INFERTILITY SERVICES

Note: Prescription drugs used in the treatment of infertility through the Washington University Fertility and Reproductive Medicine Center are covered under the pharmacy benefit managed by Express Scripts. See page 5 for listing of covered drugs to treat infertility.

The following services are currently covered under the medical benefit.

1. Diagnostic testing for use in diagnosing infertility. The benefits are the same as those for testing related to any other disease or condition.
2. Therapeutic (surgical and non-surgical) procedures to correct a physical condition which is the underlying cause of the infertility are a covered health service. An infertility benefit is not required for coverage of these services (e.g. for the treatment of a pelvic mass or pelvic pain, thyroid disease, pituitary lesions, etc.)
3. Pre-implantation genetic diagnosis (PGD) for the diagnosis of known genetic disorders only when the fetus is at risk for the genetic disorder. This would include, but is not limited to the following:
   A. Autosomal dominant disorders;
   B. Sex-linked (X or Y chromosome) disorders;
   C. Autosomal recessive diseases for which very specific mutations in heterozygosity can lead to a phenotype;
   D. Recessive disorders (e.g. Spinal Muscular Atrophy) where it is not atypical for an affected child to have inherited one of the deletions in a de novo fashion.

Only proven tests and procedures are covered.

Diagnostic Procedures

Females

The following tests or procedures are proven and medically necessary for diagnosing infertility in female patients:

- Antral follicle count
- Clomiphene citrate challenge test
- The following hormone level tests:
  - antimüllerian hormone (AMH)
  - estradiol
  - follicle-stimulating hormone (FSH)
  - luteinizing hormone (LH)
  - progesterone
  - prolactin
  - thyroid-stimulating hormone (TSH)
- Hysterosalpingogram (HSG)
- Diagnostic hysteroscopy
- Diagnostic laparoscopy with or without chromatubation
- Pelvic ultrasound (transabdominal or transvaginal)
- Sonohysterogram or saline infusion ultrasound
The following tests are unproven and not medically necessary for diagnosing infertility in female patients:

- Inhibin B
- Uterine/endometrial receptivity testing (e.g., E-tegrity® and Endometrial Function Test® (EFT®))

There is insufficient evidence to permit conclusions regarding the use of these tests. More studies are needed to support improved outcomes (i.e., increased successful pregnancies with delivery of liveborn children) with use of these diagnostic tests.

**Males**

The following tests or procedures are proven and medically necessary for diagnosing infertility in male patients:

- Antisperm antibodies
- The following genetic screening tests:
  - Cystic fibrosis gene mutations
  - Karyotyping for chromosomal abnormalities
  - Y-chromosome microdeletions testing
- The following hormone level tests:
  - LH
  - FSH
  - Prolactin
  - Testosterone (total and free)
- Leukocyte count in semen
- Post-ejaculatory urinalysis
- Scrotal, testicular or transrectal ultrasound
- Semen analysis
- Testicular biopsy
- Vasography

The following tests are unproven and not medically necessary for diagnosing infertility in male patients:

- Computer-assisted sperm analysis (CASA)
- Hyaluronan binding assay (HBA)
- Postcoital cervical mucus penetration test
- Reactive oxygen species (ROS) test
- Sperm acrosome reaction test
- Sperm DNA integrity/fragmentation tests (e.g. sperm chromatin structure assay (SCSA), single-cell gel electrophoresis assay (Comet), deoxynucleotidyl transferase-mediated dUTP nick end labeling assay (TUNEL), sperm chromatin dispersion (SCD) or Sperm DNA Decondensation™ Test (SDD))
- Sperm penetration assays

There is insufficient evidence to permit conclusions regarding the use of these tests. More studies are needed to support improved outcomes (i.e., increased successful pregnancies with delivery of liveborn children) with use of these diagnostic tests.
Covered Services: Infertility

Coverage includes the following services:

- Ovulation induction;
- Insemination procedures: Artificial Insemination (AI) by Intrauterine Insemination (IUI);
- Assisted Reproductive Technologies (ART); This includes in vitro fertilization and related procedures including Intracytoplasmic sperm injection, assisted hatching, embryo cryopreservation, embryo biopsy, and embryo transfer (fresh and frozen).
- Cryopreservation of sperm or embryos is proven and medically necessary for individuals who are undergoing treatment with assisted reproductive technologies and are planning to undergo therapies that threaten their reproductive health, such as cancer chemotherapy.
- Cryopreservation of mature oocytes (eggs) is proven and medically necessary for women, under the age of 43, who are undergoing treatment with assisted reproductive technologies and are planning to undergo therapies that threaten their reproductive health, such as cancer chemotherapy.
- Cryopreservation of immature oocytes (eggs) is unproven and not medically necessary.
  Further evidence from well-designed trials is needed to determine the long-term safety and efficacy of cryopreserving immature oocytes for future in vitro maturation.
- Cryopreservation of ovarian or testicular tissue is unproven and not medically necessary.
  Ovarian tissue banking remains a promising clinical technique because it avoids ovarian stimulation and provides the opportunity for preserving gonadal function in prepubertal, as well as adult patients. However, this procedure has produced very few live births.
  Testicular tissue or testis xenografting are in the early phases of experimentation and have not yet been successfully tested in humans.

