Services Are Subject to $15,000 Lifetime Maximum (Combined with Pharmacy Costs)

UnitedHealthcare® Commercial
Coverage Determination Guideline

INFERTILITY SERVICES

Guideline Number: CDG.025.06 **Effective Date**: October 1, 2018

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INSTRUCTIONS FOR USE

This Coverage Determination Guideline provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Coverage Determination Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Coverage Determination Guideline. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Coverage Determination Guideline. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Coverage Determination Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this guideline, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Indications for Coverage

Therapeutic (medical or surgical) procedures to correct a physical condition, which is the underlying cause of the Infertility, are a covered health service (e.g., for the treatment of a pelvic mass or pelvic pain, thyroid disease, pituitary lesions, etc.).

Services for the treatment of Infertility when provided by or under the care or supervision of a Physician are limited to the following procedures:

- Ovulation induction (or controlled ovarian stimulation);
- Insemination procedures: Artificial Insemination (AI) and Intra Uterine Insemination (IUI);
- Assisted Reproductive Technologies (ART).

To be eligible for Benefits, you must meet all of the following:

- You are not able to become pregnant after the following periods of time of regular, unprotected intercourse or Therapeutic Donor Insemination:
  - One year, if you are a female under age 35.
  - Six months, if you are a female age 35 or older.
- You have Infertility not related to voluntary sterilization or to failed reversal of voluntary sterilization.

Surrogate/Gestational Carrier

A member with an Infertility benefit that is using a Surrogate/Gestational Carrier because of a known medical cause of Infertility (this does not include a member 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 member's coverage.

- Female member's ovary stimulation and retrieval of eggs are covered when a member is using a Surrogate (host uterus). **Please note**: The implantation of eggs or oocytes or donor sperm into a host uterus is not covered even if the member has the Infertility benefit.
- Male member retrieval of sperm.

When applying the Infertility benefit, consider the following:

- Female Infertility: Infertility caused by a problem that results in the inability to produce an egg, if an embryo is unable to travel to the womb, or there is a process that prevents use of the womb for reproduction.
- Male Infertility: Infertility caused by problems due to inability to ejaculate or insufficient number or motility of sperm.

Please check the member specific benefit plan document for inclusion or exclusion.

Some states mandate benefit coverage for Infertility services. Please check state mandates.

Benefit Limitations and Exclusions

When the member's plan includes benefits for Infertility, the following services are not covered:

- Assisted Reproductive Technologies, ovulation induction and insemination procedures are excluded from coverage **unless** the member has a benefit for Infertility **and** the criteria listed in the Indications for Coverage has been met.
- Pre-implantation Genetic Diagnosis (PGD) **unless** the member has a benefit for Infertility that includes the Assisted Reproductive Technologies, the criteria listed in the Indications for Coverage has been met, and the procedure is being performed for the diagnosis of known genetic disorders only when the fetus is at risk for an inheritable genetic disorder.
  - This would include, but is not limited to the following:
    - Autosomal dominant disorders;
    - Sex-linked (X or Y chromosome) disorders;
    - Autosomal recessive diseases for which very specific mutations in heterozygosity can lead to a phenotype;
    - 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.
  - Check the benefit documents and state mandates for coverage of Pre-implantation Genetic Diagnosis (PGD). PGD may be considered a covered expense if the fetus is at risk for a genetic disorder.
- Pre-implantation Genetic Screening (PGS)
- Cryo-preservation and other forms of preservation of reproductive materials, e.g., sperm, oocytes (eggs), embryos or ovarian.
- Long-term storage (greater than one year) of reproductive materials such as sperm, eggs, embryos, ovarian tissue and testicular tissue.
- Preservation of reproductive materials prior to cancer treatments and elective preservation of reproductive materials are not covered. This includes all services related, including but not limited to drug therapy, retrieval, cryopreservation and storage.
- Donor services for donor sperm, ovum or oocytes (eggs), or embryos.
  - Donor eggs - All aspects of a donor egg cycle including stimulation, retrieval, fertilization, embryo culture and embryo transfer (fresh or frozen) are excluded from coverage unless otherwise specified in the plan language.
  - 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.
- In-vitro fertilization that is not an Assisted Reproductive Technology for the treatment of Infertility. This would include but is not limited to elective fertility preservation, embryo accumulation/banking.
- Any Infertility services or supplies beyond the benefit maximum (dollars or procedures).
- Infertility treatment when the cause of the Infertility was a procedure that produces sterilization, e.g., vasectomy or tubal ligation. (Check the member specific benefit plan document).

