



# MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

## Medical Policy Assisted Reproductive Services

**Policy Number: 086**

BCBSA Reference Number: N/A

LCD/NCD: N/A

### Related Policies

- Assisted Reproductive Technology Services Form, #[694](#). **Providers SHOULD complete this ART form.**
- Genetic Testing, Including Chromosomal Microarray Analysis and Next-Generation Sequencing Panels, for Prenatal Evaluation and the Evaluation of Children with Developmental Delay-Intellectual Disability or Autism Spectrum Disorder, #[228](#)
- Preimplantation Genetic Testing, #[088](#)

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## Products Included

**Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members**

### Subscriber Certificate

**Infertility services are only covered in accordance with the individual subscriber certificate in effect at the time the service is rendered.** Members are expected to check their current subscriber certificate (Evidence of Coverage document) to determine their benefits.

Infertility drugs and delivery (such as pumps); covered only for members with pharmacy benefit. Infertility treatment medications, for members with pharmacy benefits, according to each member's pharmacy benefit plan. No fertility medications will be dispensed without a valid authorization or verification that no authorization is required.

### Gender Descriptions

The term *biological female* used in this policy refers to members with two X chromosomes (or no Y chromosome) and includes members with gender identities other than female.

The term *biological male* used in this policy refers to members with XY chromosomes and includes members with gender identities other than male.

In this policy, the terms *biological female* and *biological male* are used to clarify the reproductive capacity of the member and are not meant to exclude members with other gender identities/expressions.

### Overview of Covered Services

For all members (female, male and other gender identities), assisted reproductive services are considered to be medically necessary when policy criteria are met for the time period that fertility is naturally expected. In addition, for all members, services will no longer be covered if the treatment being requested is considered to be "futile" or has a "very poor prognosis," as defined by the American Society for Reproductive Medicine. Futile treatments are defined as having a <1% chance of achieving a live

birth. Treatments with a very poor prognosis are defined as having a 1-5% chance of achieving a live birth.

The determination of whether or not a treatment is futile or has a very poor prognosis is specific to each patient and takes into account medical history, physical exam findings, lab work, prior infertility treatments, and other factors such as population and national society of assisted reproductive techniques (SART) annual statistics.

## Fertility Services

### IUI

Intrauterine insemination (IUI) with or without medication is covered for otherwise healthy biological female members with or without a biological male partner\*. IUI is covered for the time period that fertility is naturally expected. Services will no longer be covered for members clinically determined to have less than 5% chance for a live birth (for example: after a member has done and failed to deliver with IVF).

IUI is required after an approved IVF cycle using biological male partner's sperm when switching to unmedicated IUIs with donor sperm due to male factor infertility in the member's present biological male partner.

\*Donor sperm is only covered for moderate to severe male factor infertility (as defined in this policy).

### Cryopreservation (Fertility Preservation)

Covered services for members undergoing chemotherapy that is expected to render them permanently infertile:

- One cycle of IVF with egg or embryo cryopreservation (if the member is <44 years of age). No infertility workup is required for coverage (up to 24 months).
- Sperm collection and storage (up to 24 months)
- Frozen embryo transfer is covered when transferred back to member.

Coverage for members undergoing a treatment other than chemotherapy that is expected to render them permanently infertile (excluding voluntary sterilization):

- One cycle of IVF with egg or embryo cryopreservation (if the member is <44 years of age) up to 24 months.
  - For egg cryopreservation and for embryo freezing, all members  $\geq 40$  and < 44 years of age must have ovarian reserve testing (CCCT vs alternative testing noted in this policy). If testing demonstrates diminished ovarian reserve is present, IVF cycle and cryopreservation are not covered services.
- Sperm collection and storage (up to 24 months)
- Frozen embryo transfer is covered when transferred back to member.

Egg cryopreservation will also be covered for members <44 years of age that have excess (supernumerary) eggs that cannot be fertilized (i.e. no sperm is able to be produced on the day of egg retrieval or there are too few sperm for the number of eggs retrieved on the day of egg retrieval) during a covered cycle of IVF.

### Not covered services include but are not limited to the following:

- More than one cycle of IVF, for members who will undergo treatment that is expected to render them infertile.
- Cryopreservation of embryos or eggs for fertility preservation purposes other than chemotherapy or other treatments that may render an individual infertile.
- Cryopreservation of embryos or eggs for reciprocal IVF (unless otherwise specified in the member's subscriber certificate/rider).
- Sperm storage/banking for males requesting this service for convenience or "back-up" for a fresh specimen.
- Storage of cryopreserved sperm, eggs or embryos for more than 24 months.

## Ovarian Transposition

Ovarian transposition is covered.

## Ovulation Disorders

The following treatments are covered for members with anovulation or oligoovulation:

- Oral medication, OR
- Oral medication with intrauterine insemination (IUI), OR
- Injectable medication, OR
- Injectable medication with IUI.

