

Infertility Services — Commercial

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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 NYS Mandate Section |
|------------------------|---|
| 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. |
| 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 of 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

New York State Mandate*

- A. Unlimited intrauterine insemination (IUI) for members who meet the clinical definition of infertility (Note: Clinical evidence suggests that greater than 6 IUI cycles is unlikely to yield positive results)
- **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.

*Note: Per New York Insurance Circular Letter #3 (2021), EmblemHealth covers immediate basic and comprehensive infertility treatments (e.g., intrauterine insemination procedures) that are provided to covered individuals who are unable to conceive due to their sexual orientation or gender identity.

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 ≥ 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 if ≥ 35 years of age; **OR**
- o FSH level ≥ 20 mlU/ml if < 35 years of age; **OR**
- o AMH level < 0.3 ng/ml; OR
- Antral follicle count (AFC) < 7 (ASRM); 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 ≥ 15 mm diameter for IUI
 - Minimum of 1 follicle ≥15 mm diameter for ART
- Ovarian failure where a couple is attempting conception with their own gametes
- Numerous 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
 - \circ \geq 20 for women < 35
 - \circ ≥ 15 for women ≥ 35
 - 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 <u>Definitions Section</u> and/or <u>NYS Mandate Section</u>) 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 <u>General Indications for Initial and Continuation of Infertility Treatment Coverage</u> 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 <u>General Indications for Initial and Continuation of Infertility Treatment Coverage</u> 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
 - Women with a less than 5% success rate for conception with IUI versus alternative therapies such as IVF
 - 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 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

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 ≥ 800 pg/ml
- Production of at least 5 follicles > 12 mm in diameter
- Age < 40
- Has benefit for IVF available

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

(Note: Prior authorization is required, see Infertility Preauthorization Request Form in Appendix or Provider Manual)

New York State requires large group plans to cover at least 3 IVF cycles. EmblemHealth 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:

- Hysterosalpingogram (HSG), sonohysterosalpingogram, or hysteroscopic documentation of a normal endometrial cavity within the past 2 years
- Unexplained infertility
- Premature ovarian failure
- 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 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 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 (single thawed elective embryo transfer; aka, 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 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 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
 - 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
 - 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)
- For members with frozen embryos created in an IVF cycle not initially approved by EmblemHealth, 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 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])
- FET is appropriate when genetic testing (PGT) is performed. (Approval for a FET as a continuation of the same IVF cycle will be conditional on the PGT being performed)
 - Note: A current semen analysis is not required when FET is requested
- 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 still be considered a continuation of the freeze-all cycle (both require authorization)
- Freeze-all cycles are covered for surrogacy when the infertility benefit is met

F. Assisted Hatching (AH)

Authorized as part of an IVF or Frozen Embryo Transfer (FET) procedure for women > age 38 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 <u>Preimplantation</u> <u>Genetic Testing</u> below)

G. ICSI — Intracytoplasmic Sperm Injection (ICSI)

Authorized (in conjunction with IVF) to treat sperm-related infertility problems in the male partner (see <u>Male Infertility</u> 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
- 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 <u>Preimplantation Genetic Testing</u> 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. Preimplantation Genetic Testing

- Meets ART criteria above and 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
 - 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

Limitations/Exclusions

- Preimplantation 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
- 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 EmblemHealth will not cover the following:
 - Long-term sperm, oocyte or embryo storage outside of NYS Mandated coverage (Note: Per NYS Mandate storage is covered until IVF benefits have been exhausted)
 - 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 <u>Freeze-All Cycles Section</u> 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 3 consecutive medically managed IUI cycles using normal 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])
- The female must also meet Service-Specific Criteria for IVF including documentation of a history of failed medicated IUI cycles.

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 ovarian failure (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 EmblemHealth criteria for infertility services and donor egg procedures before additional services are authorized
 - For female members (embryo recipients) without EmblemHealth 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 and storage, 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 and storage of Donor Sperm

Section 6: Fertility Preservation

(Note: 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

Covered services for members undergoing gonadotoxic cancer treatments, gender affirming treatment, or other medically necessary treatment 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 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

 Sperm storage/banking for males requesting this service for convenience or "back-up" for a fresh specimen

Section 7: Male Infertility

- A. Male Factor Infertility:
 - Mild Male Factor: abnormalities in the semen analysis where the sperm concentration is ≥10 million/ml but <15 million/ml and/or progressive motility is ≥ 30% but < 40% or ≥ 5 million total motile sperm.</p>
 - Moderate Male Factor: abnormalities in the semen analysis where the sperm concentration is
 ≥5 million/ml but < 10 million/ml and/or progressive motility is ≥ 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) (Note: medical record documentation of 3 months of abstinence from substance use may be required before ART/Infertility services will be approved)
- 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
- Gamete intrafallopian tube transfers (GIFT) or zygote intrafallopian tube transfers (ZIFT) (May be covered for some plans)
- Surrogacy (Note: Maternity service benefits are 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
- Uterine transplant for the treatment of uterine factor infertility
- Sperm-Hyaluronan Binding Assay (HBA) for selection of sperm for use with assisted reproduction technologies
- 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

