



Subject: Infertility

Revision Date: 6/25

DESCRIPTION

According to the Ohio State University Faculty and Staff Health Plans Specific Plan Details Document (SPD), infertility is the result of 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. A biological female is considered infertile if they are unable to achieve pregnancy after 12 months or cycles of exposure to sperm if under the age of 35 or 6 months/cycles if over the age of 35. A biological female must be premenopausal or experiencing menopause at a premature age and reasonably expect fertility as a natural state.

APPLICABILITY

This policy applies to all OSU Health Plan (OSUHP) benefit plans.

DEFINITIONS

In this policy, the terms biological female and biological male are used to clarify the reproductive capacity of the covered person and are not meant to exclude covered persons with other gender identities/expressions.

Biological female, as used in this policy, refers to a covered person with two X chromosomes (or no Y

chromosome) and includes covered persons with gender identities other than female.

Biological male, as used in this policy refers to a covered person with XY chromosomes and includes covered persons with gender identities other than male.

Infertility is the result of 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.

Idiopathic infertility when health care providers cannot find a specific or likely cause for infertility in females or males

Cryopreservation is a process where biological material - cells, tissues, or organs - are frozen to preserve the material for an extended period.

POLICY

Infertility treatment is considered medically necessary when the following criteria are met (*see Appendix Aⁱ for covered services*):

- The covered person must meet eligibility requirements for the infertility benefit per The Ohio State University Faculty and Staff Health Plans Specific Plan Details Document (SPD); and
- If the covered person has elected a network only plan, the rendering provider participates in the statewide network; and
- The covered person meets the definition of infertility, as evidenced by ALL of the following:
 - The biological female is not in natural menopause, as evidenced by:
 - Under the age of 40 (biological females under the age of 40 are either premenopausal or experiencing premature ovarian failure.)

- Age 40 and older:
 - An unmedicated day 3 FSH <19 mIU/mL; and/or
 - An AMH > 1 ng/mL
- Infertility, as defined by one or more of the following:
 - Idiopathic infertility, as defined by one or more of the following:
 - Failure to conceive after frequent, unprotected heterosexual intercourse for 1 year or more when the biological female is under the age of 35; or
 - Failure to conceive after frequent, unprotected heterosexual intercourse for 6 months or more when the biological female is over the age of 35; or
 - Failure to conceive after at least 12 cycles of donor insemination when the biological female is under the age of 35; or
 - Failure to conceive after at least 6 cycles of donor insemination when the biological female is over the age of 35; or
 - A biological female with infertility due to cancer treatment (e.g., bilateral oophorectomy, chemotherapy) and no evidence of tumor recurrence, as indicated by 1 or more of the following:
 - Two years or more after completion of cancer treatment for gynecologic tumors; or
 - Two years or more after completion of hematopoietic stem cell transplant; or
 - After completion of adjuvant tamoxifen, if appropriate, for breast cancer.
 - Covered person with impending infertility due to planned cancer treatment for cure (e.g., chemotherapy or oophorectomy) or medically necessary gender confirmation procedures [Authorization is for services related to embryo, oocyte or sperm retrieval and cryopreservation only]; or
 - Biological female with absent or non-patent fallopian tubes not caused by an elective sterilization procedure (e.g., from prior ectopic pregnancy or pelvic inflammatory disease); or

- Biological female with recurrent pregnancy loss:
 - Documentation meets the definition of recurrent pregnancy loss, as evidenced by one of the following:
 - Two or more failed clinical pregnancies as documented by ultrasonography or histopathologic examination; or
 - Three consecutive pregnancy losses, which are not required to be intrauterine.
 - Parent(s) without known known parental balanced chromosomal rearrangement (e.g., translocation): Authorization is for medication only (i.e., progesterone, hMG).
 - Parent(s) with known parental balanced chromosomal rearrangement (e.g., translocation): Authorization includes all covered fertility services (see Appendix Aⁱ).
- Biological female with polycystic ovary syndrome (PCOS) and ALL of the following:
 - Failure to conceive, as defined by one or more of the following:
 - Failure to conceive after frequent, unprotected heterosexual intercourse for 1 year or more when the biological female is under the age of 35; or
 - Failure to conceive after frequent, unprotected heterosexual intercourse for 6 months or more when the biological female is over the age of 35; or
 - Failure to conceive after at least 12 cycles of donor insemination when the biological female is under the age of 35; or
 - Failure to conceive after at least 6 cycles of donor insemination when the biological female is over the age of 35;
 - Failure of ovulation stimulation as evidenced by one of the following:
 - Failure to conceive after at least 6 cycles of clomiphene citrate or letrozole [cycles count toward the overall 1 year or 6-month requirement above]; or

