DRAFT Medical Coverage Policy | Expanded Fertility Services



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OVERVIEW

Various reproductive techniques are available to establish a viable pregnancy. Assisted reproductive technologies (ARTs), as defined by the Centers for Disease Control and Prevention and other organizations, refer to fertility treatments in which eggs or embryos are handled. Examples of ARTs include, but are not limited to, gamete intrafallopian transfer, transuterine fallopian transfer, natural oocyte retrieval with intravaginal fertilization, pronuclear stage tubal transfer, tubal embryo transfer, zygote intrafallopian transfer, gamete, and embryo cryopreservation, oocyte, and embryo donation, and gestational surrogacy.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet for applicable coverage.

Note: this policy applies to the following: Self-Funded Employer Expanded Fertility Coverage Self-funded employer clients can purchase expanded fertility services coverage through Blue Cross & Blue Shield of Rhode Island. This policy applies to only those members with Expanded Fertility Benefit Coverage. For all other plans with standard benefit coverage, please refer to the Infertility Services policy listed in the Related Policies section below, as well as the appropriate Subscriber Agreement for member benefits.

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SERVICES ADDRESSED IN THIS POLICY

The following services are addressed in this policy:

- Infertility treatments for members assigned female at birth (AFAB)
 - O Artificial insemination (AI) cycles, which includes the following:
 - Intrauterine insemination (IUI)
 - Intracervical insemination (ICI)
 - o In vitro fertilization (IVF), which includes the following:
 - Single embryo transfer (SET)
 - Multiple embryo transfer (MET)
 - Reciprocal IVF
- Infertility treatments for members assigned male at birth (AMAB)
 - o In vitro fertilization (IVF)
 - o Intracytoplasmic sperm injection (ICSI)
 - o Microsurgical epididymal sperm aspiration (MESA)
 - o Testicular sperm extraction (TESE)
 - o Testicular Sperm Aspiration (TESA)
- Iatrogenic infertility
- Normal menopause
- Hyaluronan binding assay
- Donor Eggs and Sperm
- Non-Covered Services

INFERTILITY DEFINED

Services Related to Infertility for Members Assigned Female at Birth (AFAB)

Infertility is defined as meeting 1, 2 and 3, below:

1. An 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.

OR

For members AFAB without exposure to sperm, infertility is determined based on the inability to conceive after 3 (three) artificial insemination (AI) (intra-cervical insemination (ICI) or intrauterine insemination (IUI)) cycles in a row performed by a qualified specialist.

Note:

- -The cost of prescription medications, professional, technical and facility charges related to the three (3) AI (ICI or IUI) cycles are covered.
- -The cost of donor sperm procurement, processing and storage will not be covered <u>until</u> a diagnosis of infertility has been established.
- -Home AI (ICI/IUI) is not covered.

OR

Documented infertility caused by the following (including but not limited to):

- Tubal factor infertility, AND/OR
- Pelvic adhesive disease, AND/OR
- Endometriosis

AND

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

MEDICAL CRITERIA

Artificial Insemination (AI) Cycles (includes ICI and IUI)

- ICI (intracervical insemination) cycles
- IUI (intrauterine insemination) cycles

Prior authorization is not needed for AI (ICI and IUI) when used to treat infertility.

Single Embryo Transfer (SET)

Prior authorization is needed for in vitro fertilization cycles with Single embryo transfers (SET). There is no medical criteria that needs to be met, including meeting a diagnosis of infertility, however, authorization is needed for cycle tracking purposes only.

*If the cycle is beyond 4 cycles, please see the medical criteria that needs to be met below. <u>After 4 In Vitro Fertilization (IVF) Cycles</u>.

Reciprocal In Vitro Fertilization (IVF)

Prior authorization is needed for reciprocal in vitro fertilization (IVF). There is no medical criteria that needs to be met, including meeting a diagnosis of infertility, however, authorization is needed for cycle tracking purposes only.

