Medical Necessity Guidelines:
Infertility Services: New Hampshire 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.

OVERVIEW

These Medical Necessity Guidelines include the coverage criteria for all infertility services covered by Tufts Health Plan policies issued under a New Hampshire license, in accordance with New Hampshire SB 279. According to New Hampshire SB 279, infertility is defined as a disease, caused by an illness, injury, underlying disease, or condition, where an individual's ability to become pregnant or to carry a pregnancy to live birth is impaired, or where an individual's ability to cause pregnancy and live birth in the individual's partner is impaired.

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CLINICAL COVERAGE CRITERIA

I. Fertility Preservation

Tufts Health Plan may prior authorize coverage for standard fertility preservation services for Members who are expected to undergo surgery or other medical treatment that is recognized by medical professionals as causing a risk of impairment of fertility. Examples of such treatment include, but are not limited to, chemotherapy and/or radiation therapy for cancer and medically necessary gender confirming treatment. Standard fertility preservation services include procurement and cryopreservation of embryos, eggs, sperm, and reproductive material determined not to be an experimental infertility procedure, and coverage will be limited to one cycle.[1,2] When authorized, storage of cryopreserved material will be covered through the duration of the Member's Contract Year, as defined by their benefit plan. A letter of medical necessity from the treating physician is required.

II. Infertility Services Clinical Coverage Criteria

A. Demonstration of Infertility

Infertility treatment services are considered medically necessary for all Members (female, male, and other gender identities) when the criteria outlined in this medical necessity guideline are met during the time period when fertility can be expected as a natural state.* Infertility services will not be covered when there is a less than 5% chance of achieving a live birth.[3]

In order to be eligible for coverage of infertility services, a biological female Member must expect fertility as a natural state*, all policy criteria for the requested service must be met, and one of the following must be met:

- The female Member is otherwise healthy, is age 35 or younger, and has been unable to achieve a successful pregnancy after 12 or more months of exposure to sperm[4], **or**
- The female Member is otherwise healthy, is age 36 or older, and has been unable to achieve a successful pregnancy after 6 months or more of exposure to sperm[4]

> **NOTE:** Exposure to sperm can be via appropriate, timed, unprotected intercourse with a male partner, or via artificial insemination (home insemination or medically supervised artificial insemination). For artificial insemination performed with donor sperm from a sperm bank, documentation will be required that the sperm was procured from a sperm bank. For artificial insemination performed with donor sperm from a known sperm donor, documentation of evaluation of the sperm donor as listed under "Evaluation of Male" will be required.

*"Fertility can be expected as a natural state" is defined as a biological female who is premenopausal or experiencing menopause or ovarian failure at a premature age (before the age of 40) and has not undergone voluntary sterilization[4, 20].

B. Evaluation Requirements

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

1. Evaluation of the Female[5]

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[6]

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 a 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.

C. 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[5,7,8]
   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[5,7,8]

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.

D. 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[5,7,8]
   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[5,7,8]

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.

E. 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%.[9]

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 sperm, oocytes, embryos/blasts

1. **In Vitro Fertilization (IVF)**
   Note: If approved for IVF, Members will be approved for one fresh **or** one freeze-all cycle per request.

   a. ART, as outlined in this medical necessity guideline, is a covered benefit for females who meet the demonstration of infertility criteria outlined in II.A. above
   Note: The day 3 FSH test needs to be repeated every 6 months for any woman ≥ 40 years of age.[5,7,8]
   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.[10]
      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.[10]
      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).[5,7,8]
      Cycle Day 3 FSH level ≥12 mIU/ml and/or the day 3 Estradiol level ≥80 pg/mL (for women age ≥42).[5,7,8]
      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)[11],
      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%.[12] 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.[8]

   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 the demonstration of infertility criteria outlined in II.A. above are met and the women's fertility is expected as a natural state 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.[8]
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).[5,7,8]
   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 43rd birthday).[5,7,8]

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.[8,12]
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).[13]
d. Women age 40 or older are not generally appropriate candidates to donate oocytes/embryos.[13]

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.)[10]

   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[14]:
   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.
   2) Poor (< 50%) or failed fertilization in a current or previous cycle
   3) ≤ 1% normal forms (Strict Kruger Morphology)

   4) 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.

