

Blue Cross Blue Shield of Massachusetts is an Independent Licenses 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.
- Preimplantation Genetic Testing, #088
- Carelon Genetic Testing Management Program, #954
  - o Reproductive Carrier Screening and Prenatal Diagnosis

## **Table of Contents**

Products Included	2
Subscriber Certificate	2
Gender Descriptions	2
Fertility Services	3
IUI	3
Cryopreservation (Fertility Preservation)	3
Ovarian Transposition	4
Ovulation Disorders	4
Infertility Services	2
Demonstration of Infertility	∠
Evaluation Requirements	5
Coverage Criteria	e
Gonadotropin Ovulation Induction Conversion to IVF	
In Vitro Fertilization (IVF)/ Zygote Intra-Fallopian Transfer (ZIFT)/ Gamete Intra-Fallopian Transfer (GIFT)	
Frozen Embryo Transfer (FET)	
Assisted Embryo Hatching	
ICSI and IVF for Male Factor Infertility	

Donor Egg/Donor Embryo	9
Donor Sperm	9
Microepididymal Sperm Aspiration (MESA)	10
Microdissection- Testicular Excisional Sperm Extraction (TESE)	10
Cryopreservation of Sperm or Testicular Tissue for Members in Active Infertility Trea	
Electroejaculation	
Sterilization Reversal	10
Additional Non-Covered Services	11
Non-covered tests/procedures include but are not limited to the following:	11
Non-covered partner/surrogate services include but are not limited to the following:	11
Non-covered medications include but are not limited to the following:	11
Designated Retail Specialty Pharmacy Network	12
Prior Authorization Information	12

## **Products Included**

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

#### **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**

#### Intrauterine insemination 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).

\*\*Authorization is not required for IUI unless services are an IUI to IVF Conversion, the IUI is being done with donor sperm, or for individual consideration for members clinically determined to have less than 5% chance of live birth.

## **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).</li>
  - Frozen embryo transfer is covered when transferred back to member.
- Ovarian tissue cryopreservation in premenarchal girls (up to 24 months)
- Sperm collection and storage (up to 24 months)

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 ≥ 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.
  - Frozen embryo transfer is covered when transferred back to member.
- Sperm collection and storage (up to 24 months)

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**

To be eligible for coverage for infertility services, biological female members or biological male members must meet the criteria in one of the following:

- 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)¹, 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 member 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
- V. A biological female member age 35 or older with an ovulation disorder who has been:
  - 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
- VII. A biological female member with a chronic condition that requires medication maintenance that may be contraindicated during the time trying to conceive or during any reproductive cycle.\*\*\*
- VIII. A biological male member with:
  - At least 2 unprocessed/processed semen analyses show <10 million total motile sperm, OR
  - b. At least 2 processed semen analyses show ≤3 million total motile sperm, OR
  - c. At least 2 unprocessed semen analyses show ≤ 2% strict Kruger normal forms.

\*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.

\*\*Intrauterine Insemination must be conducted in the office setting. Home insemination is not a covered service.

\*\*\*If the member is under 35 with a chronic condition that requires medication maintenance which may be contraindicated during the time trying to conceive or during any reproductive technology cycle, the required conception trial period may be evaluated on a case by case basis. The condition, medication regimen, and risk/benefit of taking medication during pregnancy will be weighed.

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).
  - o Testing must be done prior to initial infertility services and repeated annually.
- Semen analysis

\*Urine or serum cotinine testing is considered a covered service for members undergoing infertility services as smoking is known to increase the risk for infertility.

#### **Evaluation Requirements for Ovarian Reserve testing prior to in vitro fertilization:**

- Members <40 years old</li>
  - 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:
  - o Yearly clomiphene citrate challenge test (CCCT) **OR** alternate testing options
  - If 6 months have elapsed since the CCCT OR alternate testing options, a basal FSH and estradiol are required prior to next fresh IVF cycle
  - A new CCCT, alternative testing options, 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 with their own eggs but may qualify for donor egg/embryo (see donor egg/embryo section).</li>

#### We will accept any of the following for evaluation of ovarian reserve in individuals over 40:

- 1. Clomiphene citrate challenge test (CCCT), **OR**
- 2. Alternate testing options:
  - a. Exogenous follicle stimulating hormone ovarian reserve test (EFORT)
    - i. Inhibin B value difference of < 78.6 between Day 3 and Day 4, OR
  - b. A combination of tests:
    - i. Basal FSH, estradiol, and antral follicle count (AFC) done on the same day, **AND** an anti-mullerian hormone (AMH) drawn within 1 month.
    - ii. Lab values needed for infertility services coverage

- 1. AMH > 1.0 ng/ml, AND
- 2. AFC >6, AND
- 3. CD3 FSH ≤ 15.0 mIU/ml for 40 and 41 year olds, OR
- 4. CD3 FSH ≤12.0 mIU/ml for 42 and 43 year olds, AND
- 5. Estradiol ≤100 pg/ml.

\*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).

## **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</li>
- Estradiol 800 pg/ml or higher, AND
- 3 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
- Male factor infertility as defined in this policy
- The member has met the criteria for infertility coverage as defined in this policy.

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

- For members <35 years of age</li>
  - o 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.
  - 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 members <38 years of age and had successful IVF treatment cycle (i.e. had a live birth from that IVF treatment)
  - o 1st 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>rd</sup> and subsequent IVF treatment cycles do not need to be SET or STEET
- For members 35-38 years of age:
  - 1st 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>rd</sup> and subsequent IVF treatment cycles do not need to be SET or STEET
- 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:
  - 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.
  - 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.
  - 3rd and subsequent IVF treatment cycles do not need to be SET or STEET
- 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
- Rescue 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.

<sup>\*</sup> For all treatment cycles, all frozen embryos must be used before another fresh cycle may be approved.

## **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</li>
  - o At least 2 processed semen analyses show ≤3 million total motile sperm, OR
  - o At least 2 unprocessed or processed semen analyses show ≤ 2% strict Kruger normal forms.

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

#### **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
- ICSI is covered when used to fertilize cryopreserved eggs
- ICSI is covered when being done for approved preimplantation genetic testing

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 Cycle/Donor Embryo Cycle**

Donor egg cycle/embryo cycle\* is covered for the following clinical circumstances:

- 1. Medical illness which causes unnatural loss of egg quantity:
  - a. Premature inadequate harvest\*\*, OR
  - b. Absent ovaries prior to age 40, OR
  - c. Premature ovarian insufficiency.
- 2. The following genetic egg defects as an alternative to using IVF with one's own eggs with preimplantation genetic testing:
  - a. Member meets criteria for Preimplantation Genetic testing based on Medical policy 088, OR
  - b. Member with recurrent pregnancy loss and a diagnosis of balanced reciprocal translocation or Robertsonian translocation based on karyotype screening.

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

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 egg cycles/donor embryo cycle 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 a maximum of 2 vials per cycle, 1 vial per IVF cycle or per IUI) when the biological male partner's sperm meets the criteria below and is administered in the office setting. 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 semen analyses show ≤ 2% strict Kruger normal forms, OR
- Member meets the criteria for Preimplantation Genetic Testing based on MP 088, OR
- Biological male has a diagnosis of balanced reciprocal translocation or Robertsonian translocation based on karyotype screening of sperm and partner has a diagnosis of recurrent pregnancy loss.

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

<sup>\*\*</sup>At least two IVF treatment cycles where ≤6 eggs were retrieved with maximum ovarian stimulation

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

- Donor sperm without severe 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 when used for home insemination.

**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. MESA is no longer covered when there is <5% chance of live birth.

#### **Microdissection-Testicular Excisional Sperm Extraction (TESE)**

Microdissection-TESE is covered for non-obstructive azoospermia and spinal cord injury resulting in inability to ejaculate. TESE is no longer covered when there is <5% chance of live birth.

## 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 ≥ 20 million total motile sperm AND
     ≥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, TESE, MESA, 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:

- Selective fetal reduction (unless otherwise specified in the member's subscriber certificate)
- Gender selection
- Human zona binding assay (hemizona test)
- Serum anti-sperm antibody testing
- Sperm acrosome reaction test
- Sperm DNA fragmentation assays
- Advanced Sperm Selection Techniques (i.e. PICSI, Zeta potential, sorting by X or Y chromosome, magnetic activating cell sorting, etc.)
- Sperm hyperactivation processing/techniques
- Co-culture of embryos
- Embryo toxic factor test (ETFL) or Natural killer cell assay
- IVIG (Intravenous Immunoglobulin)
- Granulocyte Colony Stimulating Factor (G-CSF)
- Intralipid infusion
- Ovulation kits
- Post-coital testing
- Artificial oocyte activation
- 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.
- Endometrial Scratching
- Embryo Glue (hyaluronic acid)
- human chorionic gonadotropin (hCG) infusion into the uterine cavity
- uterine artery vasodilation (i.e. sildenafil)

## 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, fertilization, freezing and storage. We do not cover for egg/embryo transfer or other services done to a gestational carrier, including, but not limited to transfer, or impending pregnancy costs. 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<sup>®</sup>; 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	Encompass Fertility	Village Fertility Pharmacy
<u>1-866-297-9452</u>	<u>1-855-443-5357</u>	<u>1-877-334-1610</u>
Fax: 1-888-660-4283	Fax: 1-844-364-9364	Fax: 866-935-0719
<u>freedomfertility.com</u>	encompassfertility.com	vfppharmacygroup.com

#### **Prior Authorization Information**

#### Inpatient

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

#### Outpatient

• For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)  All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan	Diagnostic Testing Prior authorization is not required for diagnostic testing related to Assisted Reproductive Technology or Infertility services.
description.	Intrauterine Insemination Prior auth is not required for intrauterine insemination unless services are an IUI to IVF Conversion, the IUI is being done with donor sperm, or for individual consideration for members clinically determined to have less than 5% chance of live birth.
	Infertility Treatment Prior authorization is required for all treatments related to Assisted Reproductive Technology and Infertility services with the exception of Intrauterine insemination (IUI).
Commercial PPO and Indemnity	Diagnostic Testing Prior authorization is not required for diagnostic
All authorization requirements are determined by the individual's subscriber certificate, explanation of coverage, or summary plan	testing related to Assisted Reproductive Technology or Infertility services.
description.	Intrauterine Insemination

Prior auth is <b>not required</b> for intrauterine insemination unless services are an IUI to IVF Conversion, the IUI is being done with donor sperm, or for individual consideration for members clinically determined to have less than 5% chance of live birth.
Infertility Treatment Prior authorization is required 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).

#### **Requesting Prior Authorization Using Authorization Manager**

Providers will need to use <u>Authorization Manager</u> to submit initial authorization requests for services. Authorization Manager, available 24/7, is the quickest way to review authorization requirements, request authorizations, submit clinical documentation, check existing case status, and view/print the decision letter. For commercial members, the requests must meet medical policy guidelines.

To ensure the request is processed accurately and quickly:

- Enter the facility's NPI or provider ID for where services are being performed.
- Enter the appropriate surgeon's NPI or provider ID as the servicing provider, *not* the billing group.

#### **Authorization Manager Resources**

Refer to our <u>Authorization Manager</u> page for tips, guides, and video demonstrations.

Complete Prior Authorization Request Form for Assisted Reproductive Technology Services (694) using Authorization Manager

For out of network providers: Requests should still be faxed to 800-836-1112.

#### **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	Microsurgical epididymal sperm aspiration (MESA)
	Type of service 2
	Note: MESA is payable only for congenital absence or congenital obstruction of the
	vas deferens.
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
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**

CPT/HCPCS	
codes:	Code Description
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
S4015	Complete in vitro fertilization cycle, not otherwise specified, case rate
S4016	Frozen in vitro fertilization cycle, case rate
S4018	Frozen embryo transfer procedure cancelled before transfer, case rate

S4022	Assisted oocyte fertilization, case rate
89250	Culture of egg(s)/embryo(s), less than 4 days;
	Note: This procedure may be billed once per cycle.
89253	Assisted embryo hatching, microtechniques (any method)
89254	Egg identification from follicular fluid
	Note: This procedure may be billed once per cycle.

#### **Coding Information for Contracted Sperm Banks**

CPT/HCPCS	
codes:	Code Description
S4030	Sperm procurement & cryopreservation services; initial visit
	Type of service L
	Note: 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.

## **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
10/1/2023	Clarifications made to Intrauterine insemination, IVF evaluation requirements and cryopreservation after IVF cycle sections. 10/1/2023.
9/2023	Policy clarified to include prior authorization requests using Authorization Manager.
5/1/2023	Policy criteria on ICSI clarified. Minor editorial refinements to policy statements, intent unchanged. 5/1/2023.
1/1/2023	Annual policy update. Medically necessary statement added considering cryopreservation of ovarian tissue a covered service for premenarchal females based on newly published guidelines. Clarifications made to IVF evaluation requirements, donor sperm section, donor egg and embryo section, and voluntary sterilization section. Medicare prior authorization information removed. Clarified coding information. 1/1/2023.
2/2022	Clarification made to additional ICSI criteria section. ICSI is a covered service when done to fertilize cryopreserved eggs. 2/1/2022.
9/2021	Clarifications made to demonstration of infertility section. Home inseminations are non- covered. Intrauterine insemination must be done in an office setting under the direction of a provider.

-1	T
6/2021	Medically necessary statements clarified to cover donor egg cycle/donor sperm for
	members meeting criteria for preimplantation genetic testing based on medical policy
	088 or who have a diagnosis of balanced translocation or Robertsonian translocation
	and a history of or partner with a history of recurrent pregnancy loss. 6/1/2021.
4/2021	Clarifications made to demonstration of infertility section, gonadotropin ovulation
	induction section, ICSI and IVF male factor section, Donor egg cycle/donor embryo cycle
	and donor sperm sections, MESA and TESE sections. New tests added to additional
	noncovered services section. 4/2021.
5/2020	Donor sperm, cryopreservation of sperm or testicular tissue and evaluation requirements
	clarified:
	<ul> <li>Added note in donor sperm section clarifying that not all fees associated with donor</li> </ul>
	sperm are covered
	<ul> <li>Added the word "covered" to cryopreservation of sperm or testicular tissue section</li> </ul>
	<ul> <li>Clarified that Estradiol levels must be equal to or less than 100 in evaluation</li> </ul>
	requirements for IVF procedure.
3/2020	Evaluation and donor requirements clarified:
	<ul> <li>To include 3D ultrasound, and hysterosalpingo contrast sonography (HyCoSy).</li> </ul>
	<ul> <li>Non-smoking members with an initial negative cotinine level test, are not required to</li> </ul>
	have repeat or ongoing cotinine tests.
	Frozen embryo transfer for reciprocal IVF is covered if the recipient meets criteria for
	donor egg/embryo.
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.
<u> </u>	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
1/0010	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
0/0047	covered indications clarified.
6/2017	Policy clarified that for all members, assisted reproductive technologies are covered for
5/0047	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
4/0040	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
2/2217	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.
1/1996-	Annual policy updates and clarifications made. Please request policy version by year or
11/2014	date for specific updates. 4/2021.
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

- In accordance with the Massachusetts state mandate. The mandate states that we must provide benefits to insured covered spouse and/or other covered dependent: http://www.mass.gov/ocabr/docs/doi/legal-hearings/211-37.pdf.
- 2. The American College of Obstetricians and Gynecologists Practice Bulletin, Clinical Management Guidelines for Obstetrician-Gynecologists. Number 24, February 20001 (Replaces the Technical Bulletin Number 212, September 1995), Management of Recurrent Pregnancy Loss.
- 3. American Society for Reproductive Medicine, Patient's Fact Sheet, *Recurrent Pregnancy Loss*, 8/2008.
- 4. Practice Committee Report, *Definitions of Infertility and Recurrent Pregnancy Loss*, Practice Committee of the American Society for Reproductive Medicine, Fertility and Sterility Vol. 89, No. 6, June 2008.
- 5. Diagnostic evaluation of the infertile female: a committee opinion ASRM. Fertil Steril 2012; 98:302-7.
- 6. Fertility treatment when the prognosis is very poor or futile: a committee opinion. ASRM. Fertil Steril\_ 2012; 98:e6–e9
- 7. ASRM Position on Gender Selection. See also ASRM's website: www.asrm.org.
- 8. A comparison of intrauterine versus intracervical insemination in fertile single women. Carroll N, Palmer, J. Fertil Sterilt 2001;75:656–60.
- 9. Chapter 27 Infertility by Mark D. Hornstein & Daniel Schust in Novak's Gynecology, 12 Edition. Williams & Wilkins, Baltimore, 1998, pp 915-962.
- 10. Diagnostic Evaluation of Infertile Male: A Committee Opinion. ASRM. Fertil Steril 2012;98:294-301.
- 11. Post-coital testing: Diagnostic Evaluation of the Infertile Female: A Committee Opinion. ASRM. Fertil Steril 2012;98:302-7.
- 12. Aging and Infertility in Women A Committee Opinion from ASRM 2006.
- 13. Intercycle variability of ovarian reserve tests. Results of a prospective randomized study Kwee et al. Hum Reprod 2004; 19:590-5.
- 14. Chronological age vs biological age: an age-related normogram for antral follicle count, FSH and anti-Mullerian hormone. Wiweko et al. J Assist Reprod Genet (2013) 30:1563–1567
- 15. Ovulation induction combined with intrauterine insemination in women 40 years of age and older: is it worthwhile? G. Corsan, A. Trias, S. Trout and E. Kemmann. Human Reproduction vol.11 (5) 1109-1112, 1996. Live birth rate for 40 year olds was 9.6%, at 41 5.2%, at 43 2.4% and 0% beyond.

- 16.A prospective trial of intrauterine insemination of motile spermatozoa versus timed intercourse. Kirby CA1. Flaherty SP. Godfrey BM. Warnes GM. Matthews CD. Fertil Steril. 1991 Jul:56(1): 102-7.
- 17. Based upon expert advice from the Infertility Board Panel. Cumulative Birth Rates with Linked Assisted Reproductive Technology Cycles. Luke et al. N Engl J Med 2012;366:2483-91.
- 18. Cumulative Live-Birth Rates after In Vitro Fertilization. Malizia B, Hacker M, Penzia A. N Engl J Med 2009:360:236-43.
- 19. Controlled ovarian hyperstimulation and intrauterine insemination for treatment of unexplained infertility should be limited to a maximum of three trials. Aboulghar M1, Mansour R, Serour G, Abdrazek A.
- 20. Conversion from IUI to IVF guidelines: Based upon local expert opinion from Boston IVF, Brigham and Women's Center for Reproductive Medicine, Reproductive Science Center of Boston, and the New England Reproductive Center.
- 21. Salpingectomy for Hydrosalpinx Prior to INVF: A Committee Opinion from ASRM July 2001.
- 22. The role of assisted hatching in in vitro fertilization: a review of the literature. A Committee opinion. ASRM Fertility and Sterility\_ Vol. 85, No. 2, February 2006.
- 23. Elective Single-Embryo Transfer Fertil Steril 2012;97:835-42. The age cutoffs are from ASRM.
- 24.Mao C, Grimes, DA. The sperm penetration assay: can it discriminate between fertile and infertile men? Am J Obstet Gynecol 1988;159:279-86. Diagnostic evaluation of the infertile male: A Committee Opinion. ASRM Fertil Steril 2012;98:294-301.
- 25. Indications for ICSI according to ASRM, Intracytoplasmic sperm injection (ICSI) for non-male factor infertility: a committee opinion Fertil Steril\_ 2012;98:1395–9.
- 26.Intracytoplasmic Sperm Injection (ICSI) for non-male factor indications: A Committee Opinion.

  American Society for Reproductive Medicine and Society for Assisted Reproductive Technology. Fertil Steril 2020; 114:239-45.
- 27. Fertility preservation in patients undergoing gonadotoxic therapy or gonadectomy: A committee opinion. ASRM Fertility and Sterility 2019; 112:1022-22.
- 28. Practice Committee Report, Mature egg cryopreservation: A guideline, Practice Committee of the American Society of Reproductive Medicine, Fertility and Sterility. 2013 Jan;99(1):37-43. Age limit is based on statement from here "age stratified CPR per transfer were: 48.6% in ≤34 year-olds, 24.1% in 35-37 year olds, 23.3% in 38-40 year-olds, and 22.2% in 41-43 year-olds."
- 29. Diagnostic evaluation of the infertile male: A Committee Opinion. ASRM Fertil Steril 2012;98:294-301.
- 30. Chapter 14 the Infertile Couple by Rein MS, Barbieri RL in Kistner's Gynecology and Women's Health, 7th Edition, Mosby, St. Louis, 1999, pp 325-364. Obstructive abnormalities of the vas deferens, Part III, page 358.
- 31. High serum FSH levels in men with nonobstructive azoospermia does not affect success of microdissection testicular sperm extraction. Ramasamy, R et al Fertil Steril 2009;92:590-3.
- 32. Overweight men with nonobstructive azoospermia have worse pregnancy outcomes after Microdissection testicular sperm extraction. Ramasamy, R et al Fertil Steril 2013;99:372-6.
- 33. Smoking and infertility: a committee opinion. ASRM. Fertil Steril\_ 2012;98:1400-6.
- 34. Obesity increases the risk of spontaneous abortion during infertility treatment. Wang JX; Davies MJ; Norman RJ Obes Res 2002 Jun;10(6):551-4. Obesity and reproduction: an educational bulletin. ASRM Fertil Steril 2008;90:S21-9.
- 35. Third Party Reproduction: A Guide for Patients. ASRM. 1996.
- 36. Vuong, L, Dang, V, Ho, T et al. IVF Transfer of Fresh or Frozen Embryos in Women without Polycystic Ovaries. N Engl J Med 2018; 378:137-147.