*If the cycle is beyond 4 cycles, please see the medical criteria that needs to be met below: <u>After 4 In Vitro</u> <u>Fertilization (IVF) Cycles</u>.

Multiple Embryo Transfer (MET)

Infertility diagnosis is not required for multiple embryo transfers, however ONE of the following criteria must be met to determine medical necessity:

- 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:
 - o had an unsuccessful first treatment cycle using their own fresh or frozen embryo, OR
 - o 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 medical criteria that needs to be met below: <u>After 4 In Vitro</u> <u>Fertilization (IVF) Cycles</u>.

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:

- Documentation regarding the number and type of all past in vitro fertilization (IVF)/AI (ICI and 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 member has been informed of the predicted success rate and accepts the proposed services.

PRIOR AUTHORIZATION

Prior authorization is recommended for Commercial Products for the following:

- SET (Single Embryo Transfer) in vitro fertilization (IVF) cycles (for cycle tracking purposes only)
- MET (multiple embryo transfer) IVF cycles
- After 4 IVF cycles [whether single embryo transfer (SET) and/or multiple embryo transfer (MET)] that did not result in pregnancy and delivery

No prior authorization is needed for any cycle in which AI (ICI or IUI) only is rendered.

POLICY STATEMENT

Single Embryo Transfer (SET) and Reciprocal IVF Cycles

There is no medical criteria that needs to be met, including meeting a diagnosis of infertility, however, authorization is needed for cycle tracking purposes only.

Multiple Embryo Transfer (MET)

MET cycles are considered medically necessary when the medical criteria above is met.

MET cycles are considered not medically necessary when the medical criteria above is not met.

Continued in IVF Services After 4 Consecutive IVF Cycles

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

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

EmbryoGlue® (CPT Code 89398)

EmbryoGlue® (hyaluronic acid) for the treatment of infertility is not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Hyaluronan Binding Assay

Hyaluronan Binding Assay for sperm evaluation is not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

COVERED SERVICES

Testing for Infertility

Testing to determine the diagnosis of infertility is a covered service.

AI (ICI and IUI) Cycles

AI (ICI and IUI) is covered when used to diagnose or treat infertility.

Services Related to **Infertility Diagnosis**

Coverage of cryopreservation of member's own eggs, oocytes, embryos, sperm, ovarian tissue or testicular tissue is provided for:

- treatment of infertility*
- for members undergoing medical treatment that may result in iatrogenic infertility. (Iatrogenic infertility means an impairment of fertility by surgery, radiation, chemotherapy, or other medical treatment, including gender affirming services, affecting reproductive organs or processes)*

*Note: For Infertility diagnosis, cryopreservation includes cell retrieval (no lifetime retrieval limit), freezing, storage and monitoring, shipping and thawing.

Services for Fertility Preservation

Coverage of Cryopreservation of Member's Own Eggs, Oocytes, Embryos or Sperm for <u>Elective</u> Fertility Preservation

Cryopreservation of members' own eggs, oocytes, embryos or sperm are covered for elective fertility preservation. (Elective fertility preservation means to store and freeze eggs, oocytes or sperm so they can be used to conceive a child at a later time, without the need for members to prove infertility or any other underlying medical condition).**

**Note: For elective fertility preservation, cryopreservation includes cell retrieval (egg/oocyte retrieval is limited to 3 cycles per lifetime), freezing, storage and monitoring, shipping and thawing.

To ensure correct claims processing and coordination of benefits, when the service is being performed for elective fertility preservation, claims must be submitted with a PRIMARY diagnosis of Z31.84 (Encounter for fertility preservation procedure).

Donor Eggs

Egg Bank

Donor eggs (gametes) are covered;

• 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 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 maybe billed to the member by the participating facility that is providing the implantation.

Note: Cryopreservation of donor eggs includes cell retrieval, freezing, storage and monitoring, shipping and thawing.

