

EFFECTIVE DATE: 01|01|2024

POLICY LAST UPDATED: 10|18|2023

OVERVIEW

The policy addresses medical necessity criteria and coverage guidelines related to the treatment of infertility for members assigned female at birth using assisted reproductive technology such as artificial intrauterine insemination (IUI) or in vitro fertilization (IVF). While IUI is addressed in this policy, this service is not impacted by benefit limits or the prior authorization process. However, the member must meet eligibility criteria for coverage of IUI.

This policy also addresses the eligibility criteria for coverage of donor eggs and sperm, as well as the medical necessity criteria for services used for the preservation of members' own eggs, embryos, sperm or other tissues when undergoing medical treatment that may result in iatrogenic infertility.

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

Single Embryo Transfer (SET)

Single embryo transfer (SET) in vitro fertilization is medically necessary when the member has met the eligibility criteria to treat infertility for members assigned female at birth (written below in the Policy Statement section).

If the cycle is beyond 4 cycles, please see the additional medical criteria that needs to be met below.

Multiple Embryo Transfer (MET)

Multiple embryo transfer (MET) in vitro fertilization is medically necessary when the member has met the eligibility criteria to treat infertility for members assigned female at birth (written below in the Policy Statement section) and must have ONE of the following criteria below:

- Members less than 35 years of age who have diminished ovarian reserve or have had an unsuccessful single embryo transfer (SET).
- Members (any age) who have undergone 2 unsuccessful Single Embryo Transfers - in vitro fertilization (IVF) treatment cycles using donor eggs
- Members who are 35 years old and prior to 38th birthday after either:
 - had an unsuccessful first treatment cycle using their own fresh or frozen embryo, OR
 - had a prior successful in vitro fertilization (IVF) treatment cycle followed by a one failed single embryo transfer (SET)
- Members ages 38 years and older undergoing in vitro fertilization (IVF) treatment

If the cycle is beyond 4 cycles, please see the additional medical criteria that needs to be met below.

After 4 In Vitro Fertilization (IVF) Cycles

After 4 in vitro fertilization (IVF) cycles [single embryo transfer (SET) or multiple embryo transfer (MET)] that do not result in pregnancy and delivery, the requesting physician must provide the following information for review to determine if further transfer procedures will be approved (Must Have ALL):

- Documentation regarding the number and type of all past in vitro fertilization (IVF)/artificial intrauterine insemination (IUI) attempts.
- Details of a revised in vitro fertilization (IVF) methodology and the predicted success rate supported by literature statements of using the revised in vitro fertilization (IVF) methodology.

- Documentation that the patient has been informed of the predicted success rate and accepts the proposed services.

Note: For the purpose of the cycle limit of this policy, each embryo transfer procedure (whether single or multiple embryo) is considered 1 cycle. These transfers can be with fresh or frozen embryos. If pregnancy is not achieved, a new cycle will start with the next embryo transfer.

Services Related to Iatrogenic Infertility

Members not in active infertility treatment and are undergoing medical treatment that may result in infertility:

- Retrieval and cryopreservation of eggs, embryos, sperm or other tissues are covered for members not in active infertility treatment when a medically necessary medical treatment may directly or indirectly cause iatrogenic infertility. Iatrogenic infertility means an impairment of fertility by surgery, radiation, chemotherapy, or other medical treatment (including gender reassignment services) affecting reproductive organs or processes.

PRIOR AUTHORIZATION

Prior authorization is required for Medicare Advantage Plans and recommended for Commercial Products.

No prior authorization is needed for any cycle in which artificial intrauterine insemination (IUI) only is rendered.

POLICY STATEMENT

The following services are addressed in this policy:

- Testing for Infertility
- In Vitro Fertilization Eligibility Criteria to Treat A or B
 - A. Infertility for Members Assigned Female at Birth (AFAB)
 - B. Infertility for Members Assigned Male at Birth (AMAB)
- Coverage for Donor Eggs and Sperm
- Non-Covered Services
- Previous Sterilization
- Normal Menopause

Testing for Infertility

Testing to determine the diagnosis of infertility is a covered service and not subject to the infertility benefit in this policy.

In Vitro Fertilization Eligibility Criteria to Treat; Infertility for Members Assigned Female at Birth (A) OR Infertility for Members Assigned Male at Birth (B)

A. Eligibility Criteria, for services to treat infertility for members AFAB (must meet 1-3):

1. A member must have a documented inability to conceive after a period of 1 year of unprotected intercourse with exposure to sperm or 6 months if 35 years or older.

Note: For a member who has miscarried, the duration of time attempted to conceive prior to achieving that pregnancy shall be included in the calculation of the 1-year or 6-month period above, as applicable.

