed with infertility as defined by Rhode Island General Law above.
2. For females, the Member must be premenopausal and reasonably expect fertility as a natural 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, and medical history³.
3. Tufts Health Plan must receive documentation indicating that the Member has been unable to conceive or sustain a pregnancy during a period of one year or 12 menstrual cycles of exposure to sperm
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. PPO Members must also go to a Tufts Health Plan ART contracting provider for coverage at the 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](#).

B. 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 and/or the American College of Obstetrics and Gynecology.⁶
2. Infertility treatment, when infertility is the result of a non-reversed voluntary sterilization.
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 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.
5. 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.
6. 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.
7. Intrauterine insemination (IUI) or Assisted Reproductive Technology (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.
8. The cost of donor sperm, IUI, ART, and related services, if the male partner has a history of prior vasectomy.
9. The cost of donor sperm, if the infertile Member does not have a male partner with a diagnosis of male factor infertility.
10. 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).
11. Infertility services for women who are not Rubella immune.
12. Infertility services for women who are actively smoking cigarettes and/or are using nicotine containing products such as gum, patches or electronic cigarettes.⁷
13. Anti-Mullerian hormone (AMH) testing for ovarian reserve is considered experimental.
14. Uterine embryo lavage using the Previvo catheter device is considered experimental.
15. Cryopreservation, storage, and thawing of reproductive tissue (ovarian/testicular), CPT codes 0058T, 89335, 89344, and 89354 are considered experimental.

C. General Information

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

1. Evaluation of the Female

The following evaluation is required:

- a. Thyroid stimulating hormone (TSH)
- b. Rubella status (all non-immune Members must be vaccinated and wait one month thereafter before seeking approval for ART)
- c. Urine or serum Cotinine level (for a Member who has quit smoking within a year)
- d. Follicle Stimulating Hormone (FSH) and Estradiol (E2) test annually on cycle day 3 for women < age 40
- e. Clomiphene Citrate Challenge Test (CCCT), with the day 3 FSH test repeated every 6 months for any woman between the 40 and 42 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)
- f. 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 ≤ 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 non-obstructive 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.

D. 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 normal ovarian reserve as defined by:**
 - a. For women <40 years of age, documentation of normal ovarian reserve is not required
 - b. For women age 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: Tufts Health Plan may authorize a combination of AI and IUI cycles, without medication, up to a total of 12 cycles.

E. 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 above 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 in < 80 pg/mL
- b. For women \geq 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 chooses 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 \geq 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 FSH/IUI cycles. Exceptions based upon an individual's medical history will be considered.

F. ART Clinical Coverage Criteria

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 disease¹ 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 between 40 and 42 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.

If a live birth results from either of these first two SET cycles, then **one additional SET cycle will be required** if more IVF cycles are requested for women < 35 years of age at the time of the request, when at least two good-quality embryos are available at the time of transfer.

- 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.

- c. Age related infertility is not a covered benefit, and is demonstrated by an abnormal CCCT in women between 40 and 42 years of age. This is defined by:
 - 1) Cycle Days 3 and/or 10 FSH levels \geq 15 mIU/ml and/or the day 3 Estradiol Level \geq 80pg/mL (for women age 40 and 41).^{8,9}
- d. ART using a woman's own eggs continues to be the treatment of choice for women \leq age 42 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%).

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 disease¹ and the women's fertility is expected as a natural state^{11, 13} when one of the following criteria are met:
 - 1) Premature menopause or premature ovarian failure (onset prior to age 40 with an FSH \geq 15 mIU/ml on Cycle days 3 or 10). 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 normal ovarian reserve between age 40-42 as defined by:
 - a) FSH levels which are < 15 mIU/ml on Cycle days 3 and 10, and the day 3 Estradiol level is < 80 pg/mL (for women age 40-41).
 - b) FSH levels which are < 12 mIU/ml on Cycle days 3 and 10, and the day 3 Estradiol level is < 80 pg/mL (for women 42 years of age).
- b. Anonymous or designated donors must be \leq 35 years of age, or between ages 36 and 39 with normal ovarian reserve as demonstrated by a normal CCCT. (Cycle Days 3 and 10 FSH levels are < 12 mIU/ml, and the day 3 Estradiol level is < 80 pg/ml).
- c. Women age 40 or older are not generally appropriate candidates to donate oocytes or 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 \leq 37 years old and undergoing 2nd SET cycle, only a single FET will be covered unless a frozen embryo is not available (see section F.1.b.)
 - 2) Maternal age < 35 years old and 3 cryopreserved embryos of a similar developmental stage are available for transfer
 - 3) Maternal age \geq 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) \leq 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

- A. 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
- B. 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.
- C. 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 than 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 between 40 and -42 years of age, 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.¹³
2. Members must receive IVF services at a Tufts Health Plan contracting ART provider.

