Effective Date: January 1, 2025

Related Medical Policies:
None

Infertility Services

DESCRIPTION

Infertility services encompass a variety of clinical treatments and laboratory procedures, which includes the handling of human oocytes, ovarian tissue, sperm, testicular tissue, or embryos in vitro, with the intent of establishing a pregnancy immediately or in the future. In general, infertility services are used to treat the failure to establish a pregnancy or to carry a pregnancy to live birth after regular, unprotected sexual intercourse, or a person's inability to reproduce either as a single individual or with their partner without medical intervention, or a licensed physician's findings based on a patient's medical, sexual, and reproductive history, age, and/or diagnostic testing.

Descriptions

For the purpose of this guideline, the term female (or woman) refers to members born with two X chromosomes (or no Y chromosome) and includes members with gender identities other than female.

The term male used in this guideline refers to members born with XY chromosomes and includes members with gender identities other than male.

Artificial Insemination (AI) is described as involving placement of whole semen or processed sperm into the **female** reproductive tract, without intercourse, utilizing sperm from a donor.

Assisted reproductive technology (ART) is defined as reproductive services, testing, and treatments involving manipulation of eggs, sperm, and embryos to achieve pregnancy. In general, assisted reproductive technology (ART) procedures are used to retrieve eggs from a woman, combine them with sperm in the laboratory, and then implant the embryos or donate them to another woman.

OBJECTIVE

The purpose of this utilization management (UM) guideline is to promote patient safety and to facilitate the delivery of quality, effective, medically necessary services which are required as treatment for infertility. This guideline is not intended to replace or substitute independent medical judgment of a practitioner or other health care professional for treatment of an individual patient. This document does not override contractual requirements of the benefit provisions, limitations and exclusions as outlined in the Blue Cross and Blue Shield Service Benefit Plan Brochure and the Blue Cross and Blue Shield Service Benefit Plan FEP Blue Focus Brochure.

This guideline addresses artificial insemination (AI) utilizing the following methods:

- Intracervical insemination (ICI): A procedure which involves placing sperm inside the cervix to facilitate fertilization.
- Intrauterine insemination (IUI): A procedure which involves placing sperm inside the uterus to facilitate fertilization.

- Intravaginal insemination (IVI): A procedure which involves placing sperm inside the vagina to facilitate fertilization.

This guideline addresses assisted reproductive technology (ART), procedures utilizing the following methods:

- In vitro Fertilization (IVF)
- Embryo transfer and gamete intrafallopian transfer (GIFT)
- Zygote intra-fallopian transfer (ZIFT)
- Pronuclear stage tubal transfer (PROST)

NOTE:
Members **are not required** to attempt artificial insemination (AI) methods listed in this guideline prior to attempting assisted reproductive technology (ART) methods listed above.

COVERED PROVIDERS

Benefits are available for services to treat infertility when provided and billed by covered professional providers and facilities. (See benefit requirements and limitations in the Blue Cross and Blue Shield Service Benefit Plan Brochure and the Blue Cross and Blue Shield ® Service Benefit Plan FEP Blue Focus brochures.)

Healthcare professionals must be licensed, certified, or registered for the services provided as applicable by state/federal licensing regulations.

Covered facilities must meet applicable licensing and/or certification requirements in the state where services are performed.

For Members enrolled in Basic Option and FEP Blue Focus: Preferred providers must be used in order to receive benefits. See the assigned federal brochures (RI 71-005/Standard and Basic Option[2] and RI 71-017/FEP Blue Focus) for exceptions.

For Members enrolled in Standard Option: Preferred provider and non-preferred provider benefits apply.

CLINICAL REVIEW

Services to treat infertility are subject to the benefit provisions and limitations as outlined in the Blue Cross® and Blue Shield® Service Benefit Plan Basic and Standard Option and Blue Cross and Blue Shield Service Benefit Plan FEP® Blue Focus brochures and must be a covered benefit. The maximum benefit amount will always apply.

This guideline specifically addresses clinical review for services related to the treatment of infertility.

