

## Infertility Services — Commercial

Last Review Date: August 9, 2024 Number: MG.MM.ME.53jv2

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#### **Related Medical Guidelines**

#### **Recurrent Pregnancy Loss**

#### **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 (See also <a href="NYS Mandate Section">NYS Mandate Section</a>   |
|------------------------|---|
| latrogenic infertility | An impairment of fertility by surgery, radiation, chemotherapy or other medical treatment affecting reproductive organs or processes.  Note: EmblemHealth covers standard fertility preservation services when a medical treatment will directly or indirectly lead to iatrogenic infertility. Standard fertility preservation services include the collecting, preserving, and storing of ova and sperm.   |
| Male infertility       | Mild Male Factor: Abnormalities in the semen analysis where the sperm concentration is 10-15 million/mL, motility is 30–40%, and normal morphology at 2-3%  Moderate Male Factor: Abnormalities in the semen analysis where the sperm concentration is 5–10 million/mL and motility is 25–30%, and normal morphology at 2-3%  Severe Male Factor: Abnormalities in the semen analysis where the sperm concentration is less than 5 million/mL (unwashed specimen), motility is less than 25%, and morphology is < 4%, and normal morphology at 2-3%  Isolated teratospermia is considered a male factor when there is <2% normal morphology on at least two semen analyses 1–4 weeks apart. |
| 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" is defined as either all treatment that starts when preparatory medications are administered for ovarian stimulation for oocyte retrieval with the intent of undergoing invitro fertilization using a fresh embryo transfer; or medications are administered for endometrial preparation with the intent o f undergoing in-vitro fertilization using a frozen embryo transfer. |

#### **Covered Services**

#### **Basic infertility services:**

- Initial evaluation
- Semen analysis
- Laboratory evaluation
- Evaluation of ovulatory function
- Postcoital test
- Endometrial biopsy
- Pelvic ultrasound
- Hysterosalpingogram
- Sono-hystogram
- Testis biopsy
- Blood tests; and
- Medically appropriate treatment of ovulatory dysfunction

Note: Additional tests may be covered if the tests are determined to be Medically Necessary

#### Comprehensive infertility services:

- Ovulation induction and monitoring
- Pelvic ultrasound
- Artificial insemination
- Hysteroscopy
- Laparoscopy
- Laparotomy

#### Advanced infertility services:

- Three (3) cycles per lifetime of in vitro fertilization
- Cryopreservation and storage of sperm, ova, and embryos in connection with in vitro fertilization
- Coverage for storage ends when 3 IVF cycles have been exhausted

Note: Plan benefits should be reviewed to ensure that comprehensive and/or advanced infertility services are covered

### New York State Mandate — New York Insurance Circular Letter #3 (2021)

- A. Unlimited intrauterine insemination (IUI) for members who meet the clinical definition of infertility (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])
- **B.** Coverage for prescription drugs, if applicable, is limited to medications approved by the federal Food and Drug Administration for use in the diagnosis and treatment of infertility
- C. The identification of the required training, experience and other standards for health care providers for the provision of procedures and treatments for the diagnosis and treatment of infertility 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
- **D.** The determination of appropriate medical candidates by the treating physician in accordance with the standards and guidelines established and adopted by the American College of Obstetricians and Gynecologists and/or the American Society for Reproductive Medicine

E. Every large group contract that provides medical, major medical or similar comprehensive-type coverage shall provide coverage for at least three cycles of in-vitro fertilization (IVF) used in the treatment of infertility, including prescription drugs in connection with IVF

#### **General Section**

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 ≥ 5%; AND
- No evidence of significant diminished ovarian reserve (except in cases of requests for donor eggs for members with premature ovarian failure). Markers of significant diminished ovarian reserve include but are not limited to (one or more of the following within the previous 6 months):
  - o FSH level ≥ 15 mlU/ml; **OR**
  - o AMH level < 0.3 ng/ml; OR
  - Antral follicle count (AFC) < 7 (ASRM); AND</li>
- 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:
  - o 1 follicle ≥ 15 mm diameter for IUI
  - o Minimum of 1 follicle ≥15 mm diameter for ART
- Ovarian failure where a couple is attempting conception with their own gametes
- 2 or more medicated Assisted Reproductive Technologies (ART) cycles without adequate egg production, fertilization and/or embryo development

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 (e.g., hydrosalpinx); **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.