In addition, the infertility treatments above must be provided under the direction of a physician and the enrollee must meet the following criteria

- have failed to achieve or maintain a Pregnancy after twelve months of regular, unprotected heterosexual intercourse if the woman is under age 35, or after six months, if the woman is 35 or over; OR
- have failed to achieve or maintain a Pregnancy following six to twelve treatment cycles, depending on age, of medically supervised donor insemination OR
- have failed to achieve or maintain a Pregnancy due to impotence/sexual dysfunction;

AND:

- have infertility that is not related to voluntary sterilization or failed reversal of voluntary sterilization.
- under age 45, if female and using own eggs / oocytes; under age 50, if female and using donor eggs / oocytes. For treatment initiated prior to pertinent birthday, services will be covered to completion of initiated cycle.
Note:

- Infertility waiting period is waived when member has a known infertility factor, including but not limited to tubal disease, endometriosis, ovulatory disorder, or diminished ovarian reserve.
- Have diagnosis of a male factor causing infertility (e.g. treatment of sperm abnormalities including the surgical recovery of sperm).

An enrollee with an infertility benefit that is using a gestational carrier because of a known medical cause of infertility (this does not include an enrollee who has had a voluntary sterilization or a failed reversal of a sterilization procedure) will have coverage for the following services. These services will be paid per the enrollee’s coverage.

- Female enrollee ovary stimulation, retrieval of eggs, laboratory processes with sperm, oocytes and embryos are covered when enrollee is using a gestational carrier (host uterus). Please note: The transfer of eggs, embryos or sperm into the carrier (host uterus) is not covered even if the enrollee has the infertility benefit. Treatments directly involving the gestational carrier are not covered.

- Male enrollee retrieval of sperm or other sperm related services are covered.

If during the course of infertility treatment there is a change in partners, any specified lifetime maximums in the enrollee specific benefit document are still applicable.

Benefit Limitations and Exclusions

1. Assisted Reproductive Technologies, ovulation induction and insemination procedures are excluded from coverage unless the enrollee has a benefit for infertility AND the criteria listed in the Indications for Coverage has been met.

2. When the plan has a benefit for infertility services, in-vitro fertilization when it is not used as an Assisted Reproductive Technology for the treatment of infertility is not a covered health service.

3. Third party reproduction therapies including the following:
   - Fees incurred for the use of a gestational carrier (host uterus);
   - Fees for psychosocial screening and legal fees tied to third party reproduction.
   - Donor eggs-All aspects of a donor egg cycle specifically related to the oocyte donor’s treatment, including ovarian stimulation and egg retrieval. Note: Once the oocytes are obtained, the fertilization, embryo culture and embryo transfer (fresh or frozen) into the enrollee’s uterus are covered by the plan. If frozen donor oocytes are utilized, the cost of these oocytes and the shipping of the oocytes are not covered.
   - Donor sperm- The cost of procurement and storage of donor sperm is excluded. However, the thawing and insemination are covered if the member has an infertility benefit that allows for artificial donor insemination.
   - Donor embryos-The expenses for procurement of donor embryos are not covered, but once the embryos are in the laboratory, the expenses for their utilization are covered.
ADDITIONAL INFORMATION:

• As a standard, coverage is provided for maternity services (prenatal, delivery and postnatal pregnancy). If a female enrollee is pregnant and functioning as a gestational carrier, coverage would be provided for the maternity related care. Coverage is not provided for maternity services for a carrier that is not an enrollee. Please check the enrollee specific benefit documents.

4. Tests or procedures for infertility that are unproven. [http://kl/content/guidelines & clinical policies/medical_policies/infertility_diagnosis_and_treatment.doc](http://kl/content/guidelines & clinical policies/medical_policies/infertility_diagnosis_and_treatment.doc)

5. Advanced Reproductive Technology Services requested for reasons other than infertility, must be reviewed in accordance with the enrollee’s specific benefit documents (case by case determination).

6. Infertility treatment when the cause of the infertility was a procedure that produces sterilization, e.g. vasectomy or tubal ligation. (Check enrollee’s specific benefit documents).

7. Storage and retrieval of testicular tissue and ovarian tissue. Also, long term storage of all reproductive materials (sperm, eggs, embryos) prior to cancer treatments is not covered.

8. Elective cryopreservation and storage of sperm, oocytes (eggs), zygotes or embryos when there is no infertility or no condition that threatens reproductive health/function such as cancer therapy is present.

9. Self-injectable drugs for infertility. Please refer to the pharmacy benefit for information.

10. Any Infertility services or supplies beyond the benefit maximum (dollars or procedures)

The following services are currently covered under the pharmacy benefit administered by Express Scripts.

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Infertility Services

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Lower case font indicates generic drug

**DEFINITIONS**

**Assisted Reproductive Technology (ART):** the comprehensive term for procedures involving the manipulation of human reproductive materials (such as sperm and eggs or embryos) to achieve Pregnancy. Examples of such procedures are:

- In vitro fertilization (IVF).
- Intracytoplasmic sperm injection
- Assisted hatching
- Embryo transfer

**Gestational Carrier:** female that carries the pregnancy but is not the source of the egg.

**Infertility:** A disease, defined by the failure to achieve a successful pregnancy after 12 months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination. Earlier evaluation and treatment may be justified based on medical history and physical findings and is warranted after 6 months for women over age 35 years.

**Preimplantation Genetic Diagnosis (PGD):** Preimplantation genetic diagnosis (PGD) refers specifically to when one or both genetic parents have a known genetic abnormality and testing is performed on an embryo to see if it also carries a genetic abnormality. Preimplantation genetic diagnosis (PGD) is recommended when couples are at risk of transmitting a known serious genetic abnormality to their children.

**Preimplantation Genetic Screening (PGS):** preimplantation genetic screening (PGS) refers to techniques where embryos from presumed chromosomally normal genetic parents are screened for aneuploidy. At present, no specific list of indications for preimplantation genetic screening (PGS) is available.

**Therapeutic Donor Insemination (TDI):** insemination with a donor sperm sample for the purpose of conceiving a child. The donor can be an anonymous or known donor.