IV. Oocyte, Sperm or Embryo Cryopreservation

A. Clinical Coverage Criteria for Cryopreservation

Tufts Health Plan may authorize coverage for the harvest, procurement, and storage of oocytes, sperm and 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). In addition, Tufts Health Plan may authorize cryopreservation for certain medical conditions, either in the presence or absence of ongoing infertility care. Those situations in which cryopreservation may be covered include, but are not limited to:

1. Member has been diagnosed with a medical condition, which requires surgery, radiation, chemotherapy, or other medically necessary treatment (including gender confirming treatment) affecting reproductive organs or processes which is likely to cause infertility. Coverage for this indication is limited to one cycle.
2. 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.

3. 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.
4. 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:
 - a. The high probability of an adverse impact on the woman's health and well-being (e.g., severe hyperstimulation syndrome).
 - b. Single embryo transfer requirements or the high risk of multiple gestations from the transfer of an excessive number of available embryos.

B. Limitations

1. Coverage of storage of cryopreserved sperm, oocytes, or embryos related to active infertility treatment will end 90 days after the last cycle of infertility treatment ends, or if a pregnancy occurs.
2. Oocyte/sperm cryopreservation is not a covered benefit as a routine procedure for oocyte/sperm backup in the absence of a confirmed physical or psychological diagnosis requiring cryopreservation.

REFERENCES

1. American Society of Reproductive Medicine. A practice committee report: definition of infertility. July 1993. Available online: www.asrm.org.
2. National Center for Chronic Disease Prevention and Health Promotion. CDC Reproductive Health Information Source. Art Success Rates. 2000.
3. Wren, B. and L. Nachtigall. Clinical Management of Menopause. New York: McGraw-Hill, 1996.
4. Stewart, D. and Gail Erlick Robinson. A Clinician's Guide to Menopause. Washington, D.C.: Health Press, 2000.
5. Speroff, L. et al. Clinical Gynecologic Endocrinology and Infertility 6th edition. Baltimore: Lippincott, Williams, and Wilkins, 1999.
6. New York State Task Force on Life and the Law, Assisted Reproductive Technologies, analysis and recommendations for public policy. April 1998.
7. Rein, MS, Barbieri, RL. "The Infertile Couple." Gynecology and Women's Health 7th edition. Ed. Kistner. St. Louis: Mosby, 1999.
8. Magarelli, PC, Pearlstone, AC, Buyalos, RP. Discrimination between chronological and ovarian age in infertile women aged 35 years and older: predicting pregnancy using basal follicle stimulating hormone, age and number of ovulation induction/intra-uterine insemination cycles. Hum Reprod. 1996; 11:6, 1214-9.
9. Hornstein, MD, Schust, D. "Infertility." Novak's Gynecology 12th edition. Baltimore: Williams and Wilkins, 1998.
10. Roseboom, TJ, Vermeiden, JP, Schoute, E, Lens, JW, Schats, R. The probability of pregnancy after embryo transfer is affected by the age of the patient, cause of infertility, number of embryos transferred, and the average morphology score, as revealed by multiple logistic regression analysis. Hum Reprod. 1995; 10:11, 3035-41.
11. Proceedings of the XVI World Congress on Fertility and Sterility. Fertility and Reproductive Medicine, San Francisco, October 1998. New York: Elsevier Science, 1998.
12. Rosenwaks, Z, Davis, OK, Damario, MA. The role of maternal age in assisted reproduction. Hum Reprod. 1995; 10 (suppl 1), 165-73.
13. Scott, RT, Opsahl, MS, Leonardi, MR, Neall, GS, Illions, EH, Navot, D. Life table analysis of pregnancy rates in a general infertility population relative to ovarian reserve and patient age. Hum Reprod, 1995; 10: 7, 706-10.
14. Hull, MG, Fleming, CF, Hughes, AO, McDermott, A. The age-related decline in female fecundity: a quantitative controlled study of implanting capacity and survival of individual embryos after in-vitro fertilization. Fertility and Sterility 1996; 65:4, 783-90.
15. Templeton, A, Morris, JK, Parslow, W. Factors that affect outcome of in-vitro fertilization treatment. Lancet 1996; 348:9039, 1402-6.
16. Van Kooij, RJ, Looman, CW, Habbema, JD, Dorland, M, et Velde, ER. Age-dependent decrease in embryo implantation rate after in-vitro fertilization. Fertility and Sterility. 1996; 66:5,769-75.
17. Yaron, Y, Amit, A, Brenner, SM, Peyser, MR, David, MP, Lessing, JB. In-vitro fertilization and oocyte donation in women 45 years of age and older. Fertility and Sterility 1995; 63:1, 71-6.
18. Gilbert, W, Nesbitt, T, Danielsen, B. Childbearing Beyond age 40; Pregnancy outcome in 24,032 Cases. Ob/Gyn. 1999; 93(1),9-14.