Following successful infertility surgery, in the absence of other infertility factors, additional treatment is not immediately indicated for 6 months after surgery. 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:

- Markedly elevated FSH levels (≥ 15)
  - 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 with premature diminished ovarian reserve.

- AMH level < 0.3 ng/ml</li>
- Lack of viable spermatozoa
- Ovarian failure where a couple is attempting conception with their own gametes
- 2 or more medicated ART cycles without adequate egg production, fertilization and/or embryo development for transfer

#### 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)
- 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) (i.e., single female who has failed 6 consecutive medically managed IUI cycles using donor sperm)
- 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)
- 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
- 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

# 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 frozen 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:
  - 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

- 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.
- 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 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 within the past year, and at least one abnormal result within 3 months of the request, which demonstrates one of the following:
    - < 5 million/mL (unwashed specimen)</p>
    - < 25% motility</p>
    - < 4% normal morphology</p>
  - 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 nonobstructive 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 with high risk for morbidity
- 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
- A specific mutation, or set of mutations, has been identified, that specifically identifies the genetic disorder with a high degree of reliability

#### 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
  - Donor sperm for biological males with genetic sperm defects
  - For biological females without a biological 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)
- Embryo and/or egg cultures (CPT codes 89250 and 89272) for FET cycles only
- 4. Infertility treatment when infertility is the result of a non-reversed or unsuccessful reversal of a voluntary sterilization
- 5. Ovarian Reserve Assessment results (Clomiphene Citrate Challenge Test [CCCT])
- 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. Gender selection
- 11. Co-culture of embryos
- 12. Sperm-Hyaluronan Binding Assay
- 13. Embryo Glue
- 14. In vitro maturation of eggs
- 15. Genetic engineering
- 16. Egg harvesting, or other infertility treatment, performed during an operation not related to an infertility diagnosis
- 17. Chromosome studies of a donor (sperm or egg)
- 18. Infertility services in cases in which normal embryos have been or will be discarded because of gender selection
- 19. ICSI for any IVF cycle involving use of donor sperm (unless fertilizing previously frozen oocytes)
- 20. Treatments requested solely for the convenience, lifestyle, personal or religious preference of the member in the absence of medical necessity
- 21. Treatment to reverse voluntary sterilization, i.e., MESA/TESE, for a member who has undergone prior sterilization
- 22. Reciprocal IVF (including co-maternity retrievals and transfers)
- 23. Oocyte, ovarian or testicular tissue cryopreservation (excluding fertility preservation services)
- 24. Gamete intrafallopian tube transfers (GIFT) or zygote intrafallopian tube transfers (ZIFT)
- 25. Surrogacy (Note: Maternity service benefits are available for members acting as surrogate mothers)
- 26. 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
- 27. 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
- 28. Uterine transplant for the treatment of uterine factor infertility