## Infertility Services

### Demonstration of Infertility

In order to receive coverage for infertility services, biological female members must meet the criteria in one of the following sections (I-VI):

- I. In accordance with Massachusetts law (**M.G.L.c. 176A, section 8K; M.G.L.c. 176B, section 4J; M.G.L.c. 176G, section 4 and 211 C.M.R 37.09**)<sup>1</sup>, Blue Cross Blue Shield of Massachusetts may approve coverage for infertility services when:
  - a. An otherwise healthy biological female is age 35 or older and has not been able to conceive after a period of six months of actively trying\*, OR
  - b. An otherwise healthy biological female is younger than age 35 and has not been able to conceive or produce conception after twelve months or more of actively trying\*.
- II. An otherwise healthy biological female younger than age 35 with or without a biological male partner, who has completed six cycles of intrauterine inseminations (IUIs) and has not been able to conceive.
- III. An otherwise healthy biological female age 35 or older with or without a biological male partner, who has completed three cycles of intrauterine inseminations (IUIs) and has not been able to conceive.
- IV. A biological female younger than age 35 with an ovulation disorder who has been:
  - a. Treated with medication, with or without IUI for 6 cycles and has been unable to conceive.
- V. A biological female member age 35 or older with an ovulation disorder who has been:
  - a. Treated with medication, with or without IUI for 3 cycles and has been unable to conceive.
- VI. A biological female member with documented infertility caused by the following (including but not limited to):
  - a. Tubal factor infertility, AND/OR
  - b. Pelvic adhesive disease, AND/OR
  - c. Endometriosis, AND/OR
  - d. Member's biological male partner has male factor infertility as defined in this policy.\*\*

\*If the member is able to conceive but is unable to carry the pregnancy to live birth, the period of time the member attempted to conceive prior to achieving that pregnancy or after a loss of pregnancy shall be included in the calculation of the one-year/six-month period, as applicable.

\*\* Definition of biological male factor infertility for infertility services coverage:

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

For all members, assisted reproductive technologies are only covered for the time period that fertility is naturally expected. Services will no longer be covered for members clinically determined to have less than 5% chance for a live birth.

## Evaluation Requirements

**Minimal testing requirements for any infertility treatment for members:**

- Baseline hormonal blood work (including FSH and Estradiol)
- HSG/tubal patency eval (unless going directly to IVF)
- For members going directly to IVF:
  - Uterine cavity eval: HSG/hysteroscopy, Sonohystogram, 3D ultrasound, OR, hysterosalpingo contrast sonography (HyCoSy).
  - Testing must be done prior to initial infertility services and repeated annually.
- Semen analysis
- Urine or serum cotinine levels must be obtained within the month of the requested service, for all members and their partners who acknowledged smoking within the past year. Non-smoking members with an initial negative cotinine level test, are not required to have repeat or ongoing cotinine tests.

**Indications for CCCT/FSH/Estradiol\* testing prior to in vitro fertilization:**

- Members <40 years old
  - Members with premature ovarian insufficiency\*\* may qualify for IVF treatment, or may qualify for donor egg/embryo (see donor egg/embryo section)
  - There is no need to repeat a CCCT or baseline FSH/Estradiol at >39 years of age, if a member has already been diagnosed with premature ovarian insufficiency.
- Members without premature ovarian insufficiency\*\* ≥ 40 and < 44 years old by the time of treatment must meet ALL of the following criteria:
  - Yearly clomiphene citrate challenge test (CCCT)
  - If 6 months have elapsed since the CCCT, a basal FSH and estradiol are required prior to next fresh IVF cycle
  - A new CCCT or repeat FSH/Estradiol is not required for FETs from an approved IVF cycle.
- Members previously diagnosed with premature ovarian insufficiency\*\* and are now ≥ 40 and < 44, no longer qualify for IVF but may qualify for donor egg/embryo (see donor egg/embryo section)

\*Lab values needed for infertility services coverage (highest ever value at any age):

- All Day 3 or Day 10 FSH must be ≤ 15.0 mIU/ml for 40 and 41 year olds
- All Day 3 or Day 10 FSH must be ≤ 12.0 mIU/ml for 42 and 43 year olds
- All Day 3 Estradiol ≤100 pg/ml
  - If a Day 3 Estradiol (basal labs or CCCT) is found to be >100 pg/ml and a medical reason is documented for the elevated baseline estradiol (i.e. ovarian cyst), the CCCT or basal FSH/Estradiol must be repeated.
- Day 10 Estradiol >100 pg/ml

\*\*Premature ovarian insufficiency occurs below age 40 and is defined as follows:

- A Day 3 FSH >15.0 mIU/ml, OR
- A Day 3 estradiol >100 pg/ml and no medical reason is documented (i.e. ovarian cyst).

**Alternate testing options**

For members with a documented contraindication to clomiphene or ovulation disorder (i.e. PCOS, hypothalamic amenorrhea), we accept either:

- Exogenous follicle stimulating hormone ovarian reserve test (EFORT)
  - Inhibin B value difference of < 78.6 between Day 3 and Day 4, OR
- A combination of tests:
  - Basal FSH, estradiol, and antral follicle count (AFC) done on the same day, AND
  - An anti-mullerian hormone (AMH) drawn within 1 month.
  - Lab values needed for infertility services coverage
    - AMH > 1.0 ng/ml, AND
    - AFC >6, AND
    - CD3 FSH ≤ 15.0 mIU/ml for 40 and 41 year olds, OR
    - CD3 FSH ≤12.0 mIU/ml for 42 and 43 year olds, AND

- Estradiol ≤100 pg/ml.