- Failure to respond to ovarian stimulation as evidenced by:
 - Ovarian stimulation protocol is consistent with current recommendations for dose escalation; and
 - Objective data documents failure to respond:
 - Follicle diameter < 18 mm; or
 - Serum estradiol (E2) < 200 pg/mL;
 - If obese, weight loss should be encouraged;
- Biological female with surgically staged moderate (stage III) or severe (stage IV) endometriosis;
- Partner who is HIV positive and ALL of the following:
 - Adherent with highly active antiretroviral therapy; and
 - Washed sperm is required for insemination to prevent HIV transmission;
- Biological male with paraplegia and sperm retrieval is required to achieve pregnancy;
- Biological male with one or more abnormal semen analyses not related to an elective sterilization procedure:
 - Non-obstructive azoospermia or severe oligospermia (i.e., fewer than 5 million sperm per mL of ejaculate); or
 - Abnormal morphology (i.e., less than 4% normal forms)
 - Abnormal motility (i.e., less than 32% progressive motility or less than 40% total motility)
- The following documentation is provided:
 - Progress notes from an OB/GYN or Reproductive Endocrinologist documenting infertility as defined; and
 - Sperm counts (if applicable); and
 - Ultrasounds, lab results and other supportive documentation when applicable to the case; and

- Documentation of prior donor inseminations (if applicable), including:
 - If inseminations performed by a physician:
 - Semen analysis for each insemination; and
 - Medical records documenting each cycle.
 - If inseminations are not performed by a physician:
 - Semen analysis for the sperm utilized;
 - Dates of insemination;
 - Description of how sperm was handled during cycles (i.e., time between collection and insemination, temperature exposure, etc.).
 - All receipts for the sperm purchased from a sperm bank.
- Biological females who are morbidly obese (BMI ≥ 40) should have a maternal fetal medicine/high risk obstetrics consult within the previous 12 months (For the initial request, documentation of a referral to MFM or high-risk OB is sufficient. The subsequent request should include documentation that consultation was performed in order to meet continued medical necessity criteria. Only one consult is required.)

Human chorionic gonadotropin (hCG) is considered medically necessary for biological males with secondary hypogonadism when the following criteria are met:

- Diagnosis of hypogonadism; and
- 2 abnormal semen analyses; and
- Documentation that the covered person has tried to conceive:
 - Failure to conceive after frequent, unprotected heterosexual intercourse for 1 year or more if biological female is under the age of 35; or
 - Failure to conceive after frequent, unprotected heterosexual intercourse for 6 months or more if biological female is over the age of 35.

Refer to policy MMPP 30.0 for coverage of preimplantation genetic diagnosis (PGD).

PROCEDURES

See Appendix Aⁱ for services included in the infertility benefit.

Donor sperm is covered when the criteria for infertility are met and there is documentation of an abnormal semen analysis (fewer than 5 million sperm per mL of ejaculate, less than 4% normal morphology, less than 32% progressive motility or less than 40% total motility) that is not related to a voluntary sterilization procedure.

Donor egg/donor embryos are covered when the criteria for infertility are met and there is documentation of one of the following medical illnesses that cause unnatural loss of oocyte quality:

- Absent ovaries
- Premature diminished ovarian reserve

Injectable medications are covered through the prescription benefit. Refer to Express Scripts for specific coverage limitations.

PRIOR AUTHORIZATION

All infertility services require prior authorization. The following guidelines apply:

- An infertility evaluation and the OSU Health Plan request for authorization must be completed and submitted by an Obstetrician/Gynecologist or Reproductive Endocrinologist.
- Covered services will be performed at facilities that conform to the American Society of

Reproductive

Medicine's most current standards and guidelines.

- Participating providers will complete medical criteria form for each new couple and submit the form to OSU Health Plan for medical review and approval.
- The evaluation should include the type of infertility that the covered person is experiencing, and the type of treatment recommended.
- Injectable infertility medications require prior authorization.
- The treatment plan and required documentation will be reviewed to determine that the recommended.
- Treatment meets the OSU Health Plan's medical necessity coverage guidelines.