For members AFAB, ages 39 and younger, without exposure to sperm, infertility is determined based on the inability to conceive after 6 artificial insemination (AI) (intra-cervical insemination or artificial intrauterine insemination (IUI) cycles performed by a qualified specialist using donor sperm). AI cycles with donor sperm are not a covered benefit because

the diagnosis of infertility cannot be established until the cycles are completed. The 6 failed cycles must include the following number of documented failed medicated assisted artificial intrauterine insemination (IUI) cycles to qualify for in vitro fertilization (IVF) services:

- Members younger than 35 years old: 3 medicated artificial intrauterine insemination (IUI) cycles
- Members 35-39 years old: 2 medicated artificial intrauterine insemination (IUI) cycles

In addition, all costs associated with these six (6) artificial intrauterine insemination (IUI) cycles, including but not limited to the cost of donor sperm, (procurement, processing and storage), prescription medications, and professional, technical and facility charges are at the member's expense.

For members AFAB, ages 40 and older, without exposure to sperm, infertility is determined based on the inability to conceive after 3 artificial insemination (AI) (intra-cervical insemination or artificial intrauterine insemination (IUI) cycles performed by a qualified specialist using donor sperm). AI cycles with donor sperm are not a covered benefit because the diagnosis of infertility cannot be established until the cycles are completed. The 3 failed cycles must include the following number of documented failed medicated assisted artificial intrauterine insemination (IUI) cycles to qualify for in vitro fertilization (IVF) services:

- Members 40 and older = no medicated IUI cycles are required

In addition, all costs associated with these three (3) artificial intrauterine insemination (IUI) cycles, including but not limited to the cost of donor sperm, (procurement, processing and storage), prescription medications, and professional, technical and facility charges are at the member's expense.

2. The members attempting to conceive must be presumably healthy without a history of past sterilization (or reversal).
3. For members AFAB, a postmenopausal state must not be the cause of infertility, unless the member is under age 43 and had premature ovarian failure.

Services to treat infertility for member AFAB (artificial intrauterine insemination (IUI) and in vitro fertilization (IVF) [SET (single embryo transfer) or MET (multiple embryo transfer)] are covered for members that meet eligibility criteria. For members that do not meet the eligibility criteria above, services will be denied as not covered as these services would be considered a non-covered benefit.

For members who meet the eligibility criteria, in vitro fertilization (IVF) with SET (single embryo transfer) or MET (multiple embryo transfer) is medically necessary when the medical criteria above are met. Services not meeting the criteria are not medically necessary.

Continued in vitro fertilization (IVF) services after 4 consecutive in vitro fertilization (IVF) cycles that do not result in pregnancy and delivery is considered medically necessary when all of the medical criteria above has been met.

B. Treatment of infertility for members assigned male at birth (AMAB)

In vitro fertilization is covered when the member has been confirmed as having moderate to severe* infertility that cannot be improved by conservative standard treatments.

*Severe infertility is defined with the following parameters documented on 2 semen analyses showing:

- I. < 10 million total motile sperm/ejaculate (pre-wash specimen); or
- II. < 3 million total motile sperm (post-wash specimen); or
- III. ≤ 2% normal forms (Strict Kruger Morphology)

The following services are covered:

- Intracytoplasmic Sperm Injection (ICSI)
- MESA (Microsurgical epididymal sperm aspiration)
- TESE (Testicular Sperm Extraction)
- TESA (Testicular Sperm Aspiration)

Hyaluronan Binding Assay for sperm evaluation is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Coverage for Donor Eggs and Sperm

Egg Bank

Donor eggs (gametes) are covered when the member meets the criteria for services to treat infertility for members AFAB. If donor eggs are obtained through an egg bank, reimbursement is provided for the cost of the eggs. Additional services related to the implantation of the embryo are covered and maybe billed to the member by the facility and provider performing the implantation services.

In cases where the member has been billed directly, the member must use the below-attached claim form for member submitted claims:

[Donor Egg and Sperm Reimbursement Form](#)

Egg Donation Facilitation Agency

Services provided by an egg donation facility agency are not covered as these charges are not related to the egg donation. These agencies generally facilitate the contractual agreements between the member and the egg donor. Some agencies will also cover transportation costs for the donor, which is also not a covered service. Once the donor is identified, all services related to egg retrieval including medication are covered. Egg retrieval and other services related to the implantation maybe billed to the member by the participating facility that is providing the implantation.

Donor Sperm

Donor sperm is covered;

- as part of treatment for infertility for members AFAB when the eligibility criteria for infertility have been met, and there is a need for donor sperm, either because there is no partner AMAB or the partner has been diagnosed as having infertility for members AMAB
- for treatment of confirmed infertility for members AMAB (and not the result of a sterilization procedure), even when there is no infertility for members AFAB

Donor sperm can be obtained from a sperm bank or a known donor. Services related to the procurement of the sperm are covered. Fees associated with collection and finding a donor are not covered.

Non-Covered Services

The following services are not covered:

- Freezing, storage and thawing of embryos, sperm, or other tissues, for future use, unless the freezing, storage and thawing is needed due to potential iatrogenic infertility.
- Reversal of voluntary sterilization or infertility treatment for a person that previously had a voluntary sterilization procedure.
- Fees associated with finding an egg or sperm donor, related storage, donor stipend, or shipping charges.
- Services related to surrogate parenting, when the surrogate is not a member of this plan.

Previous Sterilization

Services to treat infertility are excluded by contract for members who have previously undergone a sterilization procedure. Only in cases where there is medical certainty that a prior sterilization procedure is in no manner related to the present inability to conceive or sustain pregnancy will it be determined that the contractual exclusion is not applicable.*

*Requests for infertility services for a member who has undergone a previous sterilization procedure will undergo review by a clinician. A determination that the contractual exclusion does apply (i.e., that inability may be related to a previous sterilization procedure) is an administrative denial and does not involve medical necessity review.

Normal Menopause/Premature Ovarian Failure

Members whom have underdone normal menopause do not meet medically necessity criteria for infertility services. Amenorrhea and an elevated FSH (follicle stimulating hormone) after age 42 is considered to be normal menopause. Menopause occurring prior to age 42 is not considered normal menopause, as defined in this policy.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for applicable coverage.

BACKGROUND

Infertility treatment is included in the Rhode Island Benchmark Plan that defines the EHBs for RI QHPs. Federal mandates regarding EHBs supersede RI state mandates with regards to removing any annual and lifetime dollar limits. **Also, Blue Cross & Blue Shield of Rhode Island (BCBSRI) does not restrict services based on age.**

The following is the State of Rhode Island Mandate regarding coverage of infertility services for ~~female~~ members assigned female at birth **§ 27-20-20. Coverage for infertility.**

(a) Any nonprofit medical service contract, plan, or insurance policies delivered, issued for delivery, or renewed in this state, except contracts providing supplemental coverage to Medicare or other governmental programs, that includes pregnancy-related benefits, shall provide coverage for the medically necessary expenses of diagnosis and treatment of infertility for women between the ages of twenty-five (25) and forty-two (42) years and for standard fertility-preservation services when a medically necessary medical treatment may directly or indirectly cause iatrogenic infertility to a covered person. To the extent that a nonprofit medical service corporation provides reimbursement for a test or procedure used in the diagnosis or treatment of conditions other than infertility, those tests and procedures shall not be excluded from reimbursement when provided attendant to the diagnosis and treatment of infertility for women between the ages of twenty-five (25) and forty-two (42) years.; provided, that subscriber copayment, not to exceed twenty percent (20%), may be required for those programs and/or procedures the sole purpose of which is the treatment of infertility.

(b) For purposes of this section, "infertility" means the condition of an otherwise presumably healthy individual who is unable to conceive or sustain a pregnancy during a period of one year.

(c) For the purposes of this section, "standard fertility-preservation services" means procedures consistent with established medical practices and professional guidelines published by the American Society for Reproductive Medicine, the American Society of Clinical Oncology, or other reputable professional medical organizations.

(d) For the purposes of this section, "iatrogenic infertility" means an impairment of fertility by surgery, radiation, chemotherapy, or other medical treatment affecting reproductive organs or processes.

(e) For the purposes of this section, "may directly or indirectly cause" means treatment with a likely side effect of infertility as established by the American Society for Reproductive Medicine, the American Society of Clinical Oncology, or other reputable professional organizations.

(f) The health insurance contract may limit coverage to a lifetime cap of one hundred thousand dollars (\$100,000).

Definitions:

Artificial Intrauterine Insemination (IUI)

Artificial insemination by IUI process bypasses the cervix, allowing the sperm to target the ova without being slowed or stopped by the lower portions of the reproductive tract. For this reason, ICI (intracervical insemination) is rarely used. When IUI is used in conjunction with ultrasound to track follicular development, the procedure can be timed to maximize the chances for getting pregnant. Fertility drugs may also be used.

Assisted Hatching

One key component of a successful attempt at in vitro fertilization is implantation of the embryo in the uterus. Although the exact steps in implantation are poorly understood, one critical component is thought to be the normal rupture of the surrounding zona pellucida with escape of the developing embryo, termed hatching. It is hypothesized that during the in vitro component of the in vitro fertilization, the zona pellucida becomes hardened, thus impairing the hatching process. Alternatively, some embryos may have some inherent inability to induce thinning of the zona pellucida before hatching. In either case, mechanical disruption of the zona pellucida (i.e., assisted hatching) has been proposed as a mechanism to improve implantation rates.

Randomized controlled trials (RCTs) and meta-analyses of these trials have not found that assisted hatching significantly improves the live birth rate compared to a control intervention. Meta-analyses of heterogeneous studies have found that the clinical pregnancy rate is improved with assisted hatching.

Blastocyst Transfer

This refers to the extended culture of oocytes/embryos, i.e., for greater than 4 days. The rationale behind blastocyst transfer is that embryos progressing to the blastocyst stage have a much greater chance of implanting successfully in the uterus and resulting in an ongoing pregnancy. Due to the higher probability of implantation, it is thought that fewer blastocysts can be transferred, ultimately resulting in a decreased incidence of triplets and higher-order pregnancies.

According to evidence from RCTs, observational studies and meta-analyses of published studies, blastocyst transfer results in higher live birth rates compared to cleavage stage transfer. Based on evidence from RCTs of a higher live birth rate than cleavage-stage embryo transfer, as well as on supportive clinical input, blastocyst transfer may be considered medically necessary.

Embryo Co-Culture

In routine in vitro fertilization (IVF) procedures, the embryo is transferred to the uterus on day 2 or 3 of development, when it has between 4 and 8 cells. However, with this approach the implantation rate is estimated to be between 5% and 30%, potentially related to the fact that under normal conditions the embryo reaches the uterus at a blastocyst stage of development. Embryo co-culture techniques, used successfully in domestic animals, represent an effort to improve the culture media for embryos such that a greater proportion of embryos will reach the blastocyst stage, in hopes of improving the implantation and pregnancy rate. In addition, if co-culture results in a higher implantation rate, fewer embryos could be transferred at each cycle, resulting in a decreased incidence of multiple pregnancies. A variety of co-culture techniques have been investigated, involving the use of feeder cell layers derived from a range of tissues, including the use of human reproductive tissues (i.e., oviducts) to non-human cells (i.e., fetal bovine uterine or oviduct cells) to established cell lines (i.e., Vero cells or bovine kidney cells). However, no standardized method of co-culture has emerged, and no controlled trials have evaluated an improved implantation or pregnancy rate associated with co-culture. (3-8) For example, Wetzels and colleagues reported on a study that randomized in vitro fertilization (IVF) treatments to include co-culture with human fibroblasts or no culture. (8) Patients in the 2 groups were stratified according to age (older or younger than 36 years) and prior in vitro fertilization (IVF) attempts (yes vs. no). The authors reported that fibroblast co-culture did not affect the implantation or the pregnancy rate. Updated literature reviews did not identify any additional published studies that would prompt reconsideration of the relevant policy statement. There is a lack of controlled trials demonstrating improved outcomes with co-culture, and no standardized method of co-culture has emerged in the literature.

Fertility Treatment

Once the condition of infertility or recurrent pregnancy loss has been established fertility services typically include artificial intrauterine insemination, and assisted reproductive technology (ART) services such as in vitro fertilization, including assisted oocyte fertilization, also known as intra-cytoplasmic sperm injection, frozen/cryo embryo transfer, preimplantation genetic testing, zygote intra-fallopian transfer and gamete intra-fallopian transfer, donor oocyte procedures, and assisted embryo hatching.

In Vitro Fertilization (IVF)

In vitro fertilization is a method of assisted reproduction that involves combining an egg with sperm in a laboratory dish. If the egg fertilizes and begins cell division, the resulting embryo is transferred into the individual's uterus where it will hopefully implant in the uterine lining and further develop. In vitro fertilization (IVF) bypasses the fallopian tubes and is usually the treatment choice for those whom have badly damaged tubes.

Services received as part of an in vitro fertilization (IVF) procedure may include office visits, drugs, lab and pathology, surgical procedures, etc. Mechanically assisted fertilization (MAF) may be performed as part of an in vitro fertilization (IVF) procedure. Such procedures include Zona "drilling" or (PZD) where the zona pellucida of the oocyte is mechanically interrupted so as to assist sperm entry, and intracytoplasmic sperm injection.

Modifications of the in vitro fertilization (IVF) procedure include such procedures as GIFT (gamete intrafallopian transfer), ZIFT (zygote intrafallopian transfer), PROST (pronuclear stage transfer), TEST (tubal embryo stage transfer), and TET (tubal embryo transfer). While many of the services received during these procedures are similar to in vitro fertilization (IVF), in GIFT, eggs and sperm are transferred to the fallopian tube where fertilization occurs. In ZIFT, PROST, TEST, and TET, fertilized embryos are transferred at various stages of development into the fallopian tube, either from the fimbrial end via laparoscopy or through catheterization of the uterine end, the latter with or without ultrasound guidance.

A typical in vitro fertilization (IVF) cycle may consist of the steps noted below, all of which take place during one menstrual cycle:

1. **Controlled ovarian hyperstimulation.**
Fertility drugs are administered to stimulate the ovaries so that multiple follicles and eggs develop. In a normal cycle, the ovaries typically make and release only one egg.
2. **Egg retrieval.**
The eggs are typically removed from the ovaries in an outpatient surgical setting. The fertility doctor uses a needle passed through the vagina under ultrasound guidance to aspirate the fluid from the follicles and pull out the egg.
3. **In vitro fertilization.**
The eggs are placed with sperm in the laboratory dish, or the embryologist may use a procedure known as intracytoplasmic sperm injection (ICSI) in which one sperm is injected directly into the egg for fertilization.
4. **Uterine embryo transfer.**
The embryos are transferred into the individual's uterus using a tiny catheter and ultrasound guidance.
5. **Monitoring and support.**
The fertility specialists will monitor the individual to check blood levels to assess the quality of the uterine lining. If the individual gets pregnant, the individual will have an ultrasound two weeks after a positive result to check for the fetal heartbeat.

Intracytoplasmic Sperm Injection (ICSI) for infertility for members AMAB

ICSI is performed in cases of infertility when either insufficient numbers of sperm, abnormal morphology, or poor motility preclude unassisted in vitro fertilization. Using ICSI, fertilization rates of up to 76% have been reported, considerably better than the competing technique of sub-zonal insemination (up to 18%), in which

sperm are injected into the perivitelline space (as opposed to into the oocyte itself), and by definition better than the negligible to absent fertilization rates seen in patients with infertility. Fertilization rates represent an intermediate outcome; the final outcome is the number of pregnancies per initiated cycle or per embryo transfer, reported in the largest series as 44.7% and 49.6%, respectively. (26-30) These rates are very competitive with those of the standard *in vitro* fertilization. A 2012 committee opinion of the American Society of Reproductive Medicine and Society for Assisted Reproductive Technology stated that ICSI is a safe and effective treatment for infertility. (31) The document also stated that ICSI for unexplained fertility, low oocyte yield and advanced maternal age does not improve clinical outcomes. The opinion included a statement that ICSI may be beneficial for patients undergoing *in vitro* fertilization with preimplantation genetic testing, *in vitro* matured oocytes and cryopreserved oocytes.

There are data indicating that intracytoplasmic sperm injection for infertility for members AMAB has a relatively high rate of successful pregnancy.

Intracytoplasmic sperm injection has a relatively high rate of successful live births for treatment of infertility for members AMAB due to low sperm count and/or impaired sperm motility. ICSI for infertility and cryopreservation of testicular tissue in adults with azoospermia as part of an ICSI injection procedure received support from clinical reviewers. These techniques may be considered medically necessary.

Single Embryo Transfer

The transfer of a single embryo at either the cleavage stage (day 2 or 3 after an egg retrieval) or blastocyst stage (day 5 or 6 after an egg retrieval), that is selected from a larger number of available embryos. This is the best way to reduce the health risks of multiple gestations.

In a clinical based study, a total of 886,686 fresh, nondonor cycles reported to the National Assisted Reproductive Technology Surveillance System during 1999–2010, of which 17,166 met criteria for elective single Embryo Transfer (ET). The main measure of the study was to determine the rates of elective single ET and good perinatal outcome (term, singleton infant with normal birth weight). In 2010, elective single ET comprised 5.6% of all fresh transfers, representing an eightfold increase since publication of first guidelines in 2004 recommending elective single ET. Compared with other ETs, elective single ETs were nearly twice as likely to result in a good perinatal outcome (37.1% vs. 18.9%, respectively). Among members AFAB using elective single ET, those aged <35 and 35–37 years had a good perinatal outcome (40.2% and 32.5%, respectively). In multivariable, log-binomial analyses, factors positively associated with a good perinatal outcome included infertility for members AMAB, day 5 ET, and having ≥ 3 supernumerary embryos for cryopreservation. Between 1999 and 2010, national rates of elective single ET increased. Given the frequency of good perinatal outcomes among members AFAB aged 35–37 years, guidelines for elective single ET could be expanded to include patients in this age group with favorable prognoses.

Surrogate

An embryo is placed in the womb of an individual other than the member, and the “surrogate” (not the member) carries the baby. In the case of a surrogate, the embryo does not come from the member’s egg, so the baby is not biologically related to the member. A gestational surrogate is a variation where the egg is donated from one individual other than the member and the embryo is placed into a different individual that is not the member or the egg donor. A usual surrogate is the egg donor and then carries the pregnancy. All services related to surrogate parents are excluded from coverage when the surrogate is not a member of this plan.

MESA

Microepididymal Sperm Aspiration (MESA) is a procedure performed for members who have vasal or epididymal obstruction (s/p vasectomy, congenital bilateral absence of the vas deferens). It is either done as a scheduled procedure or is coordinated with an egg retrieval. MESA is performed in the operating room with general anesthesia utilizing the operating microscope. Individuals usually cryopreserve sperm during this procedure for future IVF/ICSI. MESA allows for an extensive collection of mature sperm as compared to

aspiration techniques, and it is the preferred method of retrieval for those with congenital bilateral absence of the vas deferens as it does not impact steroid production of the testis.

TESA

Testicular sperm aspiration (TESA) is a procedure performed for members who are having sperm retrieved for IVF/ICSI. It is done with local anesthesia in the operating room or office and is coordinated with an egg retrieval. A needle is inserted in the testicle and tissue/sperm are aspirated. Occasionally, TESA doesn't provide enough tissue/sperm and an open testis biopsy is needed.

TESE

Testicular sperm extraction (TESE) involves making a small incision in the testis and examining the tubules for the presence of sperm. It is either done as a scheduled procedure or is coordinated with an egg retrieval. TESE is usually performed in the operating room with sedation, but can be performed in the office with local anesthesia alone. Individuals usually cryopreserve sperm during this procedure for future IVF/ICSI. MicroTESE has replaced this as the optimal form of retrieval for those with no sperm in their ejaculate (azoospermia) from a problem with production.

Hyaluronan Binding Assay

The hyaluronan binding assay (HBA) evaluates the maturity of sperm in a fresh semen sample. The HBA is a simple technique proposed as a component of the standard semen analysis in the diagnosis of suspected infertility, to predict sperm performance and fertilization potential.

CODING

Medicare Advantage Plans and Commercial Products

The following code(s) are medically necessary under the member's infertility benefit when the eligibility and medical necessity criteria above are met:

58970	Follicle puncture for oocyte retrieval, any method
58974	Embryo transfer, intrauterine
58976	Gamete, zygote or embryo intrafallopian transfer, any method
76948	Ultrasonic Guidance for aspiration of ova, imaging supervision and interpretation
89250	Culture of oocyte(s)/embryo(s), less than 4 days
89251	Culture of oocyte(s)/embryo(s), less than 4 days; with co-culture of oocyte(s) embryo(s)
89253	Assisted embryo hatching, microtechniques (any method)
89254	Oocyte identification from follicular fluid
89280	Assisted oocyte fertilization, microtechnique; less than or equal to 10 oocytes
89281	Assisted oocyte fertilization, microtechnique; greater than 10 oocytes
S4011	In vitro fertilization; including but not limited to identification and incubation of mature oocytes, fertilization with sperm, incubation of embryo(s), and subsequent visualization for determination of development
S4013	Complete cycle, gamete intrafallopian transfer (GIFT), case rate
S4014	Complete cycle, zygote intrafallopian transfer (ZIFT), case rate
S4015	Complete in vitro fertilization cycle, not otherwise specified, case rate
S4016	Frozen in vitro fertilization cycle, case rate
S4017	Incomplete cycle, treatment cancelled prior to stimulation, case rate
S4018	Frozen embryo transfer procedure cancelled before transfer, case rate (NSR)
S4020	In vitro fertilization procedure cancelled before aspiration, case rate
S4021	In vitro fertilization procedure cancelled after aspiration, case rate
S4022	Assisted oocyte fertilization, case rate
S4023	Donor egg cycle, incomplete, case rate
S4025	Donor services for in vitro fertilization (sperm or embryo), case rate
S4042	Management of ovulation induction (interpretation of diagnostic tests and studies, non-face-to-face medical management of the patient), per cycle

Note: BCBSRI-participating facilities primarily use “S” codes when reporting infertility/in vitro fertilization services.

The following code(s) are medically necessary when the medical necessity criteria of iatrogenic infertility has been met, for all other members, they are not covered:

- 89258** Cryopreservation; embryo(s)
- 89259** Cryopreservation; sperm
- 89335** Cryopreservation, reproductive tissue, testicular
- 89337** Cryopreservation, mature oocyte(s)
- 89342** Storage (per year); embryo(s)
- 89343** Storage (per year); sperm/semen
- 89344** Storage (per year); reproductive tissue, testicular/ovarian
- 89346** Storage (per year); oocyte
- 89354** Thawing of cryopreserved; reproductive tissue; testicular/ovarian
- 89356** Thawing of cryopreserved; oocytes, each aliquot
- S4027** Storage of previously frozen embryos
- S4040** Monitoring and storage of cryopreserved embryos, per 30 days

The following service(s) may also be used for the diagnostic evaluation of infertility and therefore NOT considered part of the infertility benefit. These service(s) are covered under the applicable benefit.

- 55200** Vasotomy, cannulization with or without incision of Vas, unilateral or bilateral (separate procedure) (surgery)
- 58350** Chromotubation of oviduct, including materials
- 58750** Tubotubal anastomosis
- 88349** Electron microscopy; scanning (lab)
- 89300** Semen analysis; presence and/or motility of sperm including Huhner test (post coital) (lab)
- 89310** Semen analysis; motility and count (not including Huhner test) (lab)
- 89320** Semen analysis; complete (volume, count, motility and differential) (lab)
- 89321** Semen analysis, presence and/or motility of sperm
- 89322** Semen analysis: volume, count, and differential using strict morphologic criteria (e.g., Kruger) (lab)
- 89325** Sperm antibodies (lab)
- 89329** Sperm evaluation; hamster penetration test (lab)
- 89330** Sperm evaluation; cervical mucus penetration test, with or without spinnbarkeit test (lab)
- 89331** Sperm evaluation; for retrograde ejaculation, urine (sperm concentration, motility, and morphology as indicated) (lab)

The following infertility service(s) are covered under the members infertility benefit and no preauthorization is needed:

- 55870** Electroejaculation
- 58321** Artificial insemination; intra-cervical
- 58322** Artificial insemination; intra-uterine
- 58323** Sperm washing for artificial insemination
- 89257** Sperm identification from aspiration (other than seminal fluid)
- 89260** Sperm isolation; simple prep (e.g., sperm wash and swim-up) for insemination or diagnosis with semen analysis
- 89261** Sperm isolation; complex prep (e.g., Percoll gradient, albumin gradient) for insemination or diagnosis with semen analysis
- 89264** Sperm identification from testis tissue, fresh or cryopreserved
- S3655** Antisperm antibodies test (immunobead)
- S4026** Procurement of donor sperm from sperm bank
- S4028** Microsurgical epididymal sperm aspiration (MESA)
- S4030** Sperm procurement and cryopreservation services; initial visit

- S4031** Sperm procurement and cryopreservation services; subsequent visit
S4035 Stimulated intrauterine insemination (IUI), case rate

The following code(s) are covered but not separately reimbursed:

- 89255** Preparation of embryo for transfer (any method)
89268 Insemination of oocytes
89272 Extended culture of oocyte(s)/embryo(s), 4-7 days
89352 Thawing of cryopreserved; embryo(s)
89353 Thawing of cryopreserved; sperm/semens, each aliquot
S4037 Cryopreserved embryo transfer, case rate

The following code(s) are non-covered:

- 55400** Vasovasostomy, vasovasorrhaphy
NOTE: If 55400 Vasovasostomy/vasovasorrhaphy is performed for other than reversal of sterilization, it may be reviewed by a clinician.
88240 Cryopreservation, freezing and storage of cells, fees associated with storage are covered each cell line
88241 Thawing and expansion of frozen cells, each aliquot

Note: There are no specific CPT code(s) for the following services: hyaluronan binding sperm evaluation assay, TESE (testicular sperm extraction) nor for TESA (testicular sperm aspiration).

The following CPT code may be used:

- 89398** Unlisted reproductive medicine laboratory procedure

RELATED POLICIES

Gender Affirming Care
Non-Reimbursable Health Service Codes
Pre-Implementation Genetic Diagnosis
Prior Authorization via Web-Based Tool for Procedures
Unlisted Procedures

PUBLISHED

Provider Update, November 2023
Provider Update, June 2022
Provider Update, May 2021
Provider Update, November 2020
Provider Update, December 2019

REFERENCES

1. Carney SK, Das S, Blake D, et al. Assisted hatching on assisted conception (in vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI). *Cochrane Database Syst Rev.* Dec 2012;12:CD001894. PMID 23235584
2. Shi W, Hongwei T, Zhang W, et al. A prospective randomized controlled study of laser-assisted hatching on the outcome of first fresh IVF-ET cycle in advanced age women. *Reprod Sci.* Oct 2016;23(10):1397-1401. PMID 27071963
3. Kanyo K, Zeke J, Kriston R, et al. The impact of laser-assisted hatching on the outcome of frozen human embryo transfer cycles. *Zygote.* Oct 2016;24(5):742-747. PMID 26957232
4. Knudtson, Failor C, M., Gelfond JA, et al. Assisted hatching and live births in first-cycle frozen embryo transfers. *Fertil Steril.* Aug 30 2017;108(4):628-634. PMID 28863938
5. Kissin DM, Kawwass JF, Monsour M, et al. Assisted hatching: trends and pregnancy outcomes, United States, 2000-2010. *Fertil Steril.* Sep 2014;102(3):795-801. PMID 25044084
6. Wiemer KE, Cohen J, Tucker MJ, et al. The application of co-culture in assisted reproduction: 10 years of experience with human embryos. *Hum Reprod.* Dec 1998;13(Suppl 4):226-238. PMID 10091073

7. Ohl J, de Mouzon J, Nicollet B, et al. Increased pregnancy rate using standardized coculture on autologous endometrial cells and single blastocyst transfer : a multicentre randomized controlled trial. *Cell Mol Biol (Noisy-le-grand)*. Jan 2015;61(8):79-88. PMID 26718434
8. Donnez J, Dolmans MM, Demylle D, et al. Livebirth after orthotopic transplantation of cryopreserved ovarian tissue. *Lancet*. Oct 16-22 2004;364(9443):1405-1410. PMID 15488215
9. Johnson J, Patrizio P. Ovarian cryopreservation strategies and the fine control of ovarian follicle development in vitro. *Ann N Y Acad Sci*. Mar 2011;1221:40-46. PMID 21401628
10. Practice Committees of American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Mature oocyte cryopreservation: a guideline. *Fertil Steril*. Jan 2013;99(1):37-43. PMID 23083924
11. Cobo A, Meseguer M, Remohi J, et al. Use of cryo-banked oocytes in an ovum donation programme: a prospective, randomized, controlled, clinical trial. *Hum Reprod*. Sep 2010;25(9):2239-2246. PMID 20591872
12. Levi Setti PE, Albani E, Morengi E, et al. Comparative analysis of fetal and neonatal outcomes of pregnancies from fresh and cryopreserved/thawed oocytes in the same group of patients. *Fertil Steril*. Aug 2013;100(2):396-401. PMID 23608156
13. Glujovsky D, Blake D, Farquhar C, et al. Cleavage stage versus blastocyst stage embryo transfer in assisted reproductive technology. *Cochrane Database Syst Rev*. Jul 11 2012;7(7):CD002118. PMID 22786480
14. Glujovsky D, Farquhar C, Quinteiro Retamar AM, et al. Cleavage stage versus blastocyst stage embryo transfer in assisted reproductive technology. *Cochrane Database Syst Rev*. Jun 30 2016(6):Cd002118. PMID 27357126
15. Azimineko E, Mohseni Salehi MS, Kalantari V, et al. Pregnancy outcome after blastocyst stage transfer comparing to early cleavage stage embryo transfer. *Gynecol Endocrinol*. Oct 2015;31(11):880-884. PMID 26437606
16. Fernandez-Shaw S, Cercas R, Brana C, et al. Ongoing and cumulative pregnancy rate after cleavage-stage versus blastocyst-stage embryo transfer using vitrification for cryopreservation: impact of age on the results. *J Assist Reprod Genet*. Feb 2015;32(2):177-184. PMID 25403438
17. Kaur P, Swarankar ML, Maheshwari M, et al. A comparative study between cleavage stage embryo transfer at day 3 and blastocyst stage transfer at day 5 in in-vitro fertilization/intra-cytoplasmic sperm injection on clinical pregnancy rates. *J Hum Reprod Sci*. Jul 2014;7(3):194-197. PMID 25395745
18. Maheshwari A, Kalampokas T, Davidson J, et al. Obstetric and perinatal outcomes in singleton pregnancies resulting from the transfer of blastocyst-stage versus cleavage-stage embryos generated through in vitro fertilization treatment: a systematic review and meta-analysis. *Fertil Steril*. Dec 2013;100(6):1615-1621 e1611-1610. PMID 24083875
19. Ginström Ernstad E, Bergh C, Khatibi A, et al. Neonatal and maternal outcome after blastocyst transfer: a population-based registry study. *Am J Obstet Gynecol*. Mar 2016;214(3):378.e371-378.e310. PMID 26928152
20. Palermo G, Joris H, Derde MP, et al. Sperm characteristics and outcome of human assisted fertilization by subzonal insemination and intracytoplasmic sperm injection. *Fertil Steril*. Apr 1993;59(4):826-835. PMID 8458504
21. Boulet SL, Mehta A, Kissin DM, et al. Trends in use of and reproductive outcomes associated with intracytoplasmic sperm injection. *JAMA*. Jan 20 2015;313(3):255-263. PMID 25602996
22. Rhode Island General Law (RIGL) 27-20-20: Coverage for Infertility.
<http://www.rilin.state.ri.us/Statutes/TITLE27/27-20/27-20-20.HTM>

DRAFT

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