III. 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[13]:

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

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.

IV. 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[15]:
    a. The Member has a diagnosis of infertility and meets the demonstration of infertility criteria outlined in section II.A. above;
    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 > 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[15].
2. Members must receive IVF services at a Tufts Health Plan contracted ART contracting ART providers.

V. Sperm, Oocytes, or Embryo Cryopreservation

A. Clinical Coverage Criteria for Cryopreservation

1. In addition to fertility preservation outlined in section I above, 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 will 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), or

2) Planned freeze-all cycle, or
3) Single embryo transfer requirements.

LIMITATIONS

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[16].
2. Infertility treatment, when infertility is the result of a non-reversed voluntary sterilization.
3. Infertility services for individuals who have not met the demonstration of infertility criteria outlined in section II.A. above, or the likelihood of a 'success' (defined as a live birth rate) is less than 5%[3].
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.[8]
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[17]
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.
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 a Member or a Member's partner who is actively smoking cigarettes and/or are using nicotine containing products such as gum, patches or electronic cigarettes.[18]
14. Anti-Mullerian hormone (AMH) testing for ovarian reserve is considered experimental.
15. Uterine embryo lavage using Previvo catheter device is considered experimental.
16. Sperm cryopreservation as a routine procedure for sperm backup in the absence of a confirmed physical or psychological diagnosis requiring cryopreservation.
17. Cryopreservation, storage, and thawing of reproductive tissue (ovarian/testicular), CPT codes 0058T, 89335, 89344, and 89354 are considered experimental[1,2,19].
18. Long term sperm, oocyte, or embryo storage, defined as one or more of the following:
    a. Storage beyond the end of the policy term when approved for fertility preservation
    b. Storage beyond 90 days unless the Member is receiving approved, ongoing infertility treatment
    c. Storage beyond 90 days after the last cycle of infertility treatment ends, or if a pregnancy occurs

ADMINISTRATIVE CRITERIA

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. 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).
5. The Provider must complete a Tufts Health Plan Infertility Authorization Form when requesting services.
6. The Provider must complete the Tufts Health Plan Infertility Treatment Summary Form when requesting services.
7. Preimplantation genetic diagnosis (PGD) may be covered when specific criteria are met. Refer to Tufts Health Plan Preimplantation Genetic Diagnosis Medical Necessity Guideline.
8. Level One reviews that do not meet the guidelines and Level Two reviews will be completed by a Tufts Health Plan Medical Director.
9. Authorized services may be approved for up to six months.
10. 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.
11. 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 code(s) require prior authorization:

Table 1: CPT Codes

Code	Description
58321	Artificial insemination; intra-cervical
58322	Artificial insemination; intra-uterine
58323	Sperm washing for artificial insemination
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
89268	Insemination of oocytes
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)
89353	Thawing of cryopreserved; sperm/semen, each aliquot
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
S4026	Procurement of donor sperm from sperm bank
S4027	Storage of previously frozen embryos
S4028	Microsurgical epididymal sperm aspiration (mesa)
S4030	Sperm procurement and cryopreservation services; initial visit
S4031	Sperm procurement and cryopreservation services; subsequent visit
S4035	Stimulated intrauterine insemination (iui), case rate
S4037	Cryopreserved embryo transfer, case rate
S4040	Monitoring and storage of cryopreserved embryos, per 30 days
S4042	Management of ovulation induction (interpretation of diagnostic tests and studies, non-face-to-face medical management of the patient), per cycle