19. Pearlstone, AC, Fournet, N, Gambone, JC, et al. Ovulation induction in woman age 40 and older: the importance of basal follicle stimulating hormone level and chronological age. *Fertility and Sterility*. 1992; 58: 674-679.
20. Ron-el, R, Raziell, A, Strassburger, D, et al. Outcome of assisted reproductive technology in woman over the age of 41. *Fertility and Sterility*. 2000; 74, 471-475.
21. Sauer, M. Treating infertility in women of advanced reproductive age. *Contemporary OB/GYN*. Oct 1996; 68-76.
22. Wachenheim, D, Coleman, C. Letter. Insurance for infertility treatments-different perspectives. *Fertility and Sterility*. 2000; 73, 1267-66.
23. American Society for Reproductive Medicine. A practice committee report: Aging and infertility in women. Jan 2002.
24. Aronson, D. Stretching the biological clock. *Resolve National Newsletter*; Vol. XXII, No. 3. Summer 1997.
25. Dickey, R, et al. Comparison of the sperm quality necessary for successful intrauterine insemination with WHO threshold values for normal sperm. *Fertility and Sterility*. 1999; 71(4):684-689.
26. Van Voorhis, B, et al. Effect of the total motile sperm count on the efficacy and cost-effectiveness of intrauterine insemination and in-vitro fertility. *Fertility Sterility*. 2001; 75(4):661-668.
27. American Society for Reproductive Medicine. A practice committee report: The menopausal transition. Dec 2001.
28. Dorland's Medical Dictionary. 1988:481. The definition of a disease.
29. 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.
30. Aboulghar, M, et al. Controlled ovarian hyperstimulation and intrauterine insemination for treatment of unexplained infertility should be limited to a maximum of three trials. *Fertility and Sterility*. 2001; (1): 88-91.
31. Corsan G, et al. Ovulation induction combined with intrauterine insemination in women 40 years of age and older: is it worthwhile? *Fertility and Sterility*. *Hum Reprod*. 1996; 11: 1109-12.
32. Frederick JL, et al. Is there a role for ovarian stimulation and intra-uterine insemination after age 40? *Fertility and Sterility*. *Hum Reprod*. 1994; 9:2284-6.
33. Brzechffa PR, Buyalos RP. Female and male partner age and menotrophin requirements influence pregnancy rates with human menopausal gonadotropin therapy in combination with intrauterine insemination. *Fertility and Sterility*. *Hum Reprod*. 1997; 12: 29-33.
34. Ghosh, C, et al. Follicular response and pregnancy among infertile women undergoing ovulation induction and intrauterine insemination. *Fertility and Sterility*. 2003; 80(2): 328-335.
35. American Society for Reproductive Medicine. The Practice Committee. Effectiveness and treatment for unexplained infertility. *Fertility and Sterility*. September 2004; 1(suppl):S160-S163.
36. American Society for Reproductive Medicine. The Practice Committee. Smoking and infertility. *Fertility and Sterility*. April 2004; 81(4): 1181-1186.
37. 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.
38. American Society for Reproductive Medicine. Reproductive Aging in Women. Patient's Fact Sheet April 2003.
39. American Society for Reproductive Medicine. Prediction of Fertility Potential in Older Female Patients August 1996.
40. National Center for Chronic Disease Prevention and Health Promotion. CDC Reproductive Health Information Source. 2002 National Summary.
41. National Center for Chronic Disease Prevention and Health Promotion. CDC Reproductive Health Information Source. Section 2: ART Cycles Using Fresh, Non-donor Eggs or Embryos.
42. World Health Organization. WHO laboratory manual for the examination of human semen and cervical-mucus interaction, 4th ed. New York: Cambridge University Press. 1999.
43. Reindollar, R, et al. A randomized clinical trial to evaluate optimal treatment for unexplained infertility: the fast track and standard treatment (FASST) trial. *Fertility and Sterility*. August 2010; 94(3): 888-899.
44. Published jointly by the Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology, 'Criteria for number of embryos to transfer: a committee opinion', *Fertility and Sterility*. 2013 Jan;99(1):pp. 44-46.
45. Smith, Andrew D., et al. Live-Birth Rate Associated With Repeat In Vitro Fertilization Treatment Cycles. *Journal of the American Medical Association*. December 2015; 314 (24):2654-2662.

