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OVERVIEW

This policy addresses treatments for infertility using assisted reproductive technology such as artificial insemination (AI), which includes intrauterine insemination (IUI), intracervical insemination (ICI) or in vitro fertilization (IVF). There are two sets of criteria that must be met for the coverage of treatments for infertility:

1. Eligibility Criteria: Must meet the definition of infertility for benefit coverage, with the exception of iatrogenic infertility. Refer to Services Related to Iatrogenic Infertility.
2. Medical Necessity Criteria: Once the Eligibility Criteria has been met, some services may require Prior Authorization, as Medical Necessity Criteria must also be met.

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.

COVERAGE

Benefits may vary between groups/contracts. Inclusion of a service in this policy does not guarantee coverage of the service requested. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for applicable coverage.

This policy applies to Standard Benefit Coverage; however, some self-funded employer plans have opted for expanded coverage of these services under the Self-Funded Employer Expanded Fertility Coverage option, which is subject to a different medical policy. For plans with customized coverage under the Self-Funded Employer Expanded Fertility Coverage option, please refer to the Expanded Fertility Services policy listed in the Related Policies section below.

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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)
  - Artificial insemination (AI) cycles, which includes the following:
    - Intrauterine insemination (IUI)
    - Intracervical insemination (ICI)
  - 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)
  - In vitro fertilization (IVF)
  - Intracytoplasmic sperm injection (ICSI)
  - Microsurgical epididymal sperm aspiration (MESA)
  - Testicular sperm extraction (TESE)
  - Testicular Sperm Aspiration (TESA)
- Iatrogenic infertility
- Normal menopause
- Hyaluronan binding assay
- Donor Eggs and Sperm
- Non-Covered Services

ELIGIBILITY CRITERIA

Eligibility Criteria for Members Assigned Female at Birth (AFAB)

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.

2. 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 IUI cycles as part of the requirement for diagnosing infertility
    - Members 35-39 years old: 2 medicated IUI cycles as part of the requirement for diagnosing infertility

    In addition, services related to these six (6) AI cycles, including but not limited to the cost of donor sperm, (procurement, processing and storage), prescription medications, and professional, technical and facility charges are not covered.

3. 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. For members AFAB ages 40 and older, no medicated IUI cycles are required as part of the requirement for diagnosing infertility.

    In addition, services related to these three (3) AI cycles, including but not limited to the cost of donor sperm, (procurement, processing and storage), prescription medications, and professional, technical and facility charges are not covered.

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 members AFAB (AI and IVF) 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 AFAB who meet the eligibility criteria, IVF with SET (single embryo transfer) or MET (multiple embryo transfer) is medically necessary when the medical criteria below are met. Services not meeting the medical criteria below are not medically necessary.

Continued 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 below has been met.

Eligibility Criteria for Members Assigned Male at Birth (AMAB)
B. For AMAB members, treatment of male factor infertility is covered when the member meets the eligibility criteria for the specified treatment, below:

IVF (In Vitro Fertilization (IVF)
ICSI (Intracytoplasmic Sperm Injection)
Member AMAB has infertility defined with the following parameters documented on 2 semen analyses showing:

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

MESA (Microsurgical Epididymal Sperm Aspiration)
Member AMAB has congenital absence or congenital obstruction of the vas deferens (typically diagnosed by the absence of fructose in semen) and confirmed by exam. MESA is no longer covered when there is <5% chance of live birth.

TESE (Testicular Sperm Extraction)
Member AMAB has non-obstructive azoospermia and spinal cord injury resulting in inability to ejaculate. TESE is no longer covered when there is <5% chance of live birth.

TESA (Testicular Sperm Aspiration)
Member AMAB has absence of sperm secondary to blockage or abnormality of the ejaculatory ducts due to history of spinal cord injury resulting in an inability to ejaculate.

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

*For a definition of **IVF Cycles,** refer to the **Definitions** section of this policy, below.

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

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

Artificial insemination (AI) is medically necessary when the member has met the eligibility criteria to treat infertility for members AFAB in the **Eligibility Criteria** section.

If the requested cycle is after 4 cycles have been performed, please see the additional medical criteria that needs to be met below: **After 4 In Vitro Fertilization (IVF) Cycles.**

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 AFAB in the **Eligibility Criteria** section.

If the requested cycle is after 4 cycles have been performed, please see the additional medical criteria that needs to be met below: **After 4 In Vitro Fertilization (IVF) Cycles.**

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 AFAB in the **Eligibility Criteria** section~~)~~.

- 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 requested cycle is after 4 cycles have been performed, please see the additional medical criteria that needs to be met below: **After 4 In Vitro Fertilization (IVF) Cycles.**

Reciprocal In Vitro Fertilization (IVF)
Reciprocal in vitro fertilization (IVF) utilizing frozen embryo transfer (FET) with donor eggs or embryos is medically necessary when the member has met the eligibility criteria to treat infertility for members AFAB in the **Eligibility Criteria** section, and must have ONE of the following criteria below:

1. Medical illness which causes unnatural loss of egg quantity:
    - Premature inadequate harvest*, OR
      *At least two IVF treatment cycles where ≤6 eggs were retrieved with maximum ovarian stimulation
    - Absent ovaries prior to age 40, OR
    - Premature ovarian insufficiency.
2. The following genetic egg defects as an alternative to using IVF with one's own eggs due to recurrent pregnancy loss and a diagnosis of balanced reciprocal translocation or Robertsonian translocation based on karyotype screening.