REFERENCES

1. American Society for Reproductive Medicine. Fertility Preservation in Patients Undergoing Gonadotoxic Therapy or Gonadectomy: A Committee Opinion. Fertility and Sterility. Vol. 100, No. 5; November 2013. Available at asrm.org. Last accessed November 12, 2019.
2. Oktay, Kutluk, et al. Fertility Preservation in Patients With Cancer: ASCO Clinical Practice Guideline Update. Journal of Clinical Oncology. Vol. 36, No. 19, July 1, 2018.
3. American Society for Reproductive Medicine. Fertility Treatment When the Prognosis is Very Poor or Futile: An Ethics Committee Opinion. Fertility and Sterility. Vol. 111, No. 4; April, 2019. Available at asrm.org. Last accessed November 12, 2019.
4. American Society for Reproductive Medicine. Definitions of Infertility and Recurrent Pregnancy Loss: A Committee Opinion. Fertility and Sterility. Vol. 99, No. 1; January, 2013. Available at asrm.org. Last accessed October 15, 2019.
5. American Society for Reproductive Medicine. Diagnostic Evaluation of the Infertile Female: A Committee Opinion. Fertility and Sterility. Vol. 103, No.6; June, 2015. Available at asrm.org. Last accessed November 5, 2019.

6. American Society for Reproductive Medicine. Diagnostic Evaluation of the Infertile Male: A Committee Opinion. Fertility and Sterility. Vol. 103, No. 3; March, 2015. Available at asrm.org. Last accessed November 5, 2019.
7. Kuohung, Wendy, M.D., et al. Evaluation of Female Infertility. UpToDate. April 1, 2019. Available at uptodate.com. Last accessed November 7, 2019.
8. American Society for Reproductive Medicine. Female Age-Related Fertility Decline. Committee Opinion No. 589. Fertility and Sterility. Vol. 101, No.3; March, 2014. Available at asrm.org. Last accessed November 7, 2019.
9. 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.
10. American Society for Reproductive Medicine. Guidance On the Limits to the Number of Embryos to Transfer: A Committee Opinion. Fertility and Sterility. Vol. 107, No. 4; April, 2017. Available at asrm.org. Last accessed November 7, 2019.
11. Teranishi, A., et al. A Theoretical model for Single Blastocyst Transfer. Journal of Assisted Reproductive Genetics. Vol. 26, No. 6; June, 2009. Available at ncbi.nlm.nih.gov/pmc/articles/PMC2729859/ . Last accessed November 12, 2019.
12. Society for Assisted Reproductive Technology. 2016 National Summary Report (IVF Outcomes). Available at sart.org. Last accessed November 14, 2019.
13. American Society for Reproductive Medicine. Recommendations for Gamete and Embryo Donation: A Committee Opinion. Fertility and Sterility. Vol. 99, No. 1; January, 2013. Available at asrm.org. Last accessed November 14, 2019.
14. American Society for Reproductive Medicine. Intracytoplasmic Sperm Injection (ICSI) for Non-Male Factor Infertility: A Committee Opinion. Fertility and Sterility. Vol. 98, No. 6; December, 2012. Available at asrm.org. Last accessed November 14, 2019.
15. American Society for Reproductive Medicine. Prevention and Treatment of Moderate to Severe Ovarian Hyperstimulation Syndrome: A Guideline. Fertility and Sterility. Vol. 106, No. 7; December, 2016. Available at asrm.org. Last accessed November 12, 2019.
16. American Society for Reproductive Medicine. Definition of Experimental Procedures: A Committee Opinion. Fertility and Sterility. Vol. 99, No. 5; April, 2013. Available at asrm.org. Last accessed November 7, 2019.
17. 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.
18. American Society for Reproductive Medicine. Smoking and Infertility: A Committee Opinion. Fertility and Sterility. Vol. 110, No. 4; September, 2018. Available at asrm.org. Last accessed November 8, 2019.
19. American Society for Reproductive Medicine. Ovarian Tissue Cryopreservation: A Committee Opinion. Fertility and Sterility. Vol. 101, No. 5; May, 2014. Available at asrm.org. Last accessed October 29, 2019.
20. Kuohung, Wendy, M.D., et al. Overview of Infertility. UpToDate. March 13, 2019. Available at uptodate.com. Last accessed November 7, 2019.

APPROVAL HISTORY

November 20, 2019: Reviewed by the Integrated Medical Policy Advisory Committee (IMPAC) for an effective date of January 1, 2020

Subsequent endorsement date(s) and changes made:

- February 19, 2020: Reviewed by IMPAC, update to criteria II.E.3.b.2, update to note in general limitation number 4.
- February 20, 2020: Unify fax number updated.
- May 20, 2020: Reviewed by IMPAC, renewed without changes.

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