46. Wang, Ange, M.D., et al. Freeze-Only Versus Fresh Embryo Transfer in a Multicenter Matched Cohort Study: Contribution of Progesterone and Maternal Age to Success Rates. *Fertility and Sterility*. August 2017; 108 (2): 254-261.
47. Gundeson, Tina Djernis, et al. Association Between Use of Marijuana and Male Reproductive Hormones and Semen Quality: A Study Among 1,215 Healthy Young Men. *American Journal of Epidemiology*. August 2015; 182 (6): 473-481.

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. The Provider must complete the [Tufts Health Plan Infertility Treatment Summary Form](#) 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 HCPCS/CPT 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

Code	Description
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
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

November 1, 2008 for January 1, 2009 Effective Date: New Infertility Services Medical Necessity Guideline created in concert with the state of Rhode Island Mandate (R.I.G.L. Title 27, Chapter 27-18-30 and .I.G.L. Title 27, Chapter 27-41-33)

Subsequent endorsement date(s) and changes made:

- June 1, 2009: Reviewed and renewed without changes.
- December 17, 2009: Requirement of 1-2 cycles of IUI required for women between 40-42 years of age has been deleted.
- January 22, 2010: Reviewed by the Medical Specialty Policy Advisory Committee (MSPAC): 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: Formatting changes. No clinical changes.
- April 2011: Reviewed by MSPAC. BMI (body mass index) language added Section A points 3, 4 and 5. Section B, point 1 Experimental language reformatted. Section B, point 3 "therapeutic intervention" removed from statement. Treatment Required to ART cycles (FSHI, IUI) section deleted. Assisted Hatching language removed. Administrative Process language condensed. Appendix condensed. Glossary deleted.
- July 2011: Reviewed by the Integrated Medical Policy Advisory Committee (IMPAC). BMI Criteria added; Reversal of sterilization treatment coverage criteria added; AMH testing limitation added; urology consult for male deleted; authorization form updated. Effective date October 1, 2011.
- December 23, 2011: Reviewed by IMPAC. Provision added for coverage for Members who are parties to a civil union, in accordance with the change in Rhode Island law.
- April 11, 2012: Reviewed by IMPAC, no changes
- April 10, 2013: Reviewed by IMPAC, Evaluation by a Reproductive Endocrinologist removed.

- July 10, 2013: Reviewed by IMPAC, 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.
- May 14, 2014: Reviewed by IMPAC, Section I. C 1(g), 'Females With Elevated Body Mass Index', criteria removed.
- June 11, 2014: Reviewed by IMPAC, for an October 1, 2014 effective date. The following changes were made: 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
- August 28, 2014: Additional wording clarification
- January 14, 2015: Age clarified in Sections I. D(b), E(2), and I. E (4).
- January 14, 2015: Reviewed by IMPAC. Single Embryo Transfer (SET) criteria added to Section I. F 1(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 D. 1. and E. 1.
- March 25, 2015: Clarification of SET requirements added to FET section, F. 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.B.5. and I.C.2.b. 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.C.2.b.2.
- December 14, 2016: reviewed by IMPAC, updates to criteria in sections I.B. and I.E.
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- August 1, 2017: Modifications to align with amendments to Rhode Island General Law.
- September 13, 2017: Reviewed by IMPAC, update to criteria in section IV.B.1.
- October 11, 2017: Reviewed by IMPAC, update to general limitation in section I.B.7, effective 4/1/2018
- November, 2017: Coding updated
- December 13, 2017: Reviewed by IMPAC, update to criteria in section I.A.
- February 14, 2018: Reviewed by IMPAC, update to criteria in section I.F.1.d.
- March 14, 2018: Reviewed by IMPAC. Minor language change in reference to updated coverage of IVF with PGD; update to section I.B.
- September 12, 2018: Reviewed by IMPAC, update to language in section I.B.6 and to criteria in section I.C.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 B.5., update to note in section F.1.d.; addition of code 89272 to table of codes which require prior authorization, effective May 9, 2019.
- July 17, 2019: Reviewed by IMPAC, update to sections IV A and IV C
- November 20, 2019: Reviewed by IMPAC, note added to section I.F.1., existing note updated in section I.F.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.F.1.d, update to criteria in section I.F.4.a., and update to section IV.A.1, effective January 1, 2020.
- February 19, 2020: Reviewed by IMPAC, update to criteria I.F.3.b.2.
- 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 ageing 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. "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.
8. 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.*
9. "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.*
10. 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.
11. 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.*

12. 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.
13. 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.
14. 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

[Provider Services](#)