Members meeting our definition(s) of infertility, are eligible for the following reproductive services once **prior approval** has been obtained:

FEP Standard Option Members
Assisted Reproductive Technology (ART)

- In vitro fertilization (IVF)
- Gamete intrafallopian transfer (GIFT)
- Zygote intra-fallopian transfer (ZIFT)
- Pronuclear stage tubal transfer (PROST)

FEP Standard Option, Basic Option, and Blue Focus Plan Members
Artificial insemination (AI)

- Intracervical insemination (ICI)
- Intrauterine insemination (IUI)
- Intravaginal insemination (IVI)

Medical Necessity Criteria:

Artificial Insemination and Assistive Reproductive Technology:

For all members (female, male and other gender identities), assisted reproductive technology services are **medically necessary** when brochure benefit criteria are met for the time period that fertility is naturally expected and **in addition, one of the following must be met:**

A. An otherwise healthy individual or person(s) with two X chromosomes (or no Y chromosome) is age 35 or older and has not been able to conceive after a period of six months of actively trying, OR
B. An otherwise healthy individual or person(s) with two X chromosomes (or no Y chromosome) is younger than age 35 and has not been able to conceive or produce conception after twelve months or more of actively trying
C. An individual or person(s) with two X chromosomes (or no Y chromosome) with documented infertility caused by the inability to achieve a successful pregnancy based on an individual's medical, sexual, and reproductive history, age, physical findings, diagnostic testing, or any combination of those factors.

NOTE:
Individual health may alter the age and or time period an individual or person(s) is expected to actively try to conceive.

For members who meet the criteria for Assisted Reproductive Technology (ART), the associated preimplantation genetic testing of embryos is considered **medically necessary**.

Cryopreservation (Fertility Preservation)

- **Medically necessary** services for members undergoing chemotherapy that is expected to render them permanently infertile:
  - One cycle of IVF with egg cryopreservation (if the member is <44 years of age). **No infertility workup is required for coverage
    - Frozen embryo transfer is medically necessary when transferred back to member and benefit available.
  - Sperm collection and storage (up to 12 months)
- **Medically necessary** services for members undergoing a treatment other than chemotherapy that is expected to render them permanently infertile (excluding voluntary sterilization):
  - One cycle of IVF with egg cryopreservation (if the member is <44 years of age) up to 12 months.
  - Egg cryopreservation is also medically necessary for members <44 years of age that have excess (supernumerary) eggs that cannot be fertilized (i.e. no sperm is able to be produced on the day of egg retrieval or there are too few sperm for the number of eggs retrieved on the day of egg retrieval) during a covered cycle of IVF.

Donor Sperm

- Cryopreservation of testicular tissue/sperm is **medically necessary** for postpubescent members with XY chromosomes with azoospermia in conjunction with the testicular biopsy to identify sperm in preparation for an intracytoplasmic sperm injection procedure if sperm are found.
- Microdissection- Testicular Excisional Sperm Extraction (TESE) is **medically necessary** for non-obstructive azoospermia and spinal cord injury resulting in inability to ejaculate.

Medical necessity shall mean healthcare services that a physician, hospital, or other covered professional or facility provider, exercising prudent clinical judgment, would provide to a patient for the

purpose of preventing, evaluating, diagnosing, or treating an illness, injury, disease, or its symptoms, and that are:

- In accordance with generally accepted standards of medical practice in the United States; and
- Clinically appropriate, in terms of type, frequency, extent, site, and duration; and considered effective for the patient's illness, injury, disease, or its symptoms; and
- Not primarily for the convenience of the patient, physician, or other healthcare provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results for the diagnosis or treatment of that patient's illness, injury, or disease, or its symptoms; and
- Not part of or associated with scholastic education or vocational training of the patient; and
- In the case of inpatient care, when provided safely only in the inpatient setting.

Guidance on limits to the number of embryos to transfer:

- Individuals less than 35 years of age should be strongly encouraged to receive a single-embryo transfer, regardless of the embryo stage.
- For individuals between 35 and 37 years of age, strong consideration should be made for a single-embryo transfer.
- For individuals between 38 and 40 years of age, no more than 3 untested cleavage-stage embryos or 2 blastocysts should be transferred.
- Individuals 41years of age and older should plan to receive no more than 4 untested cleavage-stage embryos or 3 blastocysts.

Other Considerations:

- For members meeting benefit and medical necessity criteria, reimbursement for ART services is limited to $25,000 annually.
- With **prior approval**, the covered AI procedures and associated drugs listed in this guideline, and the prescription during associated with ART procedures **are not** subject to the $25,000 annual maximum.

Non-Covered Services:

- All related donor expenses including but not limited to the cost of donor sperm or oocytes.
- Fallopian tube ligations and vasectomy reversals.
- Services requiring the use of a surrogate.
- Other services, supplies, or drugs provided to individuals not enrolled in the Plan, including **surrogates**.
- Services determined to be not medically necessary.
- Family balancing
    - Family balancing is a measured approach to a non-medically indicated use of preconception gender selection.
- Sperm penetration assay to determine whether intracytoplasmic sperm injection should be offered for fertilization during an IVF treatment cycle.
- Mock transfer.
- Reciprocal IVF is not covered (unless covered by partner's insurer).
- Storage of cryopreserved sperm or eggs exceeding 12 months.
- Sperm storage/banking for males, individuals, or person(s) with XY chromosomes requesting this service for convenience.
- TESA or TESE for obstructive azoospermia (such as vasectomy).
- Cryopreservation of eggs for fertility preservation purposes other than chemotherapy or other treatments that may render an individual infertile.
- Cryopreservation of embryos or eggs for reciprocal IVF (unless patient is covered under the member's plan).