EXCLUSIONS

The following services are not covered by the OSU Health Plan (not an all-inclusive list):

- Any ART procedures or related treatments that are classified as experimental, investigative, or innovative by the American Society of Reproductive Medicine, The American College of Obstetrics and Gynecology, or another infertility expert recognized by the Ohio Department of Insurance
- Any infertility related service when the biological female is experiencing natural menopause
- Attempts to reverse prior elective sterilization
- Any infertility related service if the covered person and/or partner had a prior elective sterilization procedure
- Ovulation kits or sperm testing kits and supplies
- Long-term (greater than 12 months) storage fees, costs associated with storage of sperm, eggs, and embryos
- For services rendered to or for a surrogate, including, but not limited to, costs for maternity care, if the surrogate is not a covered person under the Ohio State plans.

- For costs incurred for a fertile biological female to achieve a pregnancy as a surrogate, regardless of whether the individual is a covered person under the Ohio State plans. Costs include, but are not limited to, costs for drugs necessary to achieve implantation and embryo transfer.
- Covered persons who do not meet guidelines for infertility treatment coverage
- The initial 12 (or 6 if age criteria met) cycles of Intra-uterine insemination (IUI) for biological female to establish the definition of infertility
- Coverage of donor sperm for any indication other than an abnormal semen analysis that is not related to a voluntary sterilization procedure
- Infertility medications/services for covered person who do not meet eligibility requirements or who are not approved for infertility services.
- Donor recruitment, selection & screening
- Non-medical services related to donor procurement including:
 - Non-treatment related fees (including but not limited to finder's fees, broker fees, & legal fees)
 - Compensation
 - Recruitment costs
 - Hotel charges
 - Transportation costs
 - Costs related to any complications the donor may experience related to the egg donor services (unless the donor is a covered person on the plan)
- Any service provided by a non-network provider when the covered person has elected a network only plan (such as Prime Care Advantage or Prime Care Connect)
- Treatment of infertility secondary to use of testosterone to enhance athletic performance or for other non-clinical indications.
- Infertility treatment when there is a significant comorbidity that would endanger the life of the biological female and/or fetus or affect the ability to reach fetal viability. This does not apply to fertility preservation procedures (egg retrieval, etc.) performed prior to cancer treatment.

- Infertility treatment when there is an unresolved comorbidity causing infertility. The cause should be treated and stable (when possible) prior to consideration of approval for infertility services.
- IVF/FET for recurrent pregnancy loss without a known parental balanced chromosomal rearrangement (e.g., translocation)
- Infertility treatment for dependents (coverage is limited to the covered person and/or spouse)
- Uterine transplant

Refer to the exclusions for infertility listed in The Ohio State University Faculty and Staff Health Plans Specific Plan Details.

CODES

ICD-10 code(s) covered when the above criteria are met:

Code	Description
N46	Male infertility
N97	Female infertility

Procedure codes too numerous to list. Refer to Appendix Aⁱ for a list of covered services.

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ⁱ Appendix A:

The OSU Health Plan covers the following services according to the infertility benefit when the above criteria are met:

- Medically necessary services incurred in diagnosis and treatment of infertility services for both partners
- Office visits and consultations
- Laboratory services (except genetic testing, which requires a separate authorization)

- Radiological procedures
- In vitro fertilization
- Embryo transfer (fresh or frozen)
- Intracytoplasmic sperm injection (ICSI)
- Assisted hatching techniques
- Short-Term (12 months or less) cryopreservation of embryos and sperm
- Surgical treatment (except to reverse voluntary sterilization)
- Artificial insemination
- Ovulation stimulation and monitoring, including related medications
- Oocyte retrieval, including professional and facility charges, sedation and/or anesthesia, and recovery room charges

Covered persons authorized for infertility services are eligible for the following non-experimental ART procedures:

- In-vitro fertilization (IVF) and/or embryo transfer.
- Gamete intra-fallopian transfer (GIFT)
- Zygote intrafallopian transfer (ZIFT)
- Intracytoplasmic sperm injection (ICSI)
- Assisted hatching (AH)
- Cryopreservation of embryos/blasts/sperm while the covered person is undergoing active infertility treatment