When the member's plan does not include benefits for Infertility, the following services are not covered:
- All health care services and related expenses for infertility treatments, including Assisted Reproductive Technology, regardless of the reason for the treatment.
- Storage and retrieval of all reproductive materials. Examples include eggs, sperm, testicular tissue and ovarian tissue.
- In vitro fertilization regardless of the reason for treatment.

The following services are excluded on all plans (even when the plan provides benefits for Infertility):
- Surrogate Parenting: Services and treatments for a Gestational Carrier of a pregnancy that is not our member and all related services including, but not limited to:
  - Fees for the use of a Gestational Carrier or Surrogate.
  - Pregnancy services for a Gestational Carrier or Surrogate who is not a Covered Person.
- Costs of donor eggs and donor sperm.
- Unproven tests or procedures for Infertility. Refer to the Medical Policy titled Infertility Diagnosis and Treatment.
- Self-injectable drugs for Infertility. Refer to the exclusion for self-injectable drugs in the member specific benefit plan document. Refer to the pharmacy benefit administrator for self-injectable medication benefit information.

Additional Information
- As a standard, coverage is provided for maternity services (prenatal, delivery and postnatal pregnancy) for our members. If a female member is pregnant and functioning as a Surrogate, coverage is provided for maternity services. Coverage is not provided for maternity services for a Surrogate that is not a member (see Surrogate parenting exclusion above).
- Advanced Reproductive Technology Services (IVF, GIFT, ZIFT, PROS, and TET) requested for reasons other than Infertility, must be reviewed in accordance with the member specific benefit plan document (case by case determination).

DEFINITIONS

The following definitions may not apply to all plans. Refer to the member specific benefit plan document for applicable definitions.

Assisted Reproductive Technology (ART): The comprehensive term for procedures involving the manipulation of human reproductive materials (such as sperm, eggs, and/or embryos) to achieve Pregnancy. Examples of such procedures are:
- In vitro fertilization (IVF)
- Gamete intrafallopian transfer (GIFT)
- Pronuclear stage tubal transfer (PROST)
- Tubal embryo transfer (TET)
- Zygote intrafallopian transfer (ZIFT)

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

Infertility: A disease (an interruption, cessation, or disorder of body functions, systems, or organs) of the reproductive tract which prevents the conception of a child or the ability to carry a pregnancy to delivery. It is 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 age 35 years or older.

Preimplantation Genetic Diagnosis (PGD): A laboratory test performed on an embryo prior to transfer when one or both genetic parents carry a gene mutation or a balanced chromosomal rearrangement to determine whether that specific mutation or an unbalanced chromosomal complement has been transmitted to the oocyte or embryo (Society for Assisted Reproductive Technology (SART) and ASRM 2008).

Preimplantation Genetic Screening (PGS): A laboratory test performed on an embryo prior to transfer when the genetic parents are known or presumed to be chromosomally normal to determine if the embryo has a genetic or chromosomal disorder (SART and ASRM 2008).

Surrogate: A female who becomes pregnant usually by artificial insemination or transfer of a fertilized egg (embryo) to her uterus for the purpose of carrying a fetus for another person (Merriam Webster medical dictionary).

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

REFERENCES

American Society of Reproductive Medicine (ASRM) - Gestational definition. https://www.reproductivefacts.org/resources/infographic-gallery/images/gestational-carrier-vs.-surrogate/?_ga=2.30888895.1652833951.1532022315-1669869529.1532022315. Accessed July 19, 2018.

American Society for Reproductive Medicine. Patient Information Series. Age and fertility: a guide for patients. 2012d.

Merriam Webster Medical Dictionary (Surrogate definition).

Pittsburgh Cryobank, Inc. Glossary of Terms. Available at: https://pittsburghcryobank.com/glossary-of-terms/. Accessed July 16, 2018.

Society for Assisted Reproductive Technology and American Society for Reproductive Medicine. Preimplantation genetic testing: a practice committee opinion. Fertil Steril. 2008 Nov; 90(5 Suppl):S136-43.

GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
10/01/2018	• Updated supporting information to reflect the most current references; no change to coverage rationale • Archived previous policy version CDG.025.05