References

1. American College of Obstetricians and Gynecologists and American Society for Reproductive Medicine. ACOG Committee Opinion Number 781; reaffirmed 2020. Infertility workup for the women's health specialist. Vol 133, No 6. June 2019.
2. Access to fertility treatment by gays, lesbians, and unmarried persons, Fertility and Sterility, Volume 92, Issue 4, 2009, Pages 1190-1193,ISSN 0015-0282, https://doi.org/10.1016/j.fertnstert.2009.07.977.
3. American Society for Reproductive Medicine. Minimum Standards for Practices Offering Assisted Reproductive Technologies: A Committee Opinion (2021). Retrieved March 21, 2024 from:https://www.asrm.org/practice-guidance/practice-committee-documents/minimum-standards-for-practices-offering-assisted-reproductive-technologies-a-committee-opinion-2021
4. Burns, L. H. (2007). Psychiatric aspects of infertility and infertility treatments. *Psychiatric Clinics of North America/˜the œPsychiatric Clinics of North America*, *30*(4), 689–716. https://doi.org/10.1016/j.psc.2007.08.001
5. 2024 Blue Cross ® and Blue Shield ® Service Benefit Plan Brochure. (R1 71-005)
6. 2024 Blue Cross ® and Blue Shield ® Service Benefit Plan FEP ® Blue Focus Brochure. (R1 71-017)
7. Florida Blue Cross Corporate Medical Policy: Infertility. Last revised. June 15, 2023. Retrieved March 21, 2024 from http://mcgs.bcbsfl.com.
8. Centers for Disease Control. What is Assisted Reproductive Technology https://www.cdc.gov/art/index.html
9. Committee on Gynecologic Practice, American Society of Reproductive Medicine. "ACOG Committee Opinion Number 781" *Obstetrics & Gynecology*. Vol.133, No.6, June 2019: e377-384
10. Centers for Disease Control and Prevention, American Society for Reproductive Medicine Society for Assisted Reproductive Technology. 2010 assisted reproductive technology: fertility clinic success rates report. Atlanta (GA): CDC; 2012. Available at: http://www.cdc.gov/art/ART2010/PDFs/ART_2010_Clinic_Report-Full.pdf. Retrieved September 13, 2013.
11. Blue Cross Blue Shield Association Evidence Position System. Reproductive Techniques. Reviewed September 2022.
12. ACOG: Committee Opinion No. 584: oocyte cryopreservation. (2014). *Obstetrics and gynecology*, *123*(1), 221–222. https://doi.org/10.1097/01.AOG.0000441355.66434.6d. Retrieved July 6, 2023, from: https://pubmed.ncbi.nlm.nih.gov/
13. In accordance with the Massachusetts state mandate. The mandate states that we must provide benefits to insured covered spouse and/or other covered dependent: http://www.mass.gov/ocabr/docs/doi/legal-hearings/211-37.pdf.
14. American Urological Association (AUA), Inc.-Infertility Report on Evaluation of the Azoospermic Male (An AUA Best Practice Policy and American Society of Reproductive Medicine (ASRM) Practice committee Report), 2001.
15. The Ethics committee of the American Society for Reproductive Medicine-Fertility Preservation and Reproduction in Cancer Patients. Fertility and Sterility 2005; 83(6): 1622-1628.
16. Porcu E, Fabbri R, Damiano G et al. Clinical Experience and Applications of Oocyte Cryopreservation. Molecular and Cellular Endocrinology 2000; 169: 33-37

17. Oktay K, Buyuk E, Veeck L et al. Embryo Development After Heterotopic Transplantation of Cryopreserved Ovarian Tissue. Lancet 2004; 363: 837-840.
18. Blue Cross Blue Shield of Massachusetts Corporate Medical Policy Number 086 Assisted Reproductive Services. Last revised. May 1, 2023.
19. Society for Assisted Reproductive Technology. Preliminary National Summary Report for 2021.Retrieved September 28, 2023 from: https://sartcorsonline.com/CSR/PublicSnapshotReport?ClinicPKID=0&reportingYear=2021
20. Fertility treatment when the prognosis is very poor or futile: a committee opinion. ASRM. Fertil Steril_ 2012; 98: e6–e9

HISTORY

Date	Action	Description
September 2024	New guideline	UM Guideline for Infertility Services