If the requested cycle is after 4 cycles have been performed, 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
After 4 in vitro fertilization (IVF) cycles [single embryo transfer (SET), multiple embryo transfer (MET) or reciprocal IVF] 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 IVF/AI 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.

Services Related to Iatrogenic Infertility
Covered services for members AFAB or AMAB 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 affirming care services) affecting reproductive organs or processes.

POLICY STATEMENT

The following services are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products when the medical criteria above is not met:

- Single Embryo Transfer (SET)
- Multiple Embryo Transfer MET)
- Reciprocal In Vitro Fertilization (IVF) Cycles
- In Vitro Fertilization (IVF) Cycles beyond 4 cycles

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

Normal Menopause
Normal menopause is a natural condition and not a medical condition. Members who have undergone normal menopause do not meet eligibility 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.

Hyaluronan Binding Assay
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.

PRIOR AUTHORIZATION

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

*Refer to **Codes Requiring Prior Authorization** under the Coding section, below, for details:

- IVF cycles (complete, partial, incomplete), for example:
    - Frozen cycles
    - Donor egg cycles
    - Gamete intrafallopian transfer (GIFT) cycles
    - Zygote intrafallopian transfer (ZIFT) cycles
- Components of IVF cycles, for example:
    - Oocyte identification, retrieval, incubation and ultrasonic guidance
    - Assisted oocyte fertilization
    - Embryo incubation and assisted embryo hatching
    - Oocyte and embryo cultures
    - Gamete, zygote and embryo transfers
    - Single embryo transfers (SET)
    - Multiple embryo transfers (MET)
    - Management of ovulation induction
    - Donor services (sperm or embryo)
    - Intracytoplasmic Sperm Injection (ICSI)
    - MESA (Microsurgical epididymal sperm aspiration)
    - TESE (Testicular Sperm Extraction)
    - TESA (Testicular Sperm Aspiration)
- Services related to Iatrogenic Infertility, for example:
  ***Refer to **Iatrogenic Infertility** under the Coding section, below, for details
    - Cryopreservation
    - Storage
    - Monitoring
    - Thawing

COVERED SERVICES

Donor Eggs and Sperm
Egg Bank
Donor eggs (gametes) are covered when the member AFAB meets the **Eligibility 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. These should be submitted to BCBSRI for reimbursement.

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. These should be submitted to BCBSRI for reimbursement.

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 due to one of the following:
    - no partner AMAB,
    - 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 and should be submitted to BCBSRI for reimbursement. Fees associated with collection and finding a donor are not covered.

Donor Egg and Sperm Reimbursement Form
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

NONCOVERED SERVICES

The following services are not covered:

- 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.

- 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. Refer to the **Definitions** section of this policy.
- Genetic engineering.
- Disposal of embryos.

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

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.

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.

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 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)
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.

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 ~~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.

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 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.

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 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.

BACKGROUND

Introduction
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.**

Rhode Island State Mandate, Coverage for Infertility

http://webserver.rilin.state.ri.us/Statutes/TITLE27/27-20/27-20-20.htm

The following is the State of Rhode Island Mandate regarding coverage of infertility services for 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).

CODING

Medicare Advantage Plans and Commercial Products

Codes Requiring Prior Authorization
*A and B, below

A. IVF Cycles
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.

B. Iatrogenic Infertility

- Cryopreservation, Storage and Thawing

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

Covered Services

*A and B, below

A. Diagnostic Evaluation of Infertility

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
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)

B. Other Covered Infertility Service(s)

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

Covered but Not Separately Reimbursed
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/semen, each aliquot
S4037 Cryopreserved embryo transfer, case rate

Non-Covered Services
A. Cryopreservation, Storage and Thawing
The following code(s) are not covered, unless the medical necessity criteria of iatrogenic infertility has been met:
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

B. Other Non-Covered Services
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

Other Coding Guidance
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
Expanded Fertility Services
Gender Affirming Care
Non-Reimbursable Health Service Codes
Pre-Implementation Genetic Diagnosis
Prior Authorization via Web-Based Tool for Procedures
Unlisted Procedures

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REFERENCES

1. Rhode Island General Law (RIGL) 27-20-20: Coverage for Infertility. http://webserver.rilin.state.ri.us/Statutes/TITLE27/27-20/27-20-20.htm
2. 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
3. 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
4. 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
5. 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
6. 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
7. 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
8. 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
9. 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
10. 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
11. 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
12. 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
13. 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
14. 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
15. 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
16. 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
17. 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
18. 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

19. 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
20. 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
21. 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
22. 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

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