## Coverage Criteria

### Gonadotropin Ovulation Induction Conversion to IVF

Conversion from IUI to in vitro fertilization (IVF) for the current cycle is covered when ALL of the following criteria have been met:

- The member has met any of the demonstration of infertility criteria (I-VI), AND
- Age <40, AND
- Estradiol 800 pg/ml or higher, AND
- 5 or more follicles ≥13mm in size.

### In Vitro Fertilization (IVF)/ Zygote Intra-Fallopian Transfer (ZIFT)/ Gamete Intra-Fallopian Transfer (GIFT)

IVF/ZIFT/GIFT is considered to be medically necessary for any of the following conditions:

- Tubal factor infertility
- Pelvic adhesive disease
- Endometriosis
- The member has met the criteria for infertility coverage as defined in this policy
- Male factor infertility as defined in this policy for biologically male partner.

#### IVF protocol (for patients who meet above medical necessity criteria):

- For members <35 years of age
  - 1<sup>st</sup> 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.
  - 2<sup>nd</sup> IVF treatment cycle:
    - STEET (single thawed elective embryo transfer; a.k.a SET FET) is required if member has one or more embryos frozen
      - If there are no top-quality embryos after thawing, then two or more 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 or more embryos of any quality may be transferred
  - 3<sup>rd</sup> and subsequent IVF treatment cycles do not need to be SET or STEET
  - For all treatment cycles, all 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)
  - 1<sup>st</sup> IVF treatment cycle:
    - STEET is required if member has one or more embryos frozen
      - If there are no top-quality embryos after thawing, then two or more 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 or more embryos of any quality may be transferred
  - 2<sup>nd</sup> and subsequent IVF treatment cycles do not need to be SET or STEET
  - For all treatment cycles, all frozen embryos must be used before another fresh cycle may be approved.
- For members 35-38 years of age:
  - 1<sup>st</sup> IVF treatment cycle: SET is required.
    - If there are no top-quality embryos after thawing, then two or more embryos of any quality may be transferred.
  - 2<sup>nd</sup> and subsequent IVF treatment cycles do not need to be SET or STEET

- For all treatment cycles, all 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 or STEET as their risk of multiple births is low
  - For all treatment cycles, all frozen embryos must be used before another fresh cycle may be approved.
- Members of any age who meet criteria for donor egg undergoing donor egg IVF treatment:
  - 1<sup>st</sup> 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.
  - 2<sup>nd</sup> IVF treatment cycle:
    - STEET (single thawed elective embryo transfer; a.k.a SET FET) is required if member has one or more embryos frozen
      - If there are no top-quality embryos after thawing, then two or more 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 or more embryos of any quality may be transferred.
  - 3<sup>rd</sup> and subsequent IVF treatment cycles do not need to be SET or STEET
  - For all treatment cycles, all frozen embryos must be used before another fresh cycle may be approved.
- For members with frozen embryos created in an IVF cycle not initially approved by BCBSMA, 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.

**Not covered services include but are not limited to the following:**

- Sperm penetration assay to determine whether intracytoplasmic sperm injection should be offered for fertilization during an IVF treatment cycle.
- Mock transfer
- Emergency ICSI on an IVF cycle when low fertilization rate is discovered at the time of IVF
- Reciprocal IVF unless otherwise specified in the member's subscriber certificate
- Fresh IVF cycles when there are top quality cryopreserved eggs/embryos, as these should be transferred first.
  - When a member self-pays for cryopreservation of eggs/sperm/embryos to preserve fertility, they are not required to use these frozen egg/sperm/embryos before further infertility services can be provided when criteria are met.

### Cryopreservation after IVF Cycle

Embryo freezing and storage is covered for up to 24 months for embryos that are created during an approved IVF cycle through BCBSMA, except when intended for a gestational carrier.

**Not covered services include but are not limited to the following:**

- Embryo/Egg freezing and storage exceeding 24 months
- Cryopreservation after approved IVF cycle if egg/embryo is intended for a gestational carrier.

### Frozen Embryo Transfer (FET)

Frozen embryo transfer (FET) is covered when the following criteria are met:

- Embryos were created during a BCBSMA approved IVF cycle, OR
- Embryos were created while patient under insurer other than BCBSMA AND member meets infertility criteria on this policy (either at time at freezing or prior to transfer), OR
- Member was approved for donor egg/embryo and will be using donor egg/embryo for FET.

**Not covered services include but are not limited to the following:**

- Frozen embryo transfer (FET), or use of thawed eggs/sperm if not initially approved by BCBSMA OR if infertility criteria above were not met at time of freezing or at time of transfer.
- Frozen embryo transfer (FET), or use of thawed eggs/sperm if member has <5% chance of live birth, unless BCBSMA approved cryopreservation for members who underwent a procedure that was expected to render them infertile.
- Frozen embryo transfer (FET), or use of thawed eggs/sperm for use with gestational carrier or surrogate in any circumstances.

### Assisted Embryo Hatching

Assisted embryo hatching is covered under the following circumstances:

- Documented prior pregnancy following IVF with assisted hatching, OR
- 3 or more failures to implant after each embryo transfer cycle (failure to detect rise in HCG).

**Not covered services include but are not limited to the following:**

- Assisted hatching if PGT-M is done, as if PGT-M process includes opening the zona.

### ICSI and IVF for Male Factor Infertility

- ICSI is covered for male factor infertility of non-donor sperm defined as followed (same type of abnormality present in each specimen):
  - At least 2 unprocessed semen analyses show <10 million total motile sperm, OR
  - At least 2 processed semen analyses show  $\leq 3$  million total motile sperm, OR
  - At least 2 unprocessed semen analyses show  $\leq 2\%$  strict Kruger normal forms.

### Additional ICSI Criteria

- ICSI is covered on the day of IVF egg retrieval if the post processing semen 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 covered when reduced fertilization on a **prior** IVF cycle using non-donor sperm if the rate of fertilization on the **prior cycle** is less than 40% fertilization with the standard insemination of mature eggs.

**Not covered services include but are not limited to the following:**

- ICSI when using donor sperm
- ICSI for non-donor sperm failing to meet male factor infertility criteria described above.

### Donor Egg/Donor Embryo

Donor egg/embryo\* is covered for medical illness which causes unnatural loss of egg quantity:

- Premature inadequate harvest\*\*, OR
- Absent ovaries prior to age 40, OR
- Premature ovarian insufficiency.

\*The egg donor must be less than 34 years of age. Fresh or frozen donor egg is covered when criteria are met. Frozen donor embryo is covered when criteria are met.

\*\*At least two IVF treatment cycles where  $\leq 6$  eggs were retrieved with maximum ovarian stimulation

Frozen embryo transfer for reciprocal IVF is covered if the recipient meets criteria for donor egg/embryo.

Medication for donor egg IVF is covered for the donor under the following conditions:

- Recipient is a member with BCBSMA pharmacy benefits, AND
- Donor is known to the member, OR
- Infertility medications for anonymous donors if the member is sole recipient of unknown donor eggs.



Cryopreservation of donor eggs or embryos is covered up to 24 months when created during an approved IVF cycle.

**Not covered services include but are not limited to the following:**

- Donor eggs/donor embryos for biological females with genetic egg defects
- Donor eggs/donor embryos for age-related decline in egg quantity or quality, even if the member also has a medical cause of infertility which is normally treated by IVF
- Infertility medication for anonymous donors who do not meet above criteria
- Storage of frozen donor eggs/embryos
- Fees related to the payment of the egg donor; donor identification; legal services; or selection, purchase and transportation of frozen donor eggs/embryos, including the purchase of donated frozen eggs or donated frozen embryos.

## Donor Sperm

Donor sperm is covered (up to 2 vials per IVF/IUI cycle) when the biological male partner's sperm meets the criteria below. If there is no proven female factor requiring IVF, then IUIs will be approved with the donor sperm until female factor/unexplained infertility is proven by sufficient failures to conceive.

In order to receive coverage for infertility services, male members must meet the following criteria:

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

**Not 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 from cryobanks are guaranteed to be normal, so IVF or ICSI based on poor quality of these specimens is not covered
- Donor sperm for biological males with genetic sperm defects
- For biological females without a biological male partner.

**Note:** Not all fees associated with donor sperm are covered (i.e., mailing, freezing, storage) even if donor sperm is medically necessary. Please check subscriber certificates or account specific riders for more information about benefits.

## Microepididymal Sperm Aspiration (MESA)

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)

Microdissection-TESE is covered for non-obstructive azoospermia and spinal cord injury resulting in inability to ejaculate.

## Cryopreservation of Sperm or Testicular Tissue for Members in Active Infertility Treatment

Sperm storage/banking is covered for members who have undergone covered MESA or microdissection-TESE for up to 24 months.

Cryopreservation of testicular tissue/sperm is covered for adult biological males with azoospermia in conjunction with the testicular biopsy to identify sperm in preparation for an intracytoplasmic sperm injection procedure, if sperm are found.

**Not covered services include but are not limited to the following:**

- Sperm freezing and storage exceeding 24 months

- Sperm storage/banking for biological males requesting this service for convenience or “back-up” for a fresh specimen
- TESA.

### **Electroejaculation**

Electroejaculation is covered.

### **Sterilization Reversal**

Sterilization reversal is not covered. Infertility treatment needed as a result of prior voluntary sterilization or unsuccessful sterilization reversal procedure is not covered.

In order to be covered for infertility treatment after a reversal of a sterilization process the following criteria must be met:

- For biological females:
  - The member meets the definition for infertility coverage by a diagnosis that is unrelated to the sterilization procedure/reversal AND has an HSG showing at least 1 patent fallopian tube.
- For biological males\*:
  - 2 post reversal semen analyses (6 month apart) showing  $\geq 20$  million total motile sperm AND  $\geq 3\%$  normal forms, AND
  - Member has a normal semen analysis 6 months prior to the infertility service request.

\* Voluntary male sterilization (chemical or procedural) ends coverage for ICSI, IVF, and donor sperm based on male factor or unexplained infertility. Any abnormal semen analysis post a reversal ends eligibility for coverage of infertility services.

### **Additional Non-Covered Services**

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

- All infertility services if cotinine is found in the member or the member’s partner
  - Urine or serum cotinine levels must be obtained within the month of the requested service, for all members and their partners who acknowledged smoking within the past year.
- Selective fetal reduction\*
- 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 kits
- Post-coital testing
- 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
- Elective egg freezing for fertility preservation.

