

**Subject:** Infertility Policy

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## DESCRIPTION

Infertility is the condition of an individual who has been unable to conceive or produce conception during a period of one year up to the age of 35 and 6 months if over the age of 35. Infertility can arise in both men and women. A woman is considered infertile if she is unable to conceive or produce conception after the stated period of frequent, unprotected heterosexual intercourse with a fertile male. A woman without a male partner may be considered infertile if she is unable to conceive after at least twelve cycles of donor insemination if under 35 and 6 cycles if over 35. A woman must be pre-menopausal or experiencing menopause at a premature age, before the age of 43, and reasonably expect fertility as a natural state.

## POLICY

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

- The member 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 member has elected a network only plan, the rendering provider participates in the statewide network; and
- The member meets the above definition of infertility, as evidenced by ALL of the following
  - Female partner is under the age of 43; and
  - 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 for female under the age of 35; or
      - Failure to conceive after frequent, unprotected heterosexual intercourse for 6 months or more for female over the age of 35; or
      - Failure to conceive after at least 12 cycles of donor insemination for female under the age of 35; or
      - Failure to conceive after at least 6 cycles of donor insemination for female over the age of 35; or
    - Female with infertility due to cancer treatment (e.g., bilateral oophorectomy, chemotherapy) and no evidence of tumor recurrence; or
    - Female with impending infertility due to planned cancer treatment for cure (e.g., chemotherapy or oophorectomy); or
    - 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
    - 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 for female under the age of 35; or

- Failure to conceive after frequent, unprotected heterosexual intercourse for 6 months or more for female over the age of 35; or
- Failure to conceive after at least 12 cycles of donor insemination for female under the age of 35; or
- Failure to conceive after at least 6 cycles of donor insemination for female over the age of 35;
  - Failure of at least 6 cycles of clomiphene citrate [cycles count toward the overall 1 year or 6 month requirement above]; and
  - If obese, weight loss should be encouraged;
- Male 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 to female partner;
- Male partner with documented infertility due to cancer therapy (e.g., orchiectomy or chemotherapy); or
- Male partner with non-obstructive azoospermia or severe oligospermia not related to an elective sterilization procedure (i.e., fewer than 5 million sperm per mL of ejaculate); or
- Male partner with paraplegia and sperm retrieval is required to achieve pregnancy;
- The following documentation is provided:
  - Progress notes from an OB/GYN or Reproductive Endocrinologist documenting infertility as defined; and
  - Sperm counts (required for male infertility); and
  - Ultrasounds, lab results and other supportive documentation when applicable to the case; and
  - Females who are morbidly obese (BMI  $\geq$  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 consult was performed in order to meet continued medical necessity criteria. Only one consult is required.)

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

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

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

## **COVERAGE**

### 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 men and women
- 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 (90 days or less) cryopreservation of embryos and sperm
- Surgical treatment for women and men (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

Individuals 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 member is undergoing active infertility treatment of not more than 90 days.

Donor sperm is covered when the criteria for infertility are met and there is documentation of male factor infertility 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.

## **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 fertility related service for women who are 43 years of age or older
- Attempts to reverse prior elective sterilization
- Any fertility related service if the member and/or partner had a prior elective sterilization procedure
- Ovulation kits or sperm testing kits and supplies
- Long-term (greater than 90 days) 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 woman to achieve a pregnancy as a surrogate, regardless of whether the woman 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.
- Members 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 women without male partners to establish the definition of infertility
- Coverage of donor sperm for any indication other than male factor infertility that is not related to a voluntary sterilization procedure
- Infertility medications/services for members who do not meet the 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 finders 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 plan member)
- Any service provided by a non-network provider when the member has elected a network only plan (such as Prime Care Advantage or Prime Care Connect)
- Reproduction services related to gender dysphoria, including, but not limited to, sperm preservation in advance of hormone treatment or gender dysphoria surgery, cryopreservation of fertilized embryos, oocyte preservation, surrogate parenting, donor eggs, donor sperm and host uterus (*refer to MMPP 22.0 Gender Dysphoria*)
- Treatment of male infertility secondary to use of testosterone to enhance athletic performance or for other non-clinical indications.
- Fertility treatment when there is a significant comorbidity that would endanger the life of the mother and and/or fetus, or affect the mother's ability to reach fetal viability. This does not apply to fertility preservation procedures (egg retrieval, etc.) performed prior to cancer treatment.
- Fertility 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.

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

## **PRIOR AUTHORIZATION**

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

1. An infertility evaluation and the OSU Health Plan request for authorization must be completed and submitted by an **Obstetrician/Gynecologist or Reproductive Endocrinologist**.
2. Covered services will be performed at facilities that conform to the American Society of Reproductive Medicine's most current standards and guidelines.
3. Participating providers will complete medical criteria form for each new couple and submit the form to OSU Health Plan for medical review and approval.
4. The evaluation should include the type of infertility that the member is experiencing and the type of treatment recommended.
5. Injectable infertility medications require prior authorization.
6. The treatment plan and required documentation will be reviewed to determine that the recommended.
7. Treatment meets the OSU Health Plan's medical necessity coverage guidelines.