Donor Sperm

Donor sperm is covered;

- as part of the treatment of infertility for members AFAB
- for treatment of confirmed infertility for members AMAB (not the result of a previous sterilization procedure) even when there is no AFAB infertility

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.

Note: Cryopreservation of donor sperm includes cell retrieval, freezing, storage and monitoring, shipping and thawing.

Reimbursement of Cell Shipping and Storage

- Storage and shipping of donor cells and member's own Eggs, Oocytes, Embryos, Sperm is covered for fertility or elective purposes.
- Cell shipping reimbursement is covered at 100% up to a \$1,000 lifetime maximum benefit per member.
- Cell storage: The following storage codes are covered up to one year (12 months). Annual storage claims can be submitted once per benefit year. Monthly, or month-to-month storage is also covered. (Coverage benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet for applicable coverage.)
 - o 89342 Storage (per year); embryo(s)
 - o 89343 Storage (per year); sperm/semen
 - o 89346 Storage (per year); oocyte
 - o S4027 Storage of previously frozen embryos
 - o S4040 Monitoring and storage of cryopreserved embryos, per 30

*Note: Claims for multiyear storage, or storage over 12 months, is not covered as claims are only covered up to one year (12 months) per benefit year, as noted above.

In cases where the member has been billed directly, reimbursement is available. The member must use the applicable claim form, below, for Member submitted claims:

<u>Cell Shipping Reimbursement Form</u> <u>Cell Storage Reimbursement Form</u>

Services for Members Assigned Male at Birth (AMAB)

The following services are covered:

- Intracytoplasmic Sperm Injection (ICSI)
- MESA (Microsurgical epididymal sperm aspiration)

- TESE (Testicular Sperm Extraction)
- TESA (Testicular Sperm Aspiration)

NONCOVERED SERVICES

Donor Eggs

Donor eggs are not covered for members AFAB who do not meet the **Definition of Infertility**.

Donor Sperm

Donor sperm are not covered for the following indications:

- 1. When provided for members AFAB or AMAB that do not meet the **Definition of Infertility**, OR,
- 2. When provided for members AMAB who have previously underdone a sterilization procedure.

Previous Sterilization

Services to treat fertility 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 fertility 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

Services to treat fertility are excluded by contract for members whom have undergone normal menopause. Amenorrhea and an elevated FSH (follicle stimulating hormone) 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.

BACKGROUND

For the self-funded employer clients that have purchased the expanded fertility coverage through BCBSRI, in vitro fertilization cycles and freezing/storage of own cells are not contingent upon the diagnosis of infertility.

Blue Cross & Blue Shield of Rhode Island (BCBSRI) does not restrict fertility services based on age.

EmbryoGlue

It is believed the transfer medium promotes implantation of the embryo and varies according to clinic; however, the most common protein used is synthetic albumin; other additives have been investigated (e.g., hyaluronan, EmbryoGlue®), but improvement in embryo development and implantation has not been clearly established in the published literature. Yung et al. (2021) performed a randomized, double blind, controlled trial, comparing the effects of hyaluronic acid (HA) —enriched transfer medium versus standard medium on live birth rate after frozen embryo transfer (FET). A total of 550 infertile women aged 43 years or less were randomly placed in two groups. The hyaluronic acid group (HA) used an enriched medium (EmbryoGlue), with an HA concentration of 0.5 mg/ml while the control group used the conventional G -2 (Vitrolife) medium with an HA concentration of 0.125 mg/ml. Results demonstrated that live birth rates in both groups were comparable (25% versus 25.8%, respectively). Logistic regression showed that type of transfer medium did not improve the live birth rates of frozen embryo transfer. The evidence is insufficient to determine the effects of the technology on health outcomes.

DEFINITIONS

Artificial Insemination (AI)

Artificial insemination (AI) is a process that involves the introduction of sperm directly into a woman's cervix, fallopian tubes, or uterus. The most common method is called "artificial intrauterine insemination" (IUI), when a doctor places the sperm into the uterus. Another method is called "artificial intracervical insemination" (ICI), when a doctor places the sperm into the cervix.