- 29. 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
- 30. Fresh IVF cycles require normal intrauterine cavity
- 31. Embryo transfers when the 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.
  - Abnormal intrauterine cavity
- 32. Following successful infertility surgery, in the absence of other infertility factors, additional treatment is not immediately indicated for 6 months after surgery.
- 33. 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.
- 34. Long-term sperm, oocyte, or embryo storage outside of NYS mandated coverage (excluding fertility preservation)
- 35. Sperm cryopreservation as a routine procedure for sperm backup in the absence of a confirmed physical or psychological diagnosis requiring cryopreservation (excluding fertility preservation)
- 36. 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
- 37. Infertility treatment when the infertile member is not the recipient of said services (e.g., donor egg in conjunction with gestational carrier)
- 38. After proceeding to a donor egg cycle, further IVF cycles using the member's eggs are not covered
- 39. Donor sperm without documented biological male factor infertility proven with 2 abnormal semen analyses with the same defect
- 40. 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
- 41. Cost of procurement and storage of Donor Sperm (e.g., HCPCS S4026)
- 42. Cryopreservation of embryos or eggs or sperm for fertility preservation purposes other than chemotherapy or other treatments that may render an individual infertile
- 43. Cryopreservation of embryos or eggs or sperm for reciprocal IVF
- 44. Sperm storage/banking for males requesting this service for convenience or "back-up" for a fresh specimen
- 45. 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 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. Infertility treatment when infertility is the result of a non-reversed or unsuccessful reversal of a voluntary sterilization
- 4. Ovarian reserve assessment results (i.e., Clomiphene Citrate Challenge Test [CCCT] is not covered)
- 5. Selective fetal reduction without known disorders that are non-compatible with life
- Sperm DNA integrity/fragmentation tests (e.g., sperm chromatin structure assay [SCSA], singlecell gel electrophoresis assay [Comet], deoxynucleotidyl transferase-mediated dUTP nick end labeling assay [TUNEL], sperm chromatin dispersion [SCD] or Sperm DNA Decondensation™ Test [SDD])
- 7. Sperm wash without approved cycle
- 8. Laboratory tests for cycle monitoring when IUI or IVF cycle has not been approved
- 9. Chromosome studies of a donor (sperm or egg)
- 10. Treatments requested solely for the convenience, lifestyle, personal or religious preference of the member in the absence of medical necessity
- 11. Treatment to reverse voluntary sterilization, i.e., MESA/TESE, for a member who has undergone prior sterilization
- 12. Uterine transplant for the treatment of uterine factor infertility
- 13. 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
- 14. 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.
- 15. Following successful infertility surgery, in the absence of other infertility factors, additional treatment is not immediately indicated for 6 months after surgery.
- 16. > 1 insemination per cycle
- 17. Severe male factor infertility

- 18. Bilateral tubal factor infertility
- 19. Moderate or severe endometriosis unless treatment has previously been rendered and there is documentation of at least one uncompromised fallopian tube
- 20. Recurrent pregnancy loss
- 21. 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 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
  - Following ≥ 2 ART cycles that have failed to result in a conception despite good quality oocytes or embryos

## **Revision History**

| Sept. 13, 2024 | <ol> <li>Added note pertaining to costs and storage of donor sperm and IUIs commensurate with<br/>New York Insurance Circular Letter #3</li> </ol>  |
|----------------|---|
|                | 2. Replaced "numerous" (ARTs) with "2 or more medicated" (ARTs) within poor prognosis section   |
|                | 3. Added clarification RE women without male partners or exposure to sperm regarding IUI cycle prerequisite   |
|                | 4. Corrected "fresh" to "frozen" RE semen analysis in ART section   |
|                | 5. Added noncovered HCPCS code example to cost of procurement/storage limitation RE donor sperm   |
| Jun. 14, 2024  | <ul><li>6. Removed age parameters associated with FSH levels and IVF cycles throughout the policy</li><li>7. Definition</li></ul>   |
|                | <ul> <li>Added normal morphology parameters to male factor infertility definitions and<br/>replaced "≤" 4% with "&lt;" RE severe male factor</li> </ul>   |
|                | 8. General Indications  |
|                | <ul> <li>Reinstated poor prognosis language</li> </ul>  |
|                | 9. ICSI   |
|                | <ul> <li>Added severe infertility language, i.e., that 2 abnormal semen analyses must be within<br/>the past year and that at least 1 abnormal result must be within 3 mos. of the request</li> </ul> |
|                | ■ Replaced "≤" 4% with "<" RE severe male factor infertility  |
|                | 10. Preimplantation genetic testing   |
|                | <ul> <li>Added high risk of morbidity to the prerequisite pertaining to autosomal recessive<br/>disorder</li> </ul>   |
|                | 11. Donor Sperm section   |
|                | <ul> <li>Added "Donor sperm for biological males with genetic sperm defects</li> </ul>  |
|                | <ul> <li>Added "For biological females without a biological male partner"</li> </ul>  |
|                | 12. Limitations/Exclusions  |
|                | <ul> <li>Added that fresh IVF cycles require normal intrauterine cavity</li> </ul>  |
|                | <ul> <li>Added Sperm-Hyaluronan Binding Assay and Embryo Glue as investigational</li> </ul>   |
| March 14, 2024 | 1. General section: Wording clarifications and moved relevant limitations/exclusions  |
| , ,            | 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   |

