Medical Policy Criteria: Infertility (Commercial)

POLICY NUMBER	LAST REVIEW DATE	APPROVED BY
M20190006v2	05/13/2023	MPC (Medical Policy Committee)

IMPORTANT NOTE ABOUT THIS MEDICAL POLICY:

 The treating physician or primary care provider must submit to ConnectiCare, Inc. the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, ConnectiCare will not be able to properly review the request for prior authorization. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. The clinical review criteria expressed below reflects how ConnectiCare determines whether certain services or supplies are medically necessary. ConnectiCare established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). ConnectiCare, Inc. expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Each benefit plan defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by ConnectiCare, as some plans exclude coverage for services or supplies that ConnectiCare considers medically necessary. If there is a discrepancy between this guideline and a member's benefits plan, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of the State of CT and/or the Federal Government. Coverage may also differ for our Medicare members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Coverage Determinations (LCD) and/or Local Medical Review Policies(LMRP). All coding and web site links are accurate at time of publication.

Definitions

Infertility	"Infertility" is a disease or condition characterized by the incapacity to impregnate another person or to conceive, defined by the failure to establish a clinical pregnancy after twelve (12) months of regular, unprotected sexual intercourse or therapeutic donor insemination, or after six (6) months of regular, unprotected sexual intercourse or therapeutic donor insemination for a female thirty-five (35) years of age or older. Earlier evaluation and treatment may be warranted based on a member's medical history or physical findings (Section 4: IVF for Women without Male Partners or Exposure to Sperm)
Iatrogenic infertility	An impairment of fertility by surgery, radiation, chemotherapy or other medical treatment affecting reproductive organs or processes
IUI	Intrauterine insemination (IUI) is a fertility treatment in which a fine catheter is inserted through the cervix into the uterus to deposit a sperm sample directly into the uterus.
IVF	In Vitro Fertilization (IVF) is an assisted reproductive technology (ART). IVF is the process of fertilization by extracting eggs, retrieving a sperm sample, and then manually combining an egg and sperm in a laboratory dish. The embryo(s) is then transferred to the uterus.
Cycle	A cycle starts with ovulation induction and ends with retrieval of oocyte(s).
Male Factor	Mild Male Factor: Abnormalities in the semen analysis where the sperm concentration is 10-15 million/mL, and motility is 30–40%.

Connecticut State Limitations

A. Ovulation induction limited to four cycles.

B. Intrauterine Insemination (IUI) limited to three cycles.

C. In-vitro fertilization (IVF), gamete intra-fallopian transfer (GIFT), zygote intra-fallopian transfer (ZIFT) or low tubal ovum transfer limited to two cycles, with not more than two embryo implantations per cycle, for, provided each such fertilization or transfer shall be credited toward such maximum as one cycle; (IVF Cycles are defined as induction of ovulation induction and considered complete at oocyte retrieval).

D. Limit coverage for in-vitro fertilization, gamete intra-fallopian transfer, zygote intra-fallopian transfer and low tubal ovum transfer to those individuals who have been unable to conceive or produce conception or sustain a successful pregnancy through less expensive and medically viable infertility treatment or procedures covered under such policy. Nothing in this subdivision shall be construed to deny the coverage required by this section to any individual who foregoes a particular infertility treatment or procedure if the individual's physician determines that such treatment or procedure is likely to be unsuccessful.

E. Requires that covered infertility treatment or procedures be performed at facilities that conform to the standards and guidelines developed by the American Society of Reproductive Medicine or the Society of Reproductive Endocrinology and Infertility.

Massachusetts State Limitations

A. Insurers that provide pregnancy-related benefits must cover diagnostics and treatment for infertility, including artificial insemination, IVF, GIFT, egg or sperm procurement processing, sperm or egg banking, ICSI, and ZIFT.

B. IVF can only be covered if patient is unsuccessful achieving pregnancy with less expensive treatment options covered by the plan

C. IVF procedure must be performed at a fertility clinic or medical facility that conforms to standards and guidelines set by the American Society for Reproductive Medicine (ASRM) or the American College of Obstetricians and Gynecologists.

D. The following procedures identified in the mandate as exempt:
- Sterilization procedures or reversals (vasectomy or tubal ligation)
- Surrogacy
- Experimental fertility treatments
- Egg freezing

E. Medically necessary prescription drugs
- Self-administered drugs including ovulatory injections (e.g., HCG) are covered only for members with prescription drug coverage, who are in an active, authorized cycle of infertility treatment

Guideline

Section 1: General Definition of Infertility and Prognosis for Initial and Continuation of Infertility Treatment Coverage

Member must meet the general definitions for infertility services with all of the following:

1. Member has infertility benefits and has not exhausted those infertility benefits and/or cycles.

2. Member must meet one of the following:
   - Attempting to conceive for 12 months and is 34 years of age or younger
   - Attempting to conceive for 6 months and is 35 years of age or older
   - Same sex couple
   - Single female who has failed 6 consecutive medically managed IUI cycles using donor sperm (Note: Costs and storage of donor sperm, and IUIs to demonstrate infertility, are not covered except as specifically provided in New York Insurance Circular Letter #3 [2021])
   - Iatrogenic infertility/Fertility Preservation
3. No significant evidence of diminished ovarian reserve in two of the three measures obtained within the previous six months. Choose two or more of the following:
   - Follicle stimulating hormone (FSH) level ≤ 15 mIU/ml if ≥ 40 years of age or FSH level ≤ 20 mIU/ml if < 40 years of age
   - Anti-mullerian hormone (AMH) level > 0.3 ng/ml
   - Antral follicle count (AFC) > 7
   - Not applicable services (choose donor egg or fertility preservation)
   - Donor egg requests (DOR markers do not apply)
   - Fertility Preservation Requests (DOR markers do not apply)
4. No evidence of diminished ovarian reserve where a couple is attempting conception with their own gametes (with the exception of premature ovarian failure)
5. No evidence of numerous (more than one) Assisted Reproductive Technologies (ART) cycles without adequate egg production, fertilization and/or embryo development

Section 2: Artificial Insemination (IUI)

Member must meet the general definitions for infertility and prognosis and all of the following:

1. Diagnostic imaging report (i.e., hysterosalpingogram (HSG), sonohysterosalpingogram, sonohysterosalpingogram, HSG/hysteroscopy, sonohystogram, 3D ultrasound, or hysterosalpingo contrast sonography (HyCoSy) performed within 2 years showing all of the following:
   - Tubal patency of at least one tube
   - Normal endometrial cavity
2. Semen analysis (one sample within one year) demonstrating one of the following:
   - Normal semen analysis
   - Male factor infertility (excludes severe male factor infertility)
   - Not applicable (i.e., donor sperm, single female member, same sex couple)
3. Must have one of the following:
   - Unexplained infertility
   - Polycystic Ovary Syndrome (PCOS), anovulation, or oligoovulation
   - Minimal or mild endometriosis
   - Cervical factors (i.e., cervical trauma, surgical or conization procedures, anatomical irregularities)
   - Male factor infertility (excluding severe)
   - Vaginismus diagnosis
   - Sexual dysfunction
   - Use of stored sperm from male members who required sperm banking/storage as a result of medical treatment (e.g., cancer treatment) likely to cause infertility

- Women without Male Partners or Exposure to Sperm (single female/same sex couple)

4. If member had prior IUI cycles, results must be submitted and demonstrate one of the following:
   - Adequate ovarian response to stimulation (i.e., at least 2 follicles > 12 mm diameter or 1 follicle ≥15 mm)
   - Not applicable — no prior cycles or conversion
5. IUI after IVF

   This request is to obtain IUI services after IVF services have been rendered and **one** of the following apply:
   - There has been a spontaneous live birth after an unsuccessful IVF cycle
   - Members who opt to use donor sperm after discovery of a male genetic disorder
   - IUI after IUI–to–IVF conversion for hyperstimulation if the stimulation that was initially given is reduced
   - Not applicable
6. Conversion from IUI-to-IVF hyperstimulation conversion services if the stimulation was reduced and all of the following apply:
   - Estradiol level of ≥ 800 pg/ml
   - Production of at least 5 follicles > 12 mm in diameter
   - Age < 40
   - Not applicable

Section 3: Assisted Reproductive Technology (ART) cycles (including Fresh, Freeze-All, and Frozen embryo transfer cycles) all of the following

1. Member has a history of at least three failed IUI cycles unless medically indicated to go straight to IVF
2. All transferrable and/or viable oocytes/embryos have been utilized prior to this request.

   Note: The first embryo transfer performed within 120 days of a freeze-all cycle will still be considered a continuation of the prior freeze-all cycle.
3. Diagnostic imaging report within two years showing a normal endometrial cavity (i.e., hysterosalpingogram (HSG), sonohysterosalpingogram, HSG/hysteroscopy, sonohystogram, 3D ultrasound, or hysterosalpingo contrast sonography (HyCoSy)
4. Semen analysis (one sample within one year) (excluding fresh embryo transfer (FET) – no semen analysis)
5. There is the presence of one of the following:
   - Unexplained infertility
   - Premature ovarian failure
   - Ovulatory dysfunction as demonstrated by one of the following:
     - Ovulation induction has not resulted in conception
     - Poor response to ovulation induction
     - Hyper-response to ovulation induction
   - Female member with bilateral fallopian tube absence (excluding elective sterilization) or bilateral fallopian tube obstruction due to prior tubal disease with history of failed conventional therapy
   - History of severe endometriosis and/or failed medical/surgical therapies
   - Severe male factor infertility

- Women without Male Partners or Exposure to Sperm (single female/same sex couple)
- Conversion of fresh to freeze-all cycle with one of the following:
  - Member's progesterone concentration (P4) is > 1ng/mL at the time of administration of hCG trigger injection
  - Management of Ovarian Hyperstimulation Syndrome (OHSS) or suspected OHSS

6. IVF Cycle Protocol (Note: if member meets criteria for 2 embryo transfer cycle and only one embryo is available, then a new IVF cycle may be authorized if benefit is available) related to one of the following:
   - For members < 35 years of age
     - 1st IVF treatment cycle: SET (single embryo transfer) is required
       - If there are no top-quality embryos after thawing, then two or more embryos of any quality may be transferred
     - 2nd and subsequent IVF treatment cycles:
       - SET/FET is required if member has **one or more** embryos frozen
         - If there are no top-quality embryos after thawing, then two embryos of any quality may be transferred
       - Fresh IVF cycle with SET if no frozen embryos available
         - If there are no top-quality embryos after thawing, then two embryos of any quality may be transferred
   - For members 35–38 years of age
     - 1st IVF treatment cycle: SET is required
       - If no top-quality embryo is available, then two embryos of any quality may be transferred
     - 2nd and subsequent IVF treatment cycles do not need to be SET
   - For members < 38 years of age and had successful IVF treatment cycle (i.e., had a live birth from that IVF treatment)
     - 1st IVF treatment cycle:
       - SET is required if member has **one or more** embryos frozen
         - If there are no top-quality embryos after thawing, then two embryos of any quality may be transferred
     - Fresh IVF cycle with SET if no frozen embryos available
       - If only no top-quality embryo is available, then two embryos of any quality may be transferred
     - 2nd and subsequent IVF treatment cycles do not need to be SET
   - Members ≥ 38 years of age undergoing IVF treatment do not need to attempt a SET, as their risk of multiple births is low
7. Cryopreservation of Embryos: In conjunction with an approved infertility cycle, the Plan will authorize cryopreservation of embryos for one of the following:
   - For women in active infertility treatment cryopreservation for any embryos remaining after an IVF cycle. Cryopreserved embryos must be used before fresh IVF cycles using the member's or a donor's eggs are authorized.
   - Not applicable
8. Fertility Preservation: Fertility preservation services are a separate benefit to preserve fertility when

a medical treatment will directly or indirectly result in iatrogenic infertility and do not count towards the three-cycle limit on IVF benefits. No infertility workup is required for coverage. (NOTE: Preservation is only covered for egg [oocytes] retrievals and sperm collection). Preservation is considered medically necessary for one of the following medical situations:

- Members undergoing gonadotoxic cancer treatments
- Members planning gender affirming treatment
- Other medically necessary treatment that is expected to render the member permanently infertile (excluding voluntary sterilization)

9. Assisted Hatching: Assisted Hatching is considered medically necessary as part of any IVF procedure for advanced maternal age women > 38 years of age or when documentation confirms one of the following:
   - Prior failed IVF cycles that produced three or more euploid embryos with failure to implant after embryo transfer
   - Prior pregnancy resulting from IVF where assisted hatching was performed
   - Thickened zona pellucida on microscopy
10. ICSI — Intracytoplasmic Sperm Injection (ICSI) or other Male Factor Procedures (MESA/TESE)

    Member must meet the general definitions for infertility and prognosis and any of the following:
    - Severe male factor infertility evidenced by two abnormal semen analyses in one year demonstrating one of the following:
      - < 5 million/mL (unwashed specimen)
      - < 25% motility
      - ≤ 4% normal morphology
    - Reduced fertilization on a prior IVF cycle using non-donor sperm if the rate of fertilization on the prior cycle is < 40% fertilization with the standard insemination of mature eggs
    - Obstruction of the male reproductive tract unrelated to prior sterilization or sterilization reversal, and not amenable to repair (necessitating sperm retrieval via Microsurgical Epididymal Sperm Aspiration)
    - Nonobstructive azoospermia (necessitating sperm retrieval via Testicular Sperm Extraction)
    - ICSI is performed when fertilizing previously frozen oocytes in association with or without donor sperm, as exposure to cryoprotectants often lead to the hardening of the zona
    - Member has met criteria for Preimplantation Genetic Testing (PGT)
    - Retrospective authorizations will be allowed for ICSI if on the day of IVF, the egg retrieval post-processing semen is performed
    - Microepididymal Sperm Aspiration (MESA) is covered only for congenital absence or congenital obstruction of the vas deferens (typically diagnosed by the absence of fructose in semen) and confirmed by exam
    - Microdissection - Testicular Excisional Sperm Extraction (TESE) is covered for non-obstructive azoospermia and spinal cord injury resulting in inability to ejaculate
11. Preimplantation Genetic Testing (PGT)

PGT is considered medically necessary as part of an IVF procedure when documentation confirms **one** of the following:

- Both partners are known carriers of a single gene autosomal recessive disorder
- One partner is known to have a balanced translocation
- One partner has a single gene autosomal dominant disorder

- One partner is a known carrier of an x-linked disorder
- Testing is being conducted to determine the sex of an embryo when there is a documented history of an x-linked disorder, and decisions regarding management can be made based on sex alone

12. Donor Services
    A. Donor Egg (Donor Oocyte): Use of Donor egg during infertility procedures is a covered benefit for women who meet the general requirements for treatment, the recommended treatment is considered standard of care, and there is documentation of **any** of the following:
        - Congenital or surgical absence of ovaries
        - Clinically documented premature ovarian insufficiency/failure (ovarian insufficiency refers to women < 40 years of age who have elevated FSH levels in the menopausal range (at least 30–40 mIU/mL) and amenorrhea as defined by American College of Obstetricians and Gynecologists)
        - Inadequate ovarian response (i.e., fewer than 3 follicles >12 mm diameter), or inadequate embryo numbers and quality, during authorized IVF cycles within the prior 6 months. (Note: When donor egg criteria are met, a donor egg cycle is authorized for up to 6 months)
        - Genetic abnormality
    B. Donor Sperm: Use of donor sperm of normal quality is medically necessary when documentation includes any of the following:
        - Bilateral congenital absence of vas deferens (BCAVD)
        - Non-obstructive azoospermia confirmed through MESA/TESE results
        - Previous radiation or chemotherapy treatment resulting in abnormal semen analyses
        - Two or more abnormal semen analyses at least 30 days apart in the last 3 months
        - A high risk of transmitting the male partner's genetic disorder to the offspring
        - HIV+ male partner

Limitations/Exclusions

ART Limitations and Exclusions — members are not eligible for the following tests and/or procedures:

1. Infertility treatment if, based on the member's individual medical history, they have < 5% chance of a birth outcome
2. ART/Infertility services for members when clinical documentation confirms an individual or couple are using substances known to negatively interfere with fertility or fetal development (e.g., marijuana, opiates, cocaine, tobacco, or alcohol) (Note: Medical record documentation of 3 months of abstinence from substance use may be required before ART/Infertility services will be approved)
3. Long-term sperm, oocyte, or embryo storage
4. Sperm cryopreservation as a routine procedure for sperm backup in the absence of a confirmed physical or physiological diagnosis requiring cryopreservation.
5. Embryo and/or egg cultures (CPT codes 89250 and 89272) for FET cycles only
6. Infertility treatment when infertility is the result of a non-reversed or unsuccessful reversal of a voluntary sterilization
7. Donor sperm without documented biological male factor infertility proven with two abnormal semen analyses with the same defect

8. Donor sperm for biological males with genetic sperm defects
9. For biological females without a biological male partner the cost of donor sperm and storage, IUI, ART, and related services, if the male partner has a history of prior vasectomy with no subsequent successful vasectomy reversal procedure
10. Cost of procurement and storage of Donor Sperm
11. Ovarian Reserve Assessment results (Clomiphene Citrate Challenge Test [CCCT])
12. Selective fetal reduction without known disorders that are non-compatible with life
13. Sperm DNA integrity/fragmentation tests [e.g., sperm chromatin structure assay (SCSA), single-cell gel electrophoresis assay (Comet), deoxynucleotidyl transferase-mediated dUTP nick end labeling assay (TUNEL), sperm chromatin dispersion (SCD) or Sperm DNA Decondensation™ Test (SDD)]
14. Sperm wash without approved cycle
15. Laboratory tests for cycle monitoring when IUI or IVF cycle has not been approved
16. Gender selection
17. Co-culture of embryos
18. In vitro maturation of eggs
19. Genetic engineering
20. Egg harvesting, or other infertility treatment, performed during an operation not related to an infertility diagnosis
21. Chromosome studies of a donor (sperm or egg)
22. Infertility services in cases in which normal embryos have been or will be discarded because of gender selection
23. ICSI for any IVF cycle involving use of donor sperm (unless fertilizing previously frozen oocytes)
24. Treatments requested solely for the convenience, lifestyle, personal or religious preference of the member in the absence of medical necessity
25. Treatment to reverse voluntary sterilization, i.e., MESA/TESE, for a member who has undergone prior sterilization
26. Reciprocal IVF (including co-maternity retrievals and transfers)
27. Oocyte, ovarian or testicular tissue cryopreservation (excluding fertility preservation services)
28. Surrogacy (Note: Maternity service benefits are available for members acting as surrogate mothers)
29. Mock embryo transfer is not a covered procedure, as such planning, performed in anticipation of embryo transfer, is inclusive to the evaluation and management service provided
30. Preimplantation Genetic Testing (PGT) is not covered when being used for the selection of embryos with the sole purpose of determining the gender of the resultant offspring
31. Uterine transplant for the treatment of uterine factor infertility
32. All experimental/investigational procedures and treatments are not covered for the diagnosis and treatment of infertility as determined in accordance with the standards and guidelines established and adopted by the American College of Obstetricians and Gynecologists and the American Society for Reproductive Medicine
33. Member has not undergone infertility surgical interventions to relieve symptoms of any of the following:

34. Pelvic pain that is not responsive to medical management
35. Presence of a pelvic mass for which gynecologic diagnosis warrants surgical intervention (e.g., hydrosalpinx)
36. As an alternative treatment modality to the Assisted Reproductive Technologies (ART) particularly for individuals who are averse to pursuing ART for religious, social or financial concerns.
37. Following successful infertility surgery, in the absence of other infertility factors, additional treatment is not immediately indicated for 6 months after surgery.
38. Embryo banking: There is no evidence in the medical literature to support the practice of repeated ART cycles for the purpose of accumulating (banking) embryos for later use (egg retrievals without a fresh or frozen embryo transfer) with the exception of freeze all cycles for medical necessity.
39. Long-term sperm, oocyte, or embryo storage outside of NYS mandated coverage (excluding fertility preservation)
40. Sperm cryopreservation as a routine procedure for sperm backup in the absence of a confirmed physical or psychological diagnosis requiring cryopreservation (excluding fertility preservation)
41. Non-medical services related to donor egg/embryo or sperm procurement (e.g., finder fees, broker fees, legal fees, medications, donor screening, donor testing, and oocyte retrievals) are not covered
42. Infertility treatment when the infertile member is not the recipient of said services (e.g., donor egg in conjunction with gestational carrier)
43. After proceeding to a donor egg cycle, further IVF cycles using the member's eggs are not covered
44. Donor sperm without documented biological male factor infertility proven with 2 abnormal semen analyses with the same defect
45. Donor sperm for biological males with genetic sperm defects
46. For biological females without a biological male partner
47. The cost of donor sperm and storage, IUI, ART, and related services, if the male partner has a history of prior vasectomy with no subsequent successful vasectomy reversal procedure
48. Cost of procurement and storage of Donor Sperm
49. Cryopreservation of embryos or eggs or sperm for fertility preservation purposes other than chemotherapy or other treatments that may render an individual infertile
50. Cryopreservation of embryos or eggs or sperm for reciprocal IVF
51. Sperm storage/banking for males requesting this service for convenience or "back-up" for a fresh specimen
52. ART services are not covered in any of the following situations:
    - To convert an ART cycle to IUI when at least 3 follicles ≥ 15 mm in diameter are present (particularly in the setting of diminished ovarian reserve or on the 2nd or greater ART cycle when maximal dosage of gonadotropins is being used)
    - Following an ART cycle that fails to result in conception due to poor ovarian response or poor-quality oocytes or embryos
    - Following ≥ 2 ART cycles that have failed to result in a conception despite good quality oocytes or embryos

IUI Limitations and Exclusions — members are not eligible for the following tests and/or procedures:

1. Women who have been denied or failed ART services are generally not appropriate candidates for

IUI cycles (exceptions based upon an individual's medical history will be considered)

2. Infertility treatment if, based on the member's individual medical history, they have < 5% chance of a birth outcome
3. Infertility services for members when clinical documentation confirms an individual or couple are using substances known to negatively interfere with fertility or fetal development (e.g., marijuana, opiates, cocaine, tobacco, or alcohol) (Note: Medical record documentation of 3 months of abstinence from substance use may be required before ART/Infertility services will be approved)
4. Infertility treatment when infertility is the result of a non-reversed or unsuccessful reversal of a voluntary sterilization
5. Ovarian reserve assessment results (i.e., Clomiphene Citrate Challenge Test [CCCT] is not covered)
6. Selective fetal reduction without known disorders that are non-compatible with life
7. Sperm DNA integrity/fragmentation tests (e.g., sperm chromatin structure assay [SCSA], single-cell gel electrophoresis assay [Comet], deoxynucleotidyl transferase-mediated dUTP nick end labeling assay [TUNEL], sperm chromatin dispersion [SCD] or Sperm DNA Decondensation™ Test [SDD])
8. Sperm wash without approved cycle
9. Laboratory tests for cycle monitoring when IUI or IVF cycle has not been approved
10. Chromosome studies of a donor (sperm or egg)
11. Treatments requested solely for the convenience, lifestyle, personal or religious preference of the member in the absence of medical necessity
12. Treatment to reverse voluntary sterilization, i.e., MESA/TESE, for a member who has undergone prior sterilization
13. Uterine transplant for the treatment of uterine factor infertility
14. All experimental/investigational procedures and treatments are not covered for the diagnosis and treatment of infertility as determined in accordance with the standards and guidelines established and adopted by the American College of Obstetricians and Gynecologists and the American Society for Reproductive Medicine
15. Member has not undergone infertility surgical interventions to relieve symptoms of any of the following:
    - Pelvic pain that is not responsive to medical management
    - Presence of a pelvic mass for which gynecologic diagnosis warrants surgical intervention (e.g., hydrosalpinx)
    - As an alternative treatment modality to the Assisted Reproductive Technologies (ART) particularly for individuals who are averse to pursuing ART for religious, social or financial concerns.
16. Following successful infertility surgery, in the absence of other infertility factors, additional treatment is not immediately indicated for 6 months after surgery.
17. > 1 insemination per cycle
18. Severe male factor infertility
19. Bilateral tubal factor infertility
20. Women with a less than 5% success rate for conception with IUI versus alternative therapies such as IVF
21. Moderate or severe endometriosis unless treatment has previously been rendered and there is

documentation of at least one uncompromised fallopian tube

22. Recurrent pregnancy loss
23. In the setting of ART in any of the following situations:
    - To convert an ART cycle to IUI when at least 3 follicles ≥ 15 mm in diameter are present (particularly in the setting of diminished ovarian reserve or on the 2nd or greater ART cycle when maximal dosage of gonadotropins is being used)
    - Following an ART cycle that fails to result in conception due to poor ovarian response or poor-quality oocytes or embryos
    - Following ≥ 2 ART cycles that have failed to result in a conception despite good quality oocytes or embryos

Applicable Procedure Codes

58321	Artificial insemination; intra-cervical
58322	Artificial insemination; intra-uterine
58323	Sperm washing for artificial insemination
58340	Catheterization and introduction of saline or contrast material for saline infusion sonohysterography (SIS) or hysterosalpingography
58345	Transcervical introduction of fallopian tube catheter for diagnosis and/or re-establishing patency (any method), with or without hysterosalpingography
58752	Tubouterine implantation
58760	Fimbrioplasty
58970	Follicle puncture for oocyte retrieval, any method
58974	Embryo transfer, intrauterine
76831	Saline infusion sonohysterography (SIS), including color flow Doppler, when performed
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)
89257	Sperm identification from aspiration (other than seminal fluid)
89258	Cryopreservation; embryo(s)
89259	Cryopreservation; sperm
89260	Sperm isolation; simple prep (e.g., sperm wash and swim-up) for insemination or diagnosis with semen analysis
89261	Sperm isolation; complex prep (e.g., Percoll gradient, albumin gradient) for insemination or diagnosis with semen analysis
89264	Sperm identification from testis tissue, fresh or cryopreserved
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
89291	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); greater than 5 embryos
89300	Semen analysis; presence and/or motility of sperm including Huhner test (post coital)
89310	Semen analysis; motility and count (not including Huhner test)
89320	Semen analysis; volume, count, motility, and differential
89321	Semen analysis; sperm presence and motility of sperm, if performed
89322	Semen analysis; volume, count, motility, and differential using strict morphologic criteria (e.g., Kruger)
89331	Sperm evaluation, for retrograde ejaculation, urine (sperm concentration, motility, and morphology, as indicated)
89337	Cryopreservation, mature oocyte(s)
89342	Storage (per year); embryo(s)
89343	Storage (per year); sperm/semen
89346	Storage (per year); oocyte(s)
89352	Thawing of cryopreserved; embryo(s)
89353	Thawing of cryopreserved; sperm/semen, each aliquot
89356	Thawing of cryopreserved; oocytes, each aliquot
Q0115	Postcoital direct, qualitative examinations of vaginal or cervical mucous
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
S4015	Complete in vitro fertilization cycle, not otherwise specified, case rate
S4016	Frozen in vitro fertilization cycle, case rate
S4017	Incomplete cycle, treatment cancelled prior to stimulation, case rate
S4018	Frozen embryo transfer procedure cancelled before transfer, case rate
S4020	In vitro fertilization procedure cancelled before aspiration, case rate
S4021	In vitro fertilization procedure cancelled after aspiration, case rate
S4022	Assisted oocyte fertilization, case rate
S4023	Donor egg cycle, incomplete, case rate
S4025	Donor services for in vitro fertilization (sperm or embryo), case rate
S4027	Storage of previously frozen embryos
S4035	Stimulated intrauterine insemination (IUI), case rate
S4037	Cryopreserved embryo transfer, case rate

References

State Mandate Information
Connecticut Bill No. 508 / Public Act No. 05-196 Connecticut State Mandate: Sec. 38a-536.
Massachusetts: 176G §4 211 CMR 37.00

Agency for healthcare research and quality (AHRQ), U.S. Department of Health and Human Services, National Guideline Clearinghouse | Fertility: assessment and treatment for people with fertility problems. http://guideline.gov/content.aspx

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.

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Revision History

3/27/24	1. General section: Wording clarifications and moved relevant limitations/exclusions 2. ART: Combined all cycle type, wording clarifications and moved relevant limitations/exclusions 3. Assisted Hatching: Wording clarifications and moved relevant limitations/exclusions 4. Male Infertility Factor: Moved to definition section 5. ICSI: Wording clarification for severe male factor infertility and moved relevant limitations/exclusions 6. Cryopreservation of Embryos: Wording clarification for severe male factor infertility and moved relevant limitations/exclusions 7. Donor services: Wording clarification for severe male factor and moved relevant limitations/exclusions 8. Fertility Preservation: Wording clarification for severe male factor infertility and moved relevant limitations/exclusions 9. Limitations/Exclusions: 10. Added relevant section criteria, clarified substance use definition

12/8/2023	1. Freeze-All Cycles section ▪ Clarified that approval for a frozen embryo transfer (FET), as a continuation of the same IVF cycle, will be conditional on the preimplantation genetic testing (PGT) being performed ▪ Added note stating that a current semen analysis is not required when FET is requested 2. Sections pertaining to Donor Services and IVF for Women without Male Partners or Exposure to Sperm ▪ Added "storage" to notes pertaining to noncovered expenses 3. Fertility Preservation Section ▪ Added note stating that fertility preservation services are a separate benefit to preserve fertility when a medical treatment will directly or indirectly result in iatrogenic infertility and do not count towards the three-cycle limit on IVF benefits 4. Limitations/Exclusions RE individual or couple using/abusing illicit substances ▪ Added note stating that medical record documentation of 3 months of abstinence from substance use may be required before ART/Infertility services will be approved ▪ Added Sperm-Hyaluronan Binding Assay (HBA) as E/I for selection of sperm for use with assisted reproduction technologies
5/12/2023	1. Section 3: Assisted Reproductive Technology (ART): ▪ Added "Hysterosalpingogram (HSG), sonohysterosalpingogram, or hysteroscopic documentation of a normal endometrial cavity within the past 2 years" to IVF section (for consistency with IUI section) ▪ Replaced "Diminished ovarian reserve (not due to age) with "Premature ovarian failure" 2. Section 5: Donor Services ▪ Replaced (Clinically documented) "diminished premature ovarian reserve" (as defined by American College of Obstetricians and Gynecologists) with "premature ovarian failure"
02/10/2023	Added noncoverage of uterine transplant for the treatment of uterine factor infertility to Limitations/Exclusions Clarification edits (shown below in *italics*) General indications: – No evidence of significant diminished ovarian reserve *(except in cases of requests for donor eggs for members with premature ovarian failure)*. General infertility surgery: – Presence of a pelvic mass for which gynecologic diagnosis warrants surgical intervention *(e.g., hydrosalpinx)* Noncovered services: – Cryopreservation of embryos or eggs *or sperm* for fertility preservation purposes other than chemotherapy or other treatments that may render an individual infertile Cryopreservation of embryos or eggs or sperm for reciprocal IVF
09/09/2022	Removed language within Donor Services section pertaining to age 40
07/08/2022	Added noncoverage note to Limitations/Exclusions for mock embryo transfers

05/27/2022	Clarified cycle definition and edited numeric value RE progesterone concentration
06/11/2021	Corrected progesterone concentration (P4) to read < 1ng/mL in Freeze All section Corrected only "one top quality embryo" to "no top-quality embryos" in IVF Protocol Added to ICSI section that ICSI is authorized when PGT is medically indicated Added clarification to Donor Egg section communicating that use of a donor egg during infertility procedures is a covered benefit for women < 40 Changed "chemotherapy" to "gonadotoxic" in Fertility Preservation section as a descriptive for treatment that is causal to infertility Added clarification in Limitations/Exclusions, Ovulation "predictor" kits Added Home Artificial Insemination Kits to Limitations/Exclusions
02/01/2021	Change to Guideline under the general infertility surgery criteria: "conservative" changed to "medical". Change to Section 4: IVF for Women without Male Partners or Exposure to Sperm: Added "To demonstrate infertility as a disease/condition, documentation must…". Removed AI/IUI, changed to "medically managed IUI. ` Change to Section 6: Fertility Preservation: "Covered services for members undergoing chemotherapy", changed to" gonadotoxic cancer treatment". Change to Section 8: Added to Limitations/Exclusions: Home Artificial Insemination Kits Added references
12/11/2020	Change to Section 1: FSH level from ≥ 35 to ≥ 40 years of age Removed "Treatment is not indicated in the setting of using autologous oocytes in females ≥ 44 years of age". Change to Section 3: Removed STEET from B. IVF Protocol. Added "or Suspected OHSS" to E. Freeze-All Cycles
09/01/2020	Added note to Section 3A bullet RE failed IUI cycles regarding 3 IUIs before IVF
08/14/2020	Infertility Definition updated Added Section 1: General Indications for Initial and Continuation of Infertility Treatment Coverage Added sonohysterosalpingogram as a covered screening option for tubal occlusion. Enhanced male factor infertility definition (i.e., mild, moderate and severe factor parameters). Clarified that the first embryo transfer performed within 60 days of a freeze all cycle will be considered a continuation of the freeze-all cycle. Clarified that ICSI is also clinically indicated when fertilizing previously frozen oocytes. Clarified that IUIs to demonstrate infertility are not covered for women without male partners or exposure to sperm Noncovered additions to Limitations/Exclusions: a. Sperm DNA integrity/fragmentation tests [e.g., sperm chromatin structure assay (SCSA), single-cell gel electrophoresis assay (Comet), deoxynucleotidyl transferase-mediated dUTP nick end labeling assay (TUNEL), sperm chromatin dispersion (SCD) or Sperm DNA Decondensation™ Test (SDD)] b. Sperm wash without approved cycle c. Laboratory tests for cycle monitoring when IUI or IVF cycle has not been approved d. Infertility treatment when medically contraindicated (e.g. uterine or tubal abnormalities)
02/14/2020	Merged pre-implantation genetic testing criteria into policy. Clarified semen analysis must be current; within past 3 months.

11/18/2019	Clarified Experimental and Investigational treatment definition Added iatrogenic infertility definition Updated Cycle definition
08/16/2019	Removed PGD or PGS reference from document and replaced with PGT Freeze All Cycles section updated: 2nd bullet removed "diagnosis" and replaced with "testing". 3rd bullet removed…." (preimplantation genetic screening) for the reason of aneuploidy in the setting of multiple spontaneous abortions of uncertain etiology." Added IVF/PGT testing for gender selection is a benefit exclusion
4/23/2019	Additional codes added
4/01/2019	New policy