Artificial Intracervical Insemination (ICI)

Artificial insemination by ICI is a process when sperm is inserted into the cervix, which serves as the passageway to the uterus. ICI (intracervical insemination) is rarely used as it does not allow the sperm to target the ova without being slowed or stopped by the lower portions of the reproductive tract. Fertility drugs may also be used.

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.

Assigned Female at Birth (AFAB)

AFAB (Assigned Female at Birth) refers to the sex that is assigned to an infant, most often based on the infant's anatomical and other biological characteristics.

Assigned Male at Birth (AMAB) Infertility

Male at birth (AMAB) Infertility is defined as 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. $\leq 2\%$ normal forms (Strict Kruger Morphology)

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.

Elective Fertility Preservation

Means to store and freeze eggs, oocytes or sperm so they can be used to conceive a child at a later time, without the need for members to prove infertility or any other underlying medical condition.

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.

EmbryoGlue®

EmbryoGlue® (hyaluronic acid) is a specialized solution used during in vitro fertilization (IVF) that helps an embryo implant in the uterus. While its name might suggest otherwise, it is not an adhesive glue but a substance that mimics the natural environment of the womb.

Fertility Treatment

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 intracytoplasmic sperm injection, frozen/cryo embryo transfer, preimplantation genetic testing, zygote intrafallopian transfer and gamete intra-fallopian transfer, donor oocyte procedures, and assisted embryo hatching.

Home Artificial Insemination (AI)

Home AI is a process that involves the introduction of sperm directly into a woman's cervix, fallopian tubes, or uterus by the member in the home. The most common method is called "artificial intrauterine insemination" (IUI), when sperm is placed into the uterus. Another method is called "artificial intracervical insemination" (ICI), when sperm is placed into the cervix.

Home Artificial Intracervical Insemination (ICI)

Home artificial insemination (AI) by ICI is a process when sperm is inserted into the cervix by the member in the home, which serves as the passageway to the uterus. ICI is rarely used as it does not allow the sperm to target the ova without being slowed or stopped by the lower portions of the reproductive tract. Fertility drugs may also be used.

Home Artificial Intrauterine Insemination (IUI)

Home artificial insemination (AI) by IUI process is performed by the member in the home. The 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.

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.

Iatrogenic Infertility

Iatrogenic, or medically induced, infertility refers to when a person becomes or will become infertile due to a medical procedure done to treat another problem, most often chemotherapy or radiation for cancer.

Infertility

Infertility is a medical condition defined by 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. Infertility can be caused by a variety of medical conditions, including premature ovarian failure/insufficiency. Normal menopause is a natural condition and is not included as a medical condition under the definition of infertility.

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 or absent 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.

In Vitro Fertilization (IVF) Cycles Defined

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.

Intracytoplasmic Sperm Injection (ICSI) for infertility

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. 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.

Microepididymal Sperm Aspiration (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.

Multiple Embryo Transfer (MET)

The transfer of more than one 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.

Normal Menopause

Normal menopause is process that marks a time when menstrual cycles stop due to a natural decline in reproductive hormones. Normal menopause is not a medical condition; it is a natural process that eventually occurs in all individuals assigned female at birth (AFAB). Laboratory tests can confirm if an individual AFAB has normal menopause (a natural condition) or has infertility (a medical condition).

Premature Ovarian Failure/Insufficiency

Premature ovarian failure/insufficiency can cause infertility when the ovaries stop producing normal amounts of the hormone estrogen or release eggs regularly. This is also known as early menopause, which is a medical condition that causes infertility. Laboratory tests can confirm if an individual AFAB has premature ovarian failure/insufficiency (a medical condition) versus normal menopause (a natural condition).