|               | 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   |
| Dec. 8, 2023  | 1. Freeze-All Cycles section  |
|               | <ul> <li>Clarified that approval for a frozen embryo transfer (FET), as a continuation of the<br/>same IVF cycle, will be conditional on the preimplantation genetic testing (PGT) being<br/>performed</li> </ul>   |
|               | <ul> <li>Added note stating that a current semen analysis is not required when FET is<br/>requested</li> </ul>  |
|               | 2. Sections pertaining to Donor Services and IVF for Women without Male Partners or Exposure to Sperm   |
|               | <ul> <li>Added "storage" to notes pertaining to noncovered expenses</li> </ul>  |
|               | 3. Fertility Preservation Section   |
|               | <ul> <li>Added note stating that fertility preservation services are a separate benefit to<br/>preserve fertility when a medical treatment will directly or indirectly result in<br/>iatrogenic infertility and do not count towards the three-cycle limit on IVF benefits</li> </ul> |
|               | 4. Limitations/Exclusions   |
|               | <ul> <li>Added Sperm-Hyaluronan Binding Assay (HBA) as E/I for selection of sperm for use<br/>with assisted reproduction technologies</li> </ul>  |
| May 12, 2023  | Section 3: Assisted Reproductive Technology (ART):  |
| , ,           | <ul> <li>Added "Hysterosalpingogram (HSG), sonohysterosalpingogram, or hysteroscopic<br/>documentation of a normal endometrial cavity within the past 2 years" to IVF section<br/>(for consistency with IUI section)</li> </ul>   |
|               | <ul> <li>Replaced "Diminished ovarian reserve (not due to age) with "Premature ovarian<br/>failure"</li> </ul>  |
|               | 2. Section 5: Donor Services  |
|               | <ul> <li>Replaced (Clinically documented) "diminished premature ovarian reserve" (as defined<br/>by American College of Obstetricians and Gynecologists) with "premature ovarian<br/>failure"</li> </ul>  |
| Feb. 10, 2022 | 13. Added noncoverage of uterine transplant for the treatment of uterine factor infertility to Limitations/Exclusions   |
|               | 14. Clarification edits (shown below in <i>italics</i> )  |
|               | General indications:  |
|               | <ul> <li>No evidence of significant diminished ovarian reserve (except in cases of requests for<br/>donor eggs for members with premature ovarian failure)</li> </ul>   |
|               | General infertility surgery:  |
|               | <ul> <li>Presence of a pelvic mass for which gynecologic diagnosis warrants surgical<br/>intervention (e.g., hydrosalpinx)</li> </ul>   |
|               | Noncovered services:  |
|               | <ul> <li>Cryopreservation of embryos or eggs or sperm for fertility preservation purposes othe<br/>than chemotherapy or other treatments that may render an individual infertile</li> </ul>   |
|               | <ul> <li>Cryopreservation of embryos or eggs or sperm for reciprocal IVF</li> </ul>   |
| Jul. 8, 2022  | Added noncoverage note to Limitations/Exclusions for mock embryo transfers  |

## Nov. 16, 2021 Clarified that advanced infertility coverage includes cryopreservation and storage of sperm, ova, and embryos in connection with IVF Clarified that prescription drugs in connection with IVF are covered in large group contracts that provide medical, major medical or similar comprehensive-type coverage Modified age parameters pertaining to ovarian reserve within General Indications section 4. Added two indications to General Indications section regarding ovarian failure using a couple's own gametes and ART cycles without adequate egg production, fertilization and/or embryo development Removed age parameters from note pertaining to additional treatment after infertility surgery Clarified that IUI is not indicated for women with a less than 5% success rate for conception with IUI versus alternative therapies and removed age parameter 7. Progesterone concentration (P4) revised to read > 1ng/mL in Freeze All section 8. Added that freeze-all cycles are covered for surrogacy when the infertility benefit is met 9. Amended note pertaining to costs of donor sperm and IUIs within IVF section for women without male partners or exposure to sperm to communicate that costs are not covered except as specifically provided in New York Insurance Circular Letter #3 (2021) 10. Removed age parameters from Donor Services section 11. Added "gender affirming treatment, or other medically necessary treatment" as covered services to Fertility Preservation section 12. Added note pertaining to illicit/abusing substances communicating that medical record documentation of 3 months of abstinence may be required for review 13. Clarified that maternity service benefits are available for members acting as surrogate mothers June 11, 2021 Retitled New York State Limitations section to New York State Mandate and added the following note: Per New York Insurance Circular Letter #3, EmblemHealth covers infertility treatments (e.g., intrauterine insemination procedures) that are provided to individuals covered under an insurance policy or contract who are unable to conceive due to their sexual orientation or gender identity. Medical necessity criteria must be met for services to be authorized. Added re-direct link from infertility definition to New York State Mandate section 3. Changed "conservative" management to "medical" pertaining to pelvic pain in General Indications section 4. Corrected progesterone concentration (P4) to read < 1ng/mL in Freeze All section 5. Added to ICSI section that ICSI is authorized when PGT is medically indicated Added to section for women without male partners or exposure to sperm that New York Insurance Circular Letter #3 supersedes this section and added re-direct link to NYS **Mandate Section** 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 9. Added clarification in Limitations/Exclusions, Ovulation "predictor" kits 10. Added Home Artificial Insemination Kits to Limitations/Exclusions Dec. 11, 2020 Changes to Section 1(General Indications for Initial and Continuation of Infertility Treatment Coverage): Age parameters changed from 35 to 40 years of age regarding ovarian reserve FSH Removed, "Treatment is not indicated in the setting of using autologous oocytes in females ≥ 44 years of age"

|               | 2. Removed all instances of "STEET" (single thawed elective embryo transfer) acronym throughout the policy and retained "SET" (single embryo transfer)   |
|---------------|--|
|               | 3. Clarified storage coverage per NYS Mandate throughout various sections of the policy, i.e.:   |
|               | <ul> <li>Embryo storage ends when 3 IVF cycles have been exhausted</li> </ul>  |
|               | <ul> <li>Removed note previously communicating that embryo storage is covered only during<br/>an active cycle</li> </ul>   |
|               | <ul> <li>Clarified that long-term sperm, oocyte or embryo storage is not covered outside of the<br/>NYS Mandate (noting that per the mandate, storage is covered until benefits have<br/>been exhausted for IVF)</li> </ul>  |
|               | <ul> <li>Removed noncoverage language pertaining to cryopreservation and storage from<br/>Limitations/Exclusions</li> </ul>  |
| Sept. 1, 2020 | Added note to Section 3A bullet RE failed IUI cycles regarding 3 IUIs before IVF   |
| Aug. 14, 2020 | Added General Indications section that communicates ovarian reserve markers commensurate with age, poor prognosis factors and number of IUIs prior to IVF  |
|               | 2. Added sonohysterosalpingogram as a covered screening option for tubal occlusion   |
|               | 3. Enhanced male factor infertility definition (i.e., mild, moderate and severe factor parameters)   |
|               | 4. 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   |
|               | 5. Clarified that ICSI is also clinically indicated when fertilizing previously frozen oocytes   |
|               | 6. Clarified that IUIs to demonstrate infertility are not covered for women without male partners or exposure to sperm   |
|               | 7. Noncovered additions to Limitations/Exclusions:   |
|               | <ul> <li>Sperm DNA integrity/fragmentation tests [e.g., sperm chromatin structure assay<br/>(SCSA), single-cell gel electrophoresis assay (Comet), deoxynucleotidyl transferase-<br/>mediated dUTP nick end labeling assay (TUNEL), sperm chromatin dispersion (SCD) or<br/>Sperm DNA Decondensation™ Test (SDD)]</li> </ul> |
|               | <ul> <li>Sperm wash without approved cycle</li> </ul>  |
|               | <ul> <li>Laboratory tests for cycle monitoring when IUI or IVF cycle has not been approved</li> </ul>  |
|               | <ul> <li>Infertility treatment when medically contraindicated (e.g., uterine or tubal abnormalities)</li> </ul>  |
| Feb. 14, 2020 | Added pre-implantation genetic testing criteria to ART section   |
| Jan. 17, 2019 | Clarified IVF protocol for members between 35–38 years of age  |
|               | Added that SET is not necessary for members > 38 undergoing IVF  |
| Nov. 25, 2019 | Updated commensurate with New York State Mandate eff. Jan. 1, 2020   |

## **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   |

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