Revision History

| December 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 |
| | Added Sperm-Hyaluronan Binding Assay (HBA) as E/I for selection of sperm for use with assisted reproduction technologies |
| May 12, 2023 | 5. 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" |
| | 6. Section 5: Donor Services |
| | Replaced (Clinically documented) "diminished premature ovarian reserve" (as defined by American College of Obstetricians and Gynecologists) with "premature ovarian failure" |
| Feb. 10, 2022 | Added noncoverage of uterine transplant for the treatment of uterine factor infertility to Limitations/Exclusions |
| | 2. Clarification edits (shown below in <i>italics</i>) |
| | 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 |
| Jul. 8, 2022 | 1. 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 |
| | 2. Clarified that prescription drugs in connection with IVF are covered in large group contracts that provide medical, major medical or similar comprehensive-type coverage |
| | 3. 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 6. 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 1. 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. 2. Added re-direct link from infertility definition to New York State Mandate section 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 7. 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 1. 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.: Embryo storage ends when 3 IVF cycles have been exhausted

| | Removed note previously communicating that embryo storage is covered only during an active cycle | | | | | |
|---------------|---|--|--|--|--|--|
| | Clarified that long-term sperm, oocyte or embryo storage is not covered outside of the NYS Mandate (noting that per the mandate, storage is covered until benefits have been exhausted for IVF) | | | | | |
| | Removed noncoverage language pertaining to cryopreservation and storage from Limitations/Exclusions | | | | | |
| 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: | | | | | |
| | 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) | | | | | |
| 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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Appendix EmblemHealth Preauthorization Request Form

| Member/Provider Information | | | | | | | | |
|--|------------------------------------|---------------------------|---------------------------------|---|--|--|--|--|
| Date: | | Requesting Provider: | | | | | | |
| Member Name: | | Requesting Provider ID #: | | | | | | |
| Member ID #: | | | Tax ID #: | | | | | |
| Member DOB: | | | Office Con | tact Name: | | | | |
| Partner/Spouse DOB: | | | Office Contact Phone # and Ext: | | | | | |
| | | | Office Con | ntact Fax #: | | | | |
| | | | | | | | | |
| Diagnoses Codes | | | | | | | | |
| Treatment date change only? Yes I | No | If yes, f | romto | | | | | |
| | | | | | | | | |
| Patient Infertility History | | | | | | | | |
| How many intrauterine insemination | cycles has | this me | ember rece | ived? | | | | |
| How many IVF, GIFT, ZIFT or low tubal | ovum trai | nsfer cy | cles has this | s member received? | | | | |
| | | | | | | | | |
| Procedure(s) Requested | | | | | | | | |
| ICD-10/CPT Code(s): | | | | | | | | |
| Please check the procedure(s) for which | ch you are | e reques | sting covera | nge: | | | | |
| | n Vitro fe | - | _ | ulation induction | | | | |
| | Oocyte donation Donor insemination | | | | | | | |
| F | PGD | | Oth | er (please specify) | | | | |
| Number of cycles requested | | | | ,, ,, <u> </u> | | | | |
| Anticipated length of therapy: From_ | | | | | | | | |
| | | | | | | | | |
| Required Clinical Information for Preau | thorizatio | n Reque | est | | | | | |
| H & P | | | | | | | | |
| HSG, or sonohysterosalpingogram dated within 2 years (For all IVF/FET cycles, current cavity evaluation within 1 year) | | | | | | | | |
| LMP, Day 3 Labs (E2, FSH, AMH, AFC); all must be dated within last 6 months | | | | | | | | |
| Semen Analysis dated within 1 yea | ar (Two da | ited wit | hin last 3 m | nonths for severe male factor infertility — | | | | |
| Carrier Screening Report for PGT requests | | | | | | | | |
| Member will self-pay for PGT | | | | | | | | |
| Previous infertility treatment records | | | | | | | | |
| Other clinical information: | | | | | | | | |
| L. | | | | | | | | |

All medication/drug management requests are reviewed by Express Scripts (ESI). For ESI preauthorization requests, call 877-417-5383 or fax 877-251-5896

All non-medication/drug management requests are reviewed by EmblemHealth. For EmblemHealth preauthorization requests, call 800-447-8255, fax 212-946-7516, or email IVF@emblemhealth.com

Please Note:

- Services are not considered authorized until EmblemHealth issues an authorization. Lack of information will delay processing of request.
- All requests must also include both a completed form and supporting medical documentation.

This is confidential information. If you receive this form in error, please notify Provider Services immediately at 866-447-9717.