Medical Coverage Policy | Infertility Services



EFFECTIVE DATE: 10 | 01 | 2020

POLICY LAST UPDATED: 10 | 14 | 2020

OVERVIEW

The policy addresses medical necessity criteria and coverage guidelines related to the treatment of female infertility 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 criteria for coverage of donor eggs and sperm, as well as preservation for members undergoing medical treatment that may result in infertility.

Testing for Infertility

Testing to determine the diagnosis of male or female infertility is a covered service and not applicable to the infertility benefit in this policy.

MEDICAL CRITERIA

Multiple embryo transfer (MET) in vitro fertilization is medically necessary when one of the following criteria is met:

- 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 IVF treatment cycles using donor eggs
- Members who are 35 years old and prior to 38th birthday after either:
 - o had an unsuccessful first treatment cycle using their own fresh or frozen embryo, OR
 - o had a prior successful IVF treatment cycle followed by a one failed SET
- Members ages 38 years and older undergoing IVF treatment

After 4 IVF cycles (SET or 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:

- Documentation regarding the number and type of all past IVF/IUI attempts.
- Details of a revised IVF methodology and the predicted success rate supported by literature statements of using the revised IVF methodology.
- Documentation that the patient has been informed of the predicted success rate and accepts the proposed services.

Members not in active infertility treatment, undergoing medical treatment that may result in infertility: *

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

Retrieval and cryopreservation of eggs, embryos and sperm 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 affecting reproductive organs or processes.

Note: Effective as groups renewed in 2020, fees associated with storage are covered. Refer to the members appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for coverage as this benefit may vary with some groups

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial products for in vitro fertilization cycle only. No prior authorization is needed for any cycle in which IUI only is rendered.

POLICY STATEMENT

Services to treat female infertility (IUI and IVF [SET or MET]) are covered for members that meet eligibility criteria. For members that do not meet the following eligibility criteria, services will be denied as not covered as these services would be considered a non-covered benefit.

Testing for Infertility

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

For members who meet the eligibility criteria, IVF with MET is medically necessary when the medical criteria above are met. Services not meeting the criteria are not medically necessary.

Eligibility Criteria

For services to treat female infertility:

1. A female 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 she 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.

Also, for female members without male partners or without exposure to sperm, infertility is determined based on the inability to conceive after 6 artificial insemination (AI) (intra-cervical insemination or 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 IUI cycles to qualify for IVF services:

Female members younger than 35 years old: 3 medicated IUI cycles Female members 35-39 years old: 2 medicated IUI cycles Female members older than 40: no medicated IUI cycles are required

In addition, all costs associated with these six (6) 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 male and female members attempting to conceive must be presumably healthy without a history of past sterilization (or reversal).
- 3. For female members, a postmenopausal state must not be the cause of infertility, unless the member is under age 43 and had premature ovarian failure.

IVF services after 4 consecutive unsuccessful embryo transfers is considered medically necessary when all of the criteria are met.

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 to treat male infertility are covered when the member has been confirmed as having male infertility.

Coverage for Donor Eggs and Sperm Egg Bank

Donor eggs (gametes) are covered when the member meets the criteria for services to treat female infertility. 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 will be billed by the facility and provider preforming the implantation services.

In cases where the facility has not contracted with BCBSRI, 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 facilitation 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 a 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 will be billed by the participating facility that is providing the implantation.

Donor Sperm

Donor sperm is covered as part of treatment for female infertility when the eligibility criteria for female infertility have been met, and there is a need for donor sperm, either because there is no male partner, or the male partner has been diagnosed as infertile

Donor sperm is covered for treatment of male infertility even when there is no female infertility, when the male infertility is confirmed and not the result of a previous sterilization procedure.

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.

The following services are not covered:

- Freezing and storage of blood, gametes, sperm, embryos, or other tissues for future use for indications other than iatrogenic infertility
- Reversal of voluntary sterilization
- Infertility treatment for an individual that previously had a voluntary sterilization procedure
- Women who meet the definition of normal menopause
- Services related to surrogate parenting, when the surrogate is not a member of this plan.

Previous Sterilization

Services to treat male or female infertility are excluded by contract for individuals 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

Blue Cross & Blue Shield of Rhode Island (BCBSRI) considers normal menopause to be exclusionary. Amenorrhea and an elevated *follicle stimulating* hormone (FSH) after age 42 is considered to be equivalent to 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 Infertility Services coverage.

Many BCBSRI plans have yearly benefit limits of 3 IVF attempts in a 12-month period and a lifetime maximum of 8 IVF attempts not resulting in a successful pregnancy.

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, BCBSRI does not restrict services based on age.

The following is the State of Rhode Island Mandate regarding coverage of infertility services for females <u>§ 27-20-20. Coverage for infertility.</u>

- (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 heterogenous 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

Cryopreservation of Ovarian Tissue – Cryopreservation of ovarian tissue or an entire ovary with subsequent auto- or heterotopic transplant has been investigated as a technique to sustain the reproductive function of women or children who are faced with sterilizing procedures, such as chemotherapy, radiation therapy, or surgery, frequently due to malignant diseases. A variety of articles have focused on the technical feasibility of such an option. There are a few individual case reports of return of ovarian function using this technique. (9, 10) There are also several case series describing live births using cryopreserved ovarian tissue. (11-13) However, in general, the technique is not standardized and has not been sufficiently studied to determine the success rate. (14, 15) In 2011, Johnson and Patrizio commented on whole ovary freezing as a technique of fertility preservation in women with disease or disease treatment that threaten their reproductive tract function. (16) They concluded, "Although theoretically optimal from the point of view of maximal follicle protection and preservation, the risks and difficulties involved in whole ovary freezing limit this technique to experimental situations."

This technique has not been standardized, and there is insufficient published data that cryopreservation of ovarian tissue is an effective and safe reproductive technique.

Cryopreservation of Oocytes – Cryopreservation of oocytes was originally investigated primarily as an alternative to embryo cryopreservation due to ethical or religious reasons. More recently, it has been examined as a fertility preservation option for reproductive-age women undergoing cancer treatment, both single women and those who do not want the option of embryo cryopreservation. The mature oocyte is very fragile due to its large size, high water content, and chromosomal arrangement. For example, the mature oocyte is arrested in meiosis, and as such, the chromosomes are lined up in a meiotic spindle. This spindle apparatus is easily damaged both in freezing and thawing. Survival after thawing may also be associated with sublethal damage, which may further impact on the quality of the subsequent embryo. Moreover, due to the large amount of water, when the oocyte is frozen, ice crystals can form that can damage the integrity of the cell. To reduce or prevent ice crystals, oocytes are dehydrated using cryoprotectants, which replace the water in the cell. The most common method of freezing oocytes is a controlled-rate slow-cooling method. A newer technique involves a flash-freezing process known as vitrification. This technique is faster, yet requires a higher concentration of cryoprotectants.

There are insufficient published data on the safety and efficacy of cryopreservation of oocytes; data are only available from select clinical settings and select populations.

Cryopreservation of Testicular Tissue – Testicular sperm extraction refers to the collection of sperm from testicular tissue in men with azoospermia. Extraction of testicular sperm may be performed at the time of a diagnostic biopsy or performed as a subsequent procedure, specifically for the collection of spermatozoa. The spermatozoa may be isolated immediately, and a portion used for an intracytoplasmic sperm injection (ICSI) procedure at the time of oocyte retrieval from the partner, with the remainder cryopreserved. Alternatively, the entire tissue sample can be cryopreserved with portion thawed and sperm isolation performed at subsequent ICSI cycles. This technique appears to be a well-established component of the overall ICSI procedure; cryopreservation of either the isolated sperm or the tissue sample eliminates the need for multiple biopsies to obtain fresh tissue in the event of a failed initial ICSI cycle. (32) However, a unique application of cryopreservation of testicular tissue is its use to potentially preserve the reproductive capacity in prepubertal boys undergoing cancer chemotherapy; the typical cryopreservation of an ejaculate is not an option in these patients. It is hoped that re-implantation of the frozen-thawed testicular stem cells will re-initiate spermatogenesis, or alternatively, spermatogenesis could be attempted in vitro, using frozen-thaw spermatogonia. While these strategies have been explored in animals, there are inadequate human studies. (33, 34) Cryopreservation of testicular tissue in adult men with ozoospermia is a well-established component of the ICSI procedure.

Embryo Co-Culture – In routine 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 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 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 woman's uterus where it will hopefully implant in the uterine lining and further develop. IVF bypasses the fallopian tubes and is usually the treatment choice for women who have badly damaged or absent tubes.

Services received as part of an IVF procedure may include office visits, drugs, lab and pathology, surgical procedures, etc. Mechanically assisted fertilization (MAF) may be performed as part of an 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 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 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 IVF cycle may consist of the steps noted below, all of which take place during one menstrual cycle:

- Controlled ovarian hyperstimulation.
 Fertility drugs are administered to the women 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 woman's uterus using a tiny catheter and ultrasound guidance.
- 5. Monitoring and support.
 - The fertility specialists will monitor the woman to check blood levels to assess the quality of the uterine lining. If the woman gets pregnant, she will have an ultrasound two weeks after a positive result to check for the fetal heartbeat.

Intracytoplasmic Sperm Injection (ICSI) for male factor infertility – ICSI is performed in cases of male factor 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 male factor 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 male factor 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 male factor infertility has a relatively high rate of successful pregnancy.

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

The evidence is insufficient to permit conclusions concerning the effectiveness of the following reproductive techniques: assisted hatching; co-culture of embryos; cryopreservation of ovarian tissue or oocytes; cryopreservation of testicular tissue in prepubertal boys; and storage and thawing of ovarian tissue, oocytes, or testicular tissue. For these procedures, there is a lack of published data on live birth rates, the incidence of multiples and neonatal and child outcomes, compared to established reproductive techniques. Therefore, these procedures are considered not 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 women 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 male factor infertility, 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 women 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 a woman 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 female 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 woman other than the member and the embryo is placed into a different woman 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 pregnancy are not covered.

CODING

BlueCHiP for Medicare and Commercial Products

The following infertility/in vitro fertilization services CPT Codes are covered under the member's infertility benefit when the benefit and medical necessity criteria 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
89255	Preparation of embryo for transfer (any method)
89268	Insemination of oocytes

89272	Extended culture of oocyte(s)/embryo(s), 4-7 days	
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		
	of development	
S4013	1	
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	
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	
S4025	Donor services for in vitro fertilization (sperm or embryo), case rate	
S4017	Incomplete cycle, treatment cancelled prior to stimulation, case rate	
S4018	Frozen embryo transfer procedure cancelled before transfer, case rate (NSR)	
S4023	, ,	
S4042	Management of ovulation induction (interpretation of diagnostic tests and studies, non-face-to-	
	face medical management of the patient), per cycle	
NI DOD		

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

The following infertility services 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 for tests and procedures are non-covered:

The following code for tests and procedures are non-covered:		
0058T	Cryopreservation; reproductive tissue, ovarian	
0357T	Cryopreservation; immature oocyte (s)	
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, each cell line	
88241	Thawing and expansion of frozen cells, each aliquot	
89290	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic	
	diagnosis PGD); less than or equal to 5 embryos	
89291	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic	
	diagnosis PGD); greater than 5 embryos	
89335	Cryopreservation, reproductive tissue, testicular	
89354	Thawing of cryopreserved; reproductive tissue; testicular/ovarian	

The following codes are covered only for members undergoing medical treatment that may result in infertility, for all other members, they are not covered. Effective 1/1/20 as groups renew

89258	Cryopreservation; embryo(s)
89259	Cryopreservation; sperm
89342	Storage (per year); embryo(s)
89343	Storage (per year); sperm/semen
89346	Storage (per year); oocyte
89337	Cryopreservation, mature oocyte(s)
89356	Thawing of cryopreserved; oocytes, each aliquot
S4027	Storage of previously frozen embryos
S4040	Monitoring and storage of cryopreserved embryos, per 30

The following codes are covered but not separately reimbursed:

89352	Thawing of cryopreserved	l; embryo(s)
89353	Thawing of cryopreserved	d; sperm/semen, each aliquot
S4037	Cryopreserved embryo tra	ansfer, case rate

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

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55200	Vasotomy, cannulization with or without incision of Vas, unilateral or bilateral (separate
	procedure) (surgery)
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)
58350	Chromotubation of oviduct, including materials

Providers filing for sperm evaluation, hyaluronan binding assay should file the following unlisted **CPT** Category I code:

Unlisted reproductive medicine laboratory procedure 89398

Note: Since there is no applicable CPT code for TESE (testicular sperm extraction) or TESA (testicular sperm aspiration), MESA (maximum entropy spectral estimation) claims will be submitted with an unlisted code and the claim will follow the standard unlisted procedure format.

RELATED POLICIES

Gender Reassignment

PUBLISHED

Provider Update, November 2020 Provider Update, December 2019 Provider Update, September 2019 Provider Update, May 2018 Provider Update, March 2017 Provider Update, June 2016

REFERENCES

- 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, Morenghi 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. Aziminekoo 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. Massaro PA, MacLellan DL, Anderson PA, et al. Does intracytoplasmic sperm injection pose an increased risk of genitourinary congenital malformations in offspring compared to in vitro fertilization? A systematic review and meta-analysis. J Urol. May 2015;193(5 Suppl):1837-1842. PMID 25813561
- 23. Dafopoulos K, Griesinger G, Schultze-Mosgau A, et al. Cumulative pregnancy rate after ICSI with cryopreserved testicular tissue in non-obstructive azoospermia. Reprod BioMed Online. Apr 2005;10(4):461-466. PMID 15901452
- 24. Hovatta O. Cryobiology of ovarian and testicular tissue. Best Pract Res Clin Obstet Gynaecol. Apr 2003;17(2):331-342. PMID 12758103
- 25. Tournaye H, Goossens E, Verheyen G, et al. Preserving the reproductive potential of men and boys with cancer: current concepts and future prospects. Hum Reprod Update. Nov-Dec 2004;10(6):525-532. PMID 15319377
- 26. Kettner LO, Henriksen TB, Bay B, et al. Assisted reproductive technology and somatic morbidity in childhood: a systematic review. Fertil Steril. Mar 2015;103(3):707-719. PMID 25624193
- 27. Farhi A, Reichman B, Boyko V, et al. Congenital malformations in infants conceived following assisted reproductive technology in comparison with spontaneously conceived infants. J Matern Fetal Neonatal Med. Aug 2013;26(12):1171-1179. PMID 23451839
- 28. Hansen M, Kurinczuk JJ, Milne E, et al. Assisted reproductive technology and birth defects: a systematic review and meta-analysis. Hum Reprod Update. Jul-Aug 2013;19(4):330-353. PMID 23449641
- 29. Davies MJ, Moore VM, Willson KJ, et al. Reproductive technologies and the risk of birth defects. N Engl J Med. May 10 2012;366(19):1803-1813. PMID 22559061
- 30. Bay B, Mortensen EL, Hvidtjorn D, et al. Fertility treatment and risk of childhood and adolescent mental disorders: register based cohort study. BMJ. Jul 05 2013;347:f3978. PMID 23833075
- 31. Practice Committee of the American Society for Reproductive Medicine, Practice Committee of the Society for Assisted Reproductive Technology. Role of assisted hatching in in vitro fertilization: a guideline. Fertil Steril. Aug 2014;102(2):348-351. PMID 24951365
- 32. Practice Committees of the American Society for Reproductive Medicine, Society for Assisted Reproductive Technology. Intracytoplasmic sperm injection (ICSI) for non-male factor infertility: a committee opinion. Fertil Steril. Dec 2012;98(6):1395-1399. PMID 22981171
- 33. Practice Committee of American Society for Reproductive Medicine, Practice Committee of Society for Assisted Reproductive Technology. Blastocyst culture and transfer in clinical-assisted reproduction. Fertil Steril. Nov 2008;90(5 Suppl):S174-177. PMID 19007621
- 34. American College of Obstetricians and Gynecologists (ACOG). Committee opinion no. 584: oocyte cryopreservation. Obstet Gynecol. Jan 2014;123(1):221-222. PMID 24463693
- 35. Loren AW, Mangu PB, Beck LN, et al. Fertility preservation for patients with cancer: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol. Jul 1 2013;31(19):2500-2510. PMID 23715580
- 36. Oktay K, Harvey BE, Partridge AH, et al. Fertility Preservation in Patients With Cancer: ASCO Clinical Practice Guideline Update. J Clin Oncol. Apr 5 2018 36(19):1994-2001. PMID 29620997
- 37. Myers ER, McCrory DC, Mills AA, et al. Effectiveness of assisted reproductive technology (Evidence Report/Technology Assessment No. 167). Rockville, MD: Agency for Healthcare Research and Quality;
- 38. 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

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