\*Unless otherwise specified in the member’s subscriber certificate

#### **Non-covered partner/surrogate services include but are not limited to the following:**

- Reciprocal IVF is not covered unless otherwise indicated in the member’s subscriber certificate

- Coverage for a partner's services when a partner is not a member except for procurement/processing of eggs and sperm, if not covered by partner's insurer
- Coverage for a member who is not medically infertile (i.e., whose partner's infertility is age-related)
- Coverage for services related to achieving pregnancy through a surrogate or gestational surrogate.

**Note:** For BCBSMA members who require a surrogate, we do not cover any services related to the surrogate. However, for women with a clear medical contraindication to pregnancy who are using their own eggs and self-paying for a gestational carrier, we do pay for our member's infertility evaluation, stimulation, retrieval, and fertilization. We do not cover for egg/embryo transfer or other services done to a gestational carrier, including, but not limited to transfer, impending pregnancy costs or cryopreservation of embryos. Use of donor egg and gestational carrier is not covered, as the female member is not physically treated in this situation and is effectively a surrogate service.

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

- Drugs for infertility are not covered without an authorization for infertility services.
- Infertility treatment medications are not reimbursed for members who do not meet our guidelines for infertility treatment coverage or for anonymous donors.

### Designated Retail Specialty Pharmacy Network

Effective October 1, 2006, Blue Cross Blue Shield of Massachusetts (BCBSMA) members are required to fill their prescriptions for medications commonly prescribed for use in fertility at one of the designated retail specialty pharmacies, as listed below:

Plans currently excluded from this requirement are: Medex®; Blue MedicareRx, Blue Health Plan for Kids; Medicare Advantage plans that include prescription drug coverage; self-insured accounts with non-BCBSMA pharmacy benefits and closed non-group plans.

Freedom Fertility Pharmacy 12 Kent Way Byfield, MA 01922 <a href="http://www.freedomfertilitypharmacy.com">www.freedomfertilitypharmacy.com</a>	BriovaRx (800) 258-0106 <a href="http://www.briovarx.com">www.briovarx.com</a>	Metro Drugs (888) 258-0106 <a href="http://www.metrodrugs.com">www.metrodrugs.com</a>	Village Fertility Pharmacy (877) 334-1610 <a href="http://www.villagefertilitypharmacy.com">www.villagefertilitypharmacy.com</a>
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### Prior Authorization Information

#### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

#### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
<b>Commercial Managed Care (HMO and POS)</b>  All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan description.	<b>Diagnostic Testing</b> Prior authorization is <b>not required</b> for diagnostic testing related to Assisted Reproductive Technology or Infertility services.  <b>Infertility Treatment</b> Prior authorization is <b>required</b> for all treatments related to Assisted Reproductive Technology and Infertility services with the exception of Intrauterine insemination (IUI).

<p><b>Commercial PPO and Indemnity</b></p> <p>All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan description.</p>	<p><b>Diagnostic Testing</b> Prior authorization is <b>not required</b> for diagnostic testing related to Assisted Reproductive Technology or Infertility services.</p> <p><b>Infertility Treatment</b> Prior authorization is <b>required</b> for most treatments related to Assisted Reproductive Technology and Infertility services as outlined in the member's subscriber certificate, with the exception of Intrauterine insemination (IUI).</p>
<p><b>Medicare HMO Blue<sup>SM</sup></b></p>	<p>Prior authorization is <b>not required</b>.</p>
<p><b>Medicare PPO Blue<sup>SM</sup></b></p>	<p>Prior authorization is <b>not required</b>.</p>

### CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

#### CPT Codes - Coding Information for Professional Providers

CPT codes:	Code Description
54900	Epididymovasostomy, anastomosis of epididymis to vas deferens; unilateral
54901	Epididymovasostomy, anastomosis of epididymis to vas deferens; bilateral
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
76831	Saline infusion sonohysterography (SIS), including color flow Doppler, when performed
74740	Hysterosalpingography, radiological supervision and interpretation
S4026	Procurement of donor sperm from sperm bank
	Type of service 5, and 1 unit of service, for procurement of donor sperm from a sperm bank, for each vial procured (1 unit = 1vial)

CPT/HCPCS codes:	Code Description
55870	Electroejaculation
S4028	<p>Microsurgical epididymal sperm aspiration (MESA)</p> <p>Type of service 2</p> <p><b>Note:</b> MESA is payable only for congenital absence or congenital obstruction of the vas deferens.</p>
58974	Embryo transfer, intrauterine
58976	Gamete, zygote, or embryo intrafallopian transfer, any method
59866	Multifetal pregnancy reduction
58825	Transposition, ovary(s)

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 (eg. per col gradient, albumin gradient) for insemination or diagnosis with semen analysis
89261	Sperm isolation; complex prep (eg, per col gradient, albumin gradient) for insemination or diagnosis with semen analysis
89264	Sperm identification from testis tissue, fresh or cryopreserved
89268	Insemination of eggs
89272	Extended culture of egg(s)/embryo(s), 4-7 days
89280	Assisted egg fertilization, microtechnique; less than or equal to 10 egg
89281	Assisted egg fertilization, microtechnique; greater than 10 eggs
89321	Semen analysis, presence and/or motility of sperm
89335	Cryopreservation, reproductive tissue, testicular (Covered effective 11/1/2009)
89337	Cryopreservation, mature egg(s)
89342	Storage, (per year); embryo(s)
89343	Storage, (per year); sperm/semen
89346	Storage, (per year); egg
89352	Thawing for cryopreserved; embryo(s)
89353	Thawing of cryopreserved; sperm/semen, each aliquot
89356	Thawing of cryopreserved; egg(s), each aliquot

The following codes are considered **non-covered for all Plans** as they do not meet our Medical Technology Assessment Guidelines and if billed will reject leaving *no* patient balance:

<b>CPT codes:</b>	<b>Code Description</b>
89344	Storage, (per year); reproductive tissue, testicular/ovarian (except for authorized TESE)
89354	Thawing of cryopreserved; reproductive tissue, testicular/ovarian (except for authorized TESE)

#### Coding Information for Reproductive Specialist Providers

<b>CPT/HCPCS codes:</b>	<b>Code Description</b>
58970	Follicle puncture for egg retrieval, any method
S4011	In vitro fertilization, including but not limited to identification and incubation of mature eggs, fertilization with sperm, incubation of embryo(s), and subsequent visualization, determination of development  Type of service 2
89250	Culture of egg(s)/embryo(s), less than 4 days; <b>Note:</b> This procedure may be billed <b>once</b> per cycle.
89253	Assisted embryo hatching, microtechniques (any method)
89254	Egg identification from follicular fluid <b>Note:</b> This procedure may be billed once per cycle.

#### Coding Information for Contracted Sperm Banks

<b>CPT/HCPCS codes:</b>	<b>Code Description</b>
S4030	Sperm procurement & cryopreservation services; initial visit Type of service L <b>Note:</b> This procedure is limited to one visit per lifetime.
S4031	Sperm procurement & cryopreservation services; subsequent visits Type of service L

89259	Annual sperm storage due to other medical treatment rendering a member infertile Type of service L <b>Note:</b> This procedure may be billed <b>once per year</b> . The procedure may be covered for members in active infertility treatment, post microsurgical epididymal sperm aspiration (MESA), performed for congenital absence of the vas deferens.
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## Description

Infertility is defined as failure to conceive a pregnancy after 12 menstrual cycles, during which time ovulation is expected, and semen presumed to contain sperm has been present inside a person's uterus, in someone who is not undergoing menopause or perimenopause. While infertility may be caused by disease, menopause and perimenopause are natural conditions. There are many known causes of infertility, and in some cases, no specific cause is found. According to a state mandate, health plans should provide coverage for infertility diagnosis and treatment, including artificial insemination and in vitro fertilization when needed due to a medical condition.

## Summary

The purpose of this medical policy is to describe covered/non-covered assisted reproductive services and the necessary documented clinical conditions. The required workup will help determine which members have a >5% chance of live birth. The procedure protocols are based on published research, society guidelines and expert opinion and are designed to promote safe and effective treatments for infertility.

## Policy History

Date	Action
5/2020	Donor sperm, cryopreservation of sperm or testicular tissue and evaluation requirements clarified: <ul style="list-style-type: none"> <li>Added note in donor sperm section clarifying that not all fees associated with donor sperm are covered</li> <li>Added the word "covered" to cryopreservation of sperm or testicular tissue section</li> <li>Clarified that Estradiol levels must be equal to or less than 100 in evaluation requirements for IVF procedure.</li> </ul>
3/2020	Evaluation and donor requirements clarified: <ul style="list-style-type: none"> <li>To include 3D ultrasound, and hysterosalpingo contrast sonography (HyCoSy).</li> <li>Non-smoking members with an initial negative cotinine level test, are not required to have repeat or ongoing cotinine tests.</li> <li>Frozen embryo transfer for reciprocal IVF is covered if the recipient meets criteria for donor egg/embryo.</li> </ul>
10/2019	Policy clarified to update overview of covered services section. No changes to policy coverage criteria
5/2019	Policy clarified to remove Walgreens Fertility Pharmacy as designated retail specialty pharmacy network. 5/3/2019.
5/2019	Premature ovarian insufficiency removed under Demonstration of Infertility section. Effective 5/1/2019.
3/2019	Sterilization reversal section clarified to indicate that infertility treatment needed as a result of prior voluntary sterilization or unsuccessful sterilization reversal procedure is not covered.
2/2019	Donor Egg/Donor Embryo section clarified.
12/2018	Prior authorization requirement for intrauterine insemination removed. Laboratory requirement prior to IVF clarified.
4/2018	Prior authorization information clarified.
9/2017	Medically necessary criteria on all frozen embryos clarified. Frozen embryo transfers not covered indications clarified.
6/2017	Policy clarified that for all members, assisted reproductive technologies are covered for the time period that fertility is naturally expected.
5/2017	Policy title changed. Policy format restructured for clarity. Effective 5/1/2017.

1/2016	Non-covered statement on fresh IVF cycles when there are high quality cryopreserved embryos, as these should be transferred first, clarified to indicate cryopreserved eggs/embryos.
1/2016	The requirement for documented infertility for intrauterine insemination (IUI) was removed. IUI is medically necessary. Effective 1/1/2016.
11/2015	Clarified maximum age for egg cryopreservation from 35 to 38 for members that have excess (supernumerary) eggs that cannot be fertilized (i.e. no sperm is able to be produced on the day of egg retrieval or there are too few sperm for the number of eggs retrieved on the day of egg retrieval) during a covered cycle of IVF.
9/2015	Removed statement that IVF and ICSI for the sole purpose of PGD are investigational. Effective 9/1/2015.
8/2015	Cryopreservation statement on transgender members transferred to medical policy #189, Transgender Services. Prior authorization information section clarified.
7/2015	MESA for congenital absence or congenital obstruction of the vas deferens statement clarified. ICSI and IVF for severe male factor statement clarified. IVF for moderate male factor statement clarified. Prior authorization information section clarified. Cryopreservation for transgender members revised to include hormone therapy. Effective 7/1/2015.
6/2015	Updated to change maximum age for egg cryopreservation from 35 to 38 for members undergoing chemotherapy or other treatment that is expected to render them permanently infertile. Effective 6/1/2015. Added statement that egg and sperm cryopreservation is medically necessary for transgender members. Effective 6/1/2015.
5/2015	Clarified coding information.
2/2015	Removed non-coverage of IVF when self-paid Preimplantation Genetic Screening (PGS) is planned. Clarified that a new CCCT is not required for FETs (Frozen Embryo Transfers). Effective 2/1/2015.
1/2015	Clarified coding information; voluntary sterilization description clarified.
11/2014	ICSI coverage on page 7 clarified.
10/2014	New medically necessary and investigational indications described; policy statements clarified and new ART Criteria form to submit requests. Requirement criteria for single embryo transfers (SETs) added. Coding information clarified. Effective 10/1/2014.
7/2014	Updated to include CPT codes 54900 and 54901.
6/2014	Updated to include Walgreens Fertility Pharmacy - designated retail specialty pharmacy network.
11/2013	Updated to remove supplemental services Y-codes.
10/2013	Updated to clarify that supplemental services are no longer separately reimbursed; reimbursement for supplemental services is included in the global rate.
9/2012	Updated to remove coverage for SPA (sperm penetration assay) based on expert opinion. Effective 9/1/2012.
7/2012	Updated to clarify the Infertility Specialty Pharmacy provider network.
4/2012	Updated to clarify coverage of donor and non-donor sperm for in vitro fertilization.
1/2012	Updated to clarify ongoing non-coverage of CPT 89331 sperm evaluation, for retrograde ejaculation, urine (sperm concentration, motility, and morphology, as indicated); the same information is on document 400.
1/2012	Updated to clarify ongoing non-coverage of cryopreservation; reproductive tissue, ovarian and to add reference to Ascend FertilityRx as a designated retail specialty pharmacy network.
1/2012	Updated to remove the reference to IVPCare, Inc. as a designated retail specialty pharmacy network.
9/2011	Reviewed - Medical Policy Group - Urology, Obstetrics and Gynecology, no changes in coverage.
12/2010	Updated to add infertility treatment for a member with recurrent pregnancy loss in accordance with Massachusetts law (M.G.L.c. 175, section 47H and 211 C.M.R 37.09). Effective December 15, 2010.

1/21/2010	Updated to revise language from Blue Cross Blue Shield HMO Blue to Blue Cross Blue Shield of Massachusetts in third paragraph on page 1.
10/2009	Reviewed - Medical Policy Group - Obstetrics and Gynecology, no changes in coverage.
10/2009	Updated to clarify the required period for updated lab results when six months has elapsed since the CCCT; a basal FSH and estradiol are required that were done within 6 months from the date of a planned treatment. Prior Authorization section clarified.
7/2009	Updated following review of the BCBSA National medical policy on Reproductive Techniques. Coverage change to include cryopreservation of testicular tissue in adult men with azoospermia in conjunction with the testicular biopsy to identify sperm in preparation for an intracytoplasmic sperm injection procedure. Effective 11/1/2009.
10/2009	Revised to include benefit coverage information in the header section of the document that addresses infertility services when a healthy female member is age 35 or older and has not been able to conceive after a period of six months of actively trying. Clarified coverage language for: sperm storage and banking, non-coverage language for more than one cycle of IVF for a member undergoing treatment, egg tissue preservation and cryopreservation of eggs, and one cycle of IVF for a member who will undergo treatment that is expected to render them infertile.
9/2009	Updated to clarify footnote E, covered language pertaining to: embryo freezing, and sperm storage, and non-covered language that pertains to: donation, storage and banking of donor sperm, cryopreservation of embryo, and tissue preservation and cryopreservation of eggs.
7/2009	Updated to clarify coverage statement for ICSI and IVF, third bullet; reduced fertilization on a prior IVF.
3/2009	BCBSA National medical policy coding information updated on Assisted Reproductive Technologies, no coverage changes noted.
2/2008	Policy edited with the removal of coverage references for preimplantation genetic diagnosis which is now addressed in a new medical policy document, #088 Preimplantation Genetic Diagnosis (PGD).
1/2009	Updated to remove information regarding requirement of 3 FSH IUI prior to receiving IVF treatment for those that meet the definition of unexplained infertility.
10/2008	Reviewed - Medical Policy Group - Obstetrics/Gynecology, no changes in coverage.
5/2008	Review of BCBSA National policy on Laboratory Tests of Sperm Maturity, Function, and DNA Integrity. BCBSMA to cover sperm penetration assay to determine whether intracytoplasmic sperm injection should be offered as part of IVF technique. Effective 11/2008.
3/2008	Updated to include coverage language for infertility services and ART for members not previously defined as infertile, and the required number of 2 semen analysis for the diagnosis of male factor.
12/2007	Policy edited to provide clarification, i.e. non-coverage language - IVF pertaining to prior voluntary sterilization.
10/2007	Reviewed - Medical Policy Group Obstetrics and Gynecology, no changes in coverage.
10/2006	Reviewed - Medical Policy Group Obstetrics and Gynecology, no changes in coverage.
4/2006	Updated to clarify the Day 3 FSH lab result in a woman prior to the age of 40 to be 15.0 mIU/ml.
2/2006	Updated the Preferred Pharmacy Vendors list for Fertility Medications.
12/2005	Updated to clarify policy guidelines based upon discussions with IVF Centers.
10/2005	Reviewed - Medical Policy Group Obstetrics and Gynecology no changes in coverage.
5/2005	Updated to clarify our exclusion guidelines for gestational carriers or surrogacy, effective immediately; to exclude coverage for sperm acrosome reaction test, effective immediately; to clarify coverage guidelines for ICSI, effective immediately; and to exclude coverage for emergency ICSI on an IVF cycle when low fertilization rate is discovered at the time of IVF. Effective 11/1/05.
3/2005	Updated to clarify the policy guidelines.
1/2005	Updated to remove antiphospholipid antibody testing under the "when services are not covered" section of the policy.



10/2004	Reviewed - Medical Policy Group Obstetrics and Gynecology no changes in coverage.
10/2003	Updated to include guidelines on conversion from IUI to IVF. The following clarifications were made: thaw cycles do not count toward the 6 medicated cycles; no testing frequency is required for semen analysis; hysterosalpingogram is not required in patients who presents with male factor infertility; defined perimenopausal; defined what is "naturally expected to be fertile."
4/2003	Updated to expand coverage for ICSI to include reduced fertilization (effective 4/03); to clarify that Day 2, 3, or 4 FSH is acceptable; to clarify that we require a minimum of 12 intrauterine inseminations supervised by a physician that does not result in conception, as evidence of infertility (effective 8/03); and to clarify when fertility is naturally expected: for women under 40, this is premature, for women 42 and older, this is within the expected normal range, and for women 40 up to 42, the expected range is extended to 15 pg/ml. Also, to include individual consideration guidelines for patients with extenuating medical circumstances such as an elevated FSH over a prolonged period of time, especially if they have had a successful IVF treatment with similar FSH values may be approved on an exception basis.
10/2002	Updated - Medical Policy Group Obstetrics and Gynecology to include coverage for sperm penetration assay. Effective for services rendered on or after 10/01/02.
7/2002	Updated to clarify coverage guidelines for assisted embryo hatching.
6/11/02	Updated to reflect effective date for coverage exclusion for assisted embryo hatching as published in the January/February 2002 Provider Focus, (April 2002).
10/2001	Updated to exclude coverage for blastocyst transfer; antiphospholipid antibody testing, and effective May 2002 assisted embryo hatching.
9/2001	Updated to include the definitions of successful vasectomy sterilization reversal and a successful tubal sterilization reversal.
5/2001	Updated to include coverage for culture and fertilization of egg(s) and to exclude coverage for anti-sperm antibody test, embryo toxic factor test, post-coital test, and donor sperm without documented male factor infertility.
7/2000	Updated to include information on embryo freezing and storage.
4/2000	Updated to include coverage for assisted embryo hatching. Effective 4/2000.
6/1999	Updated to include revisions on procedure codes W1011 and W1004, and to include certificate language on sterilization reversal procedure and unsuccessful sterilization reversal procedure.
3/1999	Updated to clarify the role of menopause & perimenopause, rather than age, as most significant aspect of medical necessity determination, and to remove BCBSMA deleted local codes for dates of service prior to 9/1/1997.
10/1998	Updated to include 1999 CPT code 89264.
8/1998	Updated to include information from infertility booklet (#32-6070) "Important Information About Your Benefits" and clarified coverage of 6 cycles.
7/1998	Clarified coverage for sperm storage/banking for members in active infertility treatment: males who have undergone MESA; and males undergoing treatment that may cause infertility. No changes in coverage were made.
6/1998	Included billing information for culture and fertilization of egg(s) CPT code 89250.
2/1998	Updated included coverage for sperm storage for patients with congenital absence of the vas deferens.
11/1997	Updated to increase age restriction to 45th birthday, to exclude coverage for gestational carriers, and to define limits of coverage for women with uterine problems who require a surrogate.
9/1997	Updated to include age guidelines for women for services after 12/1/1997.
7/1997	Updated to include revision regarding reimbursement for local code W1000.
5/1997	Updated to include the Mayo Clinic Infertility Guideline; no changes were made to the types of services covered.
10/1996	Updated to remove the restriction for members residing outside of Massachusetts, and to allow coverage for ICSI based upon the American Society for Reproductive Medicine

	Practice Committee Statement. The policy is in accordance with state mandate H3721 Chapter 394, 1987, and DOI Regulation 211 CMR 27:00: Infertility Benefits.
12/1995	Medical policy issued.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

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<http://www.mass.gov/ocabr/docs/doi/legal-hearings/211-37.pdf>.
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