Reciprocal In Vitro Fertilization (IVF)

Is an assisted reproduction technique for female couples, in which one of the members assigned female at birth (AFAB) provides the oocytes (eggs) and the other receives the embryo (fertilized egg). *Not to be confused with surrogate, defined below.

Single Embryo Transfer (SET)

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 individuals 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 individuals aged 35–37 years, guidelines for elective single ET could be expanded to include patients in this age group with favorable prognoses.

Sterilization

Sterilization is a surgical procedure performed in individuals assigned female at birth (AFAB) or in individuals assigned male at birth (AMAB) with the intention of pregnancy prevention.

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 AFAB 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. *Not to be confused with Reciprocal In Vitro Fertilization (IVF), defined above.

Testicular Sperm Aspiration (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.

Testicular Sperm Extraction (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.

CODING

Commercial Products

The following code is covered and no prior authorization is required. Please see note below regarding elective fertility preservation*

58970 Follicle puncture for oocyte retrieval, any method

* To ensure correct claims processing and coordination of benefits, when the service is being performed for elective fertility preservation (limited to 3 cycles per lifetime), claims must be submitted with a PRIMARY diagnosis of Z31.84 (Encounter for fertility preservation procedure). This diagnosis code should not be used for those who meet the definition of infertility (no lifetime cycle limits) for members assigned female at birth.

The following codes are medically necessary when the medical necessity criteria above are met:

	8
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 (Text Revised Effective
	4/1/2025)
S4021	In vitro fertilization procedure cancelled after aspiration, case rate (Text Revised Effective
0.4000	4/1/2025)
S4022	Assisted oocyte fertilization, case rate
S4042	Management of ovulation induction (interpretation of diagnostic tests and studies, non-face-to-
	face medical management of the patient), per cycle

The following codes are covered without the diagnosis of infertility:

58321	Artificial insemination; intra-cervical
58322	Artificial insemination; intra-uterine
58323	Sperm washing for artificial insemination
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
S4035	Stimulated intrauterine insemination (IUI), case rate
55870	Electroejaculation
89264	Sperm identification from testis tissue, fresh or cryopreserved

The following codes are covered only for those who meet the definition of infertility (as defined in the policy above):

89335	Cryopreservation, reproductive tissue, testicular
89344	Storage (per year); reproductive tissue, testicular/ovarian
89354	Thawing of cryopreserved; reproductive tissue; testicular/ovarian
S4023	Donor egg cycle, incomplete, case rate

S4025	Donor services for in vitro fertilization (sperm or embryo), case rate
S4026	Procurement of donor sperm from sperm bank
S4028	Microsurgical epididymal sperm aspiration (MESA)

The following codes are covered for those who meet the definition of infertility (as defined in the policy above) or for those who are undergoing elective fertility preservation:

89257	Sperm identification from aspiration (other than seminal fluid)
89258	Cryopreservation; embryo(s)
89259	Cryopreservation; sperm
89337	Cryopreservation, mature oocyte(s)
89342	Storage (per year); embryo(s)
89343	Storage (per year); sperm/semen
89346	Storage (per year); oocyte
89356	Thawing of cryopreserved; oocytes, each aliquot
S3655	Antisperm antibodies test (immunobead)
S4027	Storage of previously frozen embryos
S4030	Sperm procurement and cryopreservation services; initial visit
S4031	Sperm procurement and cryopreservation services; subsequent visit
S4040	Monitoring and storage of cryopreserved embryos, per 30 days

The following codes are covered for those who meet the definition of infertility (as defined in the policy above) or for those who are undergoing elective fertility preservation but are 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/semen, each aliquot
S4037	Cryopreserved embryo transfer, 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 service(s) are covered under the applicable benefit.

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
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 codes 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

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
Infertility Services
Non-Reimbursable Health Service Codes
Pre-Implementation Genetic Diagnosis
Prior Authorization of Services, Treatments or Procedures
Unlisted Procedures

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