## REFERENCES AND ATTACHMENTS

- American College of Obstetricians and Gynecologists. (2014, March). Female age-related fertility decline. Committee Opinion No 589. *Obstet Gynecol*, 123, 719-21.
- American College of Obstetricians and Gynecologists. (2016, April). Obesity and Pregnancy. Retrieved from <https://www.acog.org/-/media/For-Patients/faq182.pdf?dmc=1&ts=20170810T2308570614>
- American Society for Reproductive Medicine. (2004, September). The menopause transition. A committee opinion. *Fertility and Sterility*, 82(sup. 1), S107-10.
- American Society for Reproductive Medicine. (2006, November). Aging and infertility in women. A committee opinion. *Fertility and Sterility*, 86(sup. 4), S248-52.
- American Society for Reproductive Medicine. (2013, January). Definitions of infertility and recurrent pregnancy loss: A committee opinion. *Fertility and Sterility*, 99(1), 63.
- Aronson, D. Stretching the biological clock. *Resolve National Newsletter*; Vol. XXII, No. 3. Summer 1997.
- Centers for Disease Control and Prevention, American Society for Reproductive Medicine, Society for Assisted Reproductive Technology. 2013 Assisted Reproductive Technology National Summary Report. Atlanta (GA): US Dept of Health and Human Services; 2015.
- Dickey, R, et al. Comparison of the sperm quality necessary for successful intrauterine insemination with WHO threshold values for normal sperm. *Fertility and Sterility* 1999; 71(4): 684-689.
- Dorland's Medical Dictionary 1988:481. The definition of a disease.
- Gilbert, W, Nesbitt, T, Danieisen, B. Childbearing Beyond age 40; Pregnancy outcome in 24,032 Cases. *Ob/gyn* 1999; 93(1), 9-14.
- Hornstein, MD, Schust, D. "Infertility." *Novak's Gynecology*. 12th edition. Baltimore: Williams and Wilkins, 1998.
- Hull, MG, Fleming, CF, Hughes, AO, McDermott, A. The age-related decline in female fecundity: a quantitative controlled study of implanting capacity and survival of individual embryos after in vitro fertilization. *Fertility and Sterility* 1996; 65:4, 783-90.
- Jones, H. W., Allen, B. D., Strategies for designing an efficient insurance fertility benefit: a 21<sup>st</sup> century approach. *Fertility and Sterility*, June 2009, 91; 6. 2295-2297.
- Magarelli, PC, Pearlstone, AC, Buyalos, RP. Discrimination between chronological and ovarian age in infertile women aged 35 years and older: predicting pregnancy using basal follicle stimulating hormone, age and number of ovulation induction/intra-uterine insemination cycles. *Hum Reprod* 1996; 11:6, 1214-9.
- MCG. (2017). Assisted Reproductive Technology. Retrieved from <https://careweb.careguidelines.com/ed21/index.html>
- New York State Task Force on Life and the Law, Assisted Reproductive Technologies, analysis and recommendations for public policy. April 1998.
- Pearlstone, AC, Fournet, N, Gambone, JC, et al. Ovulation induction in woman age 40 and older: the importance of basal follicle stimulating hormone level and chronological age. *Fertility And Sterility* 1992; 58: 674- 679.
- Proceedings of the XVI World Congress on Fertility and Sterility. *Fertility and Reproductive Medicine*, San Francisco October 1998. New York: Elsevier Science, 1998.
- Rein, MS, Barbieri, RL. "The Infertile Couple." *Gynecology and Women's Health*. 7th edition. Ed. Kistner. St. Louis: Mosby, 1999.
- Ron-el, R, Raziell, A, Strassburger, D, et al. Outcome of assisted reproductive technology in woman over the age of 41. *Fertility and Sterility* 2000; 74, 471-475.
- Roseboom, TJ, Vermeiden, JP, Schoute, E, Lens, JW, Schats, R. The probability of pregnancy after embryo transfer is affected by the age of the patient, cause of infertility, number of embryos transferred and the average morphology score, as revealed by multiple logistic regression analysis. *Hum Reprod* 1995; 10:11, 3035-41.
- Rosenwaks, Z, Davis, OK, Damario, MA. The role of maternal age in assisted reproduction. *Hum Reprod* 1995; 10 Suppl 1, 165-73.
- Sauer, M. Treating infertility in women of advanced reproductive age. *Contemporary OB/GYN*. Oct 1996; 68-76.
- Scott, RT, Opsahl, MS, Leonardi, MR, Neall, GS, Illions, EH, Navot, D. Life table analysis of pregnancy rates in a general infertility population relative to ovarian reserve and patient age. *Hum Reprod*, 1995; 10:7, 706-10.
- Speroff, L, et al. *Clinical Gynecologic Endocrinology and Infertility*. 6th edition. Baltimore: Lippincott, Williams and Wilkins, 1999.
- Stewart, D. and Gail Erlick Robinson. *A Clinician's Guide to Menopause*. Washington, D.C.: Health Press, 2000.
- Templeton, A, Morris, JK, Parslow, W. Factors that affect outcome of in-vitro fertilization treatment. *Lancet* 1996; 348:9039, 1402-6.
- Van Kooij, RJ, Looman, CW, Habbema, JD, Dorland, M, te Velde, ER. Age-dependent decrease in embryo implantation rate after in vitro fertilization. *Fertil Steril* 1996; 66:5, 769-75.
- Van Voorhis, B, et al. Effect of the total motile sperm count on the efficacy and cost-effectiveness of intrauterine insemination and in vitro fertility. *Fertility Sterility* 2001; 75(4): 661-668.
- Wachenheim, D, Coleman, C. Letter. Insurance for infertility treatments different perspectives. *Fertility and Sterility* 2000; 73,1267-66.
- Wren, B. and L. Nachtigall. *Clinical Management of Menopause*. New York: McGