

# Medical Policy Criteria: Infertility (Commercial)

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### **IMPORTANT NOTE ABOUT THIS MEDICAL POLICY:**

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## 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 ( <a href="#">Section 4: IVF for Women without Male Partners or Exposure to Sperm</a> )
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).

## 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 Indications for Initial and Continuation of Infertility Treatment Coverage

The below general infertility criteria are to be met for consideration of treatment:

- Prognosis for conception must be  $\geq 5\%$ ; **AND**
- No evidence of significant diminished ovarian reserve. Markers of significant diminished ovarian reserve include but are not limited to (one or more of the following within the

previous 6 months):

- FSH level  $\geq 15$  mIU/ml if  $\geq 40$  years of age; **OR**
  - FSH level  $\geq 20$  mIU/ml if  $< 40$  years of age; **OR**
  - AMH level  $< 0.3$  ng/ml; **OR**
  - Antral follicle count  $< 7$ (ASRM (a)); **AND**
- If there has been monitored, medicated-stimulated infertility treatment within the previous 6 months it must demonstrate adequate ovarian response to stimulation. Examples include but are not limited to:
    - 1 follicle  $\geq 15$  mm diameter for IUI
    - Minimum of 1 follicle  $\geq 15$  mm diameter for ART

The general infertility surgery criteria as listed below are to be met for consideration of treatment:

- Pelvic pain that is not responsive to medical management; OR
- Presence of a pelvic mass for which gynecologic diagnosis warrants surgical intervention; **OR**
- 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.

In the absence of other infertility factors or recurrence of disease additional infertility treatment is not indicated following infertility surgery for 12 months for individuals  $< 35$  and 6 months for individuals  $\geq 35$  years of age.

Infertility treatment is warranted when an infertility factor has been identified. This would include but is not limited to:

- Two abnormal semen analyses (abnormal count and/or motility), ovulatory dysfunction; compromise of the fallopian tubes; documented untreated or recurrent endometriosis; sexual dysfunction; abnormalities of the cervix or uterus that may interfere with conception.

### **Poor Prognosis and Futility**

Examples where continued treatment may be futile: (ASRM, 2006)

- Markedly elevated FSH levels
  - $\geq 20$  for women  $< 40$
  - $\geq 15$  for women  $\geq 40$ 
    - FSH levels should be evaluated in the context of other markers of ovarian reserve, such as AMH, AFC and response to prior ovarian stimulation
    - In the absence of a history of prior ovarian stimulation, a cycle of ART may be considered, **especially in women age  $< 35$** .
- Lack of viable spermatozoa
- Ovarian failure where a couple is attempting conception with their own gametes
- Numerous ART cycles without adequate egg production, fertilization and/or embryo development

## **Section 2: Artificial Insemination (IUI)**

### **A. Medical Necessity Criteria**

IUI may be authorized when the definition of infertility is met (see [Definitions](#) above) and ([Section 4: IVF for Women without Male Partners or Exposure to Sperm](#)) and there is documentation of the following:

1. Hysterosalpingography (hysterosalpingogram (HSG) or sonohysterosalpingogram) to

screen for tubal occlusion; or  
Hysteroscopy, salpingoscopy (falloscopy), hydrotubation where clinically indicated; or  
Laparoscopy and chromotubation (contrast dye) to assess tubal and other pelvic  
pathology, and to follow-up on hysterosalpingography abnormalities, within the past 2  
years confirming the presence of **both**:

- At least one patent Fallopian tube
  - Normal endometrial cavity
2. Normal ovarian reserve testing (FSH Level)
  3. **Any** of the following:
    - Unexplained infertility
    - Polycystic Ovary Syndrome (PCOS), anovulation, or oligoovulation
    - Minimal or mild endometriosis
    - Cervical factors
    - Mild to moderate male factor infertility
    - Use of stored sperm from male members who, subsequent to active infertility treatment, required sperm banking/storage as a result of medical treatment (e.g., cancer treatment) likely to cause infertility.
  4. If prior IUI, results must be submitted with each request, and demonstrate **both**:
    - Adequate ovarian response to stimulation (i.e. at least 2 follicles >12 mm diameter for any monitored IUI using standard medication doses)†
    - Adequate fresh semen and post wash semen parameters in order to continue with IUI.

## **B. Intra-uterine (IUI) Without Medication**

Natural IUI, defined as IUI without medication, for a woman who has a diagnosis of infertility may be covered when the member has documented acceptable ovarian reserve as defined above under [General Indications for Initial and Continuation of Infertility Treatment Coverage](#) AND the Member must meet one of the following:

- The woman has a history of one or more cervical surgical procedures or conization procedures that is considered a factor in the woman's infertility
- The woman has a diagnosis of vaginismus
- Use of therapeutic donor insemination

## **C. Intra-uterine (IUI) With Medication**

Medicated IUI, defined as IUI with medication, for a woman who has a diagnosis of infertility may be covered when the member has documented acceptable ovarian reserve as defined above under [General Indications for Initial and Continuation of Infertility Treatment Coverage](#) AND the Member must meet one of the following:

- Unexplained infertility
- Mild - moderate male factor infertility (see [Male Infertility](#) section)
- Minimal or mild endometriosis
- Unilateral tubal factor infertility absent any compromise of the patent fallopian tube
- Polycystic Ovary Syndrome (PCOS), anovulation, or oligoovulation

## **D. Intrauterine insemination (IUI) is not indicated in any one of the following situations:**

- >1 insemination per cycle
- Severe male factor infertility (< 1 million motile sperm after sperm preparation) (without use of donor sperm) (see [Male Infertility](#) section)
- Bilateral tubal factor infertility

- Moderate or severe endometriosis unless treatment has previously been rendered and there is documentation of at least one uncompromised fallopian tube
- Recurrent pregnancy loss
- In the setting of ART in **any** the following situations:
  - To convert an ART cycle to IUI when at least 3 follicles  $\geq 15$  mm in diameter are present (particularly in the setting of diminished ovarian reserve or on the 2<sup>nd</sup> 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, OR
  - Following  $\geq 2$  ART cycles that have failed to result in a conception despite good quality oocytes or embryos.

## E. IUI after IVF

- In the absence of an intervening live birth, subsequent IUI cycles are not authorized for members who have unsuccessfully undergone IVF for infertility treatment when further IVF cycles do not meet medical necessity criteria.
- 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).
- IUI after IUI-to-IVF conversion for hyperstimulation may be authorized if the stimulation that was initially given is reduced.
- IUI after IVF/ICSI/Preimplantation Genetic Testing (PGT) may be authorized for couples with a male genetic disorder who opt to use donor sperm after IVF/ICSI/PGT if the female member meets IUI criteria.

## F. Conversion from IUI to IVF/Hyperstimulation

Authorized when the current IUI cycle has resulted in **ALL**:

- Estradiol level of  $\geq 800$  pg/ml; AND
- Production of at least 5 follicles  $> 12$  mm in diameter.
- Age  $< 40$ , AND
- Has benefit for IVF available

## Section 3: Assisted Reproductive Technology (ART) (May not be covered for all plans)

Coverage for IVF services is limited to a benefit maximum of 2 cycles in the State of Connecticut. CCI does not deny coverage for medically necessary IVF services for any member who foregoes an infertility treatment or procedure if her physician determines that such treatment or procedure is likely to be unsuccessful.

### A. Medical Necessity Criteria

IVF services are authorized when the relevant infertility eligibility criteria are met, and there is documentation confirming **ANY** of the following:

- Unexplained infertility
- Diminished ovarian reserve (not due to age)
- Ovulatory dysfunction
  - When ovulation induction has not resulted in conception
  - Poor response to ovulation induction
  - Hyper-response to ovulation induction; hyper-response can convert to IVF

- History of failed medicated IUI cycles when IUI criteria (above) have been met (Results of prior IUI cycles must be submitted with each IVF request ([initial and subsequent requests])). (Note: 3 IUIs before IVF [unless medically necessary indicated to go straight to IVF]).
- Female member with bilateral Fallopian tube absence (excluding prior elective sterilization) or bilateral Fallopian tube obstruction due to prior tubal disease with history of failed conventional therapy
- Female member with severe endometriosis and history of failed medical and surgical therapy
- Male member with severe male factor infertility has been evaluated by a urologist who confirms condition cannot be improved by standard conservative treatment(s) and cannot be addressed via IUI.

## B. IVF Protocol

Members must meet above medical necessity criteria

- For members <35 years of age
  - 1st IVF treatment cycle: SET (single embryo transfer) is required.
    - If no top-quality embryos after thawing, then two or more embryos of any quality may be transferred.
  - 2nd and subsequent IVF treatment cycles:
    - STET (single thawed elective embryo transfer; a.k.a SET/FET- SINGLE EMBRYO TRANSFER- FROZEN EMBRYO TRANSFER) 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 is after thawing, then two embryos of any quality may be transferred
  - For all treatment cycles, all normal frozen embryos must be used before another fresh cycle may be approved.
- 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 all treatment cycles, all normal frozen embryos must be used before another fresh cycle may be approved.
- 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 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 all treatment cycles, all normal frozen embryos must be used before another fresh cycle may be approved.
- Members 38 years of age and older undergoing IVF treatment do not need to attempt a

SET, as their risk of multiple births is low.

- Max of 2 embryos per transfer.
- For all treatment cycles, all normal frozen embryos must be used before another fresh cycle may be approved.

## C. Frozen Embryo Transfers (FET)

Members seeking coverage for FET must meet the definition of infertility and expect fertility as a natural state.

- It is clinically appropriate and cost effective to utilize all appropriate frozen embryos for transfer prior to another fresh ART cycle (Fresh oocyte retrievals are not indicated when frozen oocytes or embryos are available and appropriate for transfer)
  - See IVF criteria above for # of embryos allowed per transfer
- For members with frozen embryos created in an IVF cycle not initially approved by ConnectiCare, the following criteria must be met before embryo transfer may be approved:
  - Uterine cavity evaluation completed within the last year
  - Diagnosis of infertility from treating provider
  - Fertility is naturally expected for member

## D. 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.

## E. Freeze-All Cycles

An ART cycle, when it is known at the initiation of a cycle that none of the resulting embryos will be transferred immediately and/or the intent is to cryopreserve all of the embryos for future use, will be covered only if **one** of the following is met:

- Member has no prior history of sterilization, in the presence or absence of ongoing infertility care, when the Member requires medical treatment that may render them sterile (Note: A letter of medical necessity from the treating physician is required [e.g., the member has been diagnosed with cancer and will be undergoing chemotherapy and/or radiation that will likely result in infertility])
- Member is approved by ConnectiCare for preimplantation genetic testing (PGT) with IVF
- Member is eligible for coverage of an IVF cycle based on the definitions and criteria outlined in this guideline and is privately paying for PGT (Note: IVF/PGT testing for gender selection is a benefit exclusion)
- The 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.
- The first embryo transfer performed within 60 days of a freeze all cycle will be considered a continuation of the freeze-all cycle (both require authorization).

## F. Assisted Hatching (AH)

Authorized as part of an IVF or Frozen Embryo Transfer (FET) procedure when documentation confirms **either** of the following:

- Failed IVF cycles that produced 3 or more morphologically high-quality embryos, with failure to implant after embryo transfer
- Prior pregnancy resulting from IVF that required assisted hatching

Non-covered services include but are not limited to the following:

- Assisted hatching if PGT is done, as PGT process includes opening the zona (See [Preimplantation Genetic Testing](#) below)

## G. ICSI - Intracytoplasmic Sperm Injection (ICSI)

- Authorized (in conjunction with IVF) to treat sperm-related infertility problems in the male partner ([see Male Infertility section](#)) when the use of ICSI is expected (with a greater than 5% probability) to result in a live birth, and there is documentation of ANY of the following:
- Severe male factor infertility that cannot be overcome by IVF based on semen analysis reports performed within the last 3 months; **any**:
  - At least 2 unprocessed semen analyses show <10 million total motile sperm
  - At least 2 processed semen analyses show ≤3 million total motile sperm
  - At least 2 unprocessed semen analyses show ≤ 4% strict Kruger normal forms
- ICSI is covered when reduced fertilization on a prior IVF cycle using non-donor sperm if the rate of fertilization on the prior cycle is less than 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 not authorized for any IVF cycle involving use of donor sperm, or when PGT has not been authorized. (See also [Preimplantation Genetic Testing](#) below)

ICSI is authorized when PGT is medically indicated

ICSI is covered on the day of IVF egg retrieval if the post processing semen (severe male factor infertility results above must be met) analysis of non-donor non-frozen sperm on that day meets the ICSI coverage criteria noted immediately above. Retrospective authorizations will be allowed

ICSI is also clinically indicated when fertilizing previously frozen oocytes. Exposure to cryoprotectants often lead to the hardening of the zona.

## H. Pre-implantation Genetic Testing

- Meets ART criteria above
- At least 1 of the following is present:
  - 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 on the basis of sex alone
- Must meet all of the following:
  - A specific mutation, or set of mutations, has been identified, that specifically identifies the genetic disorder with a high degree of reliability
  - The genetic disorder is associated with severe disability or has a lethal natural history
  - Testing is accompanied by genetic counseling

### PGT Limitations/Exclusions

- Based upon the Connecticare member documents, pre-implantation genetic testing is only covered if performed in conjunction with pre-authorized Advanced Reproductive Technology



- Pre-implantation genetic testing is not considered medically necessary for any of the following:
  - The selection of embryos with specific HLA typing to provide a match for a member in need of an allogenic transplant
  - The selection of embryos with the sole purpose of determining the gender of the resultant offspring.

## I. Cryopreservation of Embryos

- For women in active (authorized) infertility treatment cryopreservation for any embryos remaining after an authorized IVF cycle.
  - Storage remains non-covered
- Cryopreserved embryos must be used before additional (fresh) IVF cycles using the member's or a donor's eggs are authorized.
- If member meets criteria for 2 embryo transfers and only one embryo is available, then a fresh IVF cycle may be authorized if benefit is available.
- Requests for authorization of a Frozen Embryo Transfer (FET) cycle must meet Infertility criteria (above) at the time of the request for the FET.
- Limitations - ConnectiCare will not cover the following:
  - Long-term sperm, oocyte or embryo storage
  - Sperm cryopreservation as a routine procedure for sperm backup in the absence of a confirmed physical or psychological diagnosis requiring cryopreservation.
  - An ART cycle when it is known at the initiation of a cycle that none of the resulting embryos will be transferred during the same cycle, and/or the intent is to cryopreserve all of the embryos for future use, except as outlined above. (see [Freeze-All Cycles Section E](#) above)

## Section 4: IVF for Women without Male Partners or Exposure to Sperm

- To demonstrate infertility as a disease/condition, documentation must confirm a female without a male partner or exposure to sperm has failed 6 consecutive medically managed IUI cycles using normal donor sperm. (**Note:** Costs of donor sperm, and IUIs to demonstrate infertility are not covered)
- The female must also meet Service-Specific Criteria for IVF including documentation of a history of failed medicated IUI cycles. (Note: Age-related embryo transfer requirements outlined in the Service specific criteria for IVF also apply.)

## Section 5: Donor Services

### A. Donor Egg (Donor Oocyte)

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.

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 failure (as defined by American College of Obstetricians and Gynecologists)
- Clinically documented premature diminished ovarian reserve (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)
- A SET is required for members < 35 years of age for the first approved donor egg IVF treatment cycles with more than one top-quality embryo available for transfer
- If the donor egg procedure is not performed within 6 months, the member must be reevaluated and continue to meet ConnectiCare criteria for infertility services and donor egg procedures before additional services are authorized.  
For female members (embryo recipients) without ConnectiCare prescription drug coverage, coverage for the egg donor is limited to monitoring (up to egg retrieval), and the egg retrieval procedure.
- Genetic abnormality (case-by-case review)
- Services after oocyte retrieval from donor such as fertilization and transfer are covered when authorized.
- Limitations:
  - Infertility treatment when the infertile Member is not the recipient of said services (e.g., donor egg in conjunction with gestational carrier).
  - Medications that are directly related to a stimulated ART cycle for anonymous or designated donors unless medication is for the member.
  - After proceeding to a donor egg cycle, further IVF cycles using the member's eggs are not covered.

### B. Donor Sperm

Use of donor sperm of normal quality is authorized when documentation (by ANY of the following) confirms male factor infertility:

- 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
- A high risk of transmitting the male partner's genetic disorder to the offspring
- HIV+ male partner

In order to receive coverage for infertility services, male members must meet **either** of the following criteria based on semen analysis reports performed within the last 3 months:

- At least 2 unprocessed/processed semen analyses show <10 million total motile sperm,
- At least 2 unprocessed semen analyses show ≤ 2% strict Kruger normal forms.

Non-covered services include but are not limited to the following:

- Donor sperm without documented biological male factor infertility proven with 2 abnormal semen analyses with the same defect
- Donor sperm for biological males with genetic sperm defects
- For biological females without a biological male partner.
- The cost of donor sperm, IUI, ART, and related services, if the male partner has a history of prior vasectomy with no subsequent successful vasectomy reversal procedure.

- Cost of procurement of Donor Sperm

## Section 6: Fertility Preservation

No infertility workup is required for coverage

Covered services for members undergoing gonadotoxic cancer treatments that is expected to render them permanently infertile (excluding voluntary sterilization) are as follows:

- Medically necessary egg retrievals are covered for fertility preservation
- Sperm collection

Non-covered services include but are not limited to the following:

- Cryopreservation of embryos or eggs for fertility preservation purposes other than chemotherapy or other treatments that may render an individual infertile.
- Cryopreservation of embryos or eggs for reciprocal IVF
- Sperm storage/banking for males requesting this service for convenience or “back-up” for a fresh specimen.
- Storage of cryopreserved sperm, eggs or embryos

## Section 7: Male Infertility

A. Male Factor Infertility:

- **Mild Male Factor:** abnormalities in the semen analysis where the sperm concentration is  $\geq 10$  million/ml but  $< 15$  million/ml and/or progressive motility is  $\geq 30\%$  but  $< 40\%$  or  $\geq 5$  million total motile sperm
- **Moderate Male Factor:** abnormalities in the semen analysis where the sperm concentration is  $\geq 5$  million/ml but  $< 10$  million/ml and/or progressive motility is  $\geq 25\%$  but  $< 30\%$
- **Severe Male Factor:** abnormalities in the semen analysis where the sperm concentration is  $< 5$  million/ml or sperm preparation techniques result in a sperm concentration of  $< 1$  million motile sperm/ml
- Isolated teratospermia is considered a male factor when there is  $< 2\%$  normal morphology on at least two semen analyses 1-4 weeks apart

B. Microepididymal Sperm Aspiration (MESA)

- 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

C. Microdissection- Testicular Excisional Sperm Extraction (TESE)

- Covered for non-obstructive azoospermia and spinal cord injury resulting in inability to ejaculate

## Section 8: Limitations/Exclusions

Non-covered tests/procedures include but are not limited to the following:

- Infertility treatment if, based on the member’s individual medical history they have  $< 5\%$  chance of a birth outcome
- ART/Infertility services for Members when clinical documentation confirms an individual or couple are using illicit substances or abusing substances known to negatively interfere with fertility or fetal development (e.g. marijuana, opiates, cocaine, tobacco or alcohol)
- Infertility treatment, when infertility is the result of a non-reversed or unsuccessful reversal of a voluntary sterilization
- Ovarian Reserve Assessment results (Clomiphene Citrate Challenge Test (CCCT))

- Selective fetal reduction without known disorders that are non-compatible with life
- 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)]
- Sperm wash without approved cycle
- Laboratory tests for cycle monitoring when IUI or IVF cycle has not been approved.
- Infertility treatment when medically contraindicated (e.g. uterine or tubal abnormalities)
- Gender selection
- Human zona binding assay (hemizona test)
- Serum anti-sperm antibody testing
- Sperm acrosome reaction test
- Co-culture of embryos
- Embryo toxic factor test (ETFL)
- Ovulation predictor kits
- Home Artificial Insemination Kits
- In vitro maturation of eggs
- Direct intraperitoneal insemination (DIPI)
- Peritoneal ovum and sperm transfer (POST)
- Genetic engineering
- Egg harvesting, or other infertility treatment performed during an operation not related to an infertility diagnosis.
- Chromosome studies of a donor (sperm or egg)
- Infertility services in cases in which normal embryos have been or will be discarded because of gender selection
- ICSI for any IVF cycle involving use of donor sperm
- Treatments requested solely for the convenience, lifestyle, personal or religious preference of the member in the absence of medical necessity
- Treatment to reverse voluntary sterilization, i.e. MESA/TESE, for a member who has undergone prior sterilization
- Monitoring of non-authorized IUI cycles
- Reciprocal IVF
- Oocyte, ovarian or testicular tissue cryopreservation
- Storage of cryopreserved reproductive materials (i.e., embryos, oocytes, or sperm)
- Surrogacy (Note: Maternity service benefits may be available for members acting as surrogate mothers)
- 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
- 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.

## Applicable Procedure Codes

58321	Artificial insemination; intra-cervical
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# Medical Policy Criteria: Infertility (Commercial)

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/semens
89346	Storage (per year); oocyte(s)
89352	Thawing of cryopreserved; embryo(s)
89353	Thawing of cryopreserved; sperm/semens, 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

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**Revision History**

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



# Medical Policy Criteria: Infertility (Commercial)

06/11/2021	<p>Corrected progesterone concentration (P4) to read &lt; 1ng/mL in Freeze All section</p> <p>Corrected only "one top quality embryo" to "no top-quality embryos" in IVF Protocol</p> <p>Added to ICSI section that ICSI is authorized when PGT is medically indicated</p> <p>Added clarification to Donor Egg section communicating that use of a donor egg during infertility procedures is a covered benefit for women &lt; 40</p> <p>Changed "chemotherapy" to "gonadotoxic" in Fertility Preservation section as a descriptive for treatment that is causal to infertility</p> <p>Added clarification in Limitations/Exclusions, Ovulation "predictor" kits</p> <p>Added Home Artificial Insemination Kits to Limitations/Exclusions</p>
02/01/2021	<p>Change to Guideline under the general infertility surgery criteria: "conservative" changed to "medical".</p> <p>Change to Section 4: IVF for Women without Male Partners or Exposure to Sperm: Added "To demonstrate infertility as a disease/condition, documentation must...".</p> <p>Removed AI/IUI, changed to "medically managed IUI."</p> <p>Change to Section 6: Fertility Preservation: "Covered services for members undergoing chemotherapy", changed to "gonadotoxic cancer treatment".</p> <p>Change to Section 8: Added to Limitations/Exclusions: Home Artificial Insemination Kits</p> <p>Added references</p>
12/11/2020	<p>Change to Section 1: FSH level from <math>\geq 35</math> to <math>\geq 40</math> years of age</p> <p>Removed "Treatment is not indicated in the setting of using autologous oocytes in females <math>\geq 44</math> years of age".</p> <p>Change to Section 3: Removed STEET from B. IVF Protocol. Added "or Suspected OHSS" to E. Freeze-All Cycles</p>
09/01/2020	<p>Added note to Section 3A bullet RE failed IUI cycles regarding 3 IUIs before IVF</p>
08/14/2020	<p>Infertility Definition updated</p> <p>Added Section 1: General Indications for Initial and Continuation of Infertility Treatment Coverage</p> <p>Added sonohysterosalpingogram as a covered screening option for tubal occlusion.</p> <p>Enhanced male factor infertility definition (i.e., mild, moderate and severe factor parameters).</p> <p>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.</p> <p>Clarified that ICSI is also clinically indicated when fertilizing previously frozen oocytes.</p> <p>Clarified that IUIs to demonstrate infertility are not covered for women without male partners or exposure to sperm</p> <p>Noncovered additions to Limitations/Exclusions:</p> <ol style="list-style-type: none"> <li>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)]</li> <li>b. Sperm wash without approved cycle</li> <li>c. Laboratory tests for cycle monitoring when IUI or IVF cycle has not been approved</li> <li>d. Infertility treatment when medically contraindicated (e.g. uterine or tubal abnormalities)</li> </ol>
02/14/2020	<p>Merged pre-implantation genetic testing criteria into policy. Clarified semen analysis must be current; within past 3 months.</p>

## Medical Policy Criteria: Infertility (Commercial)

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: 2 <sup>nd</sup> bullet removed "diagnosis" and replaced with "testing". 3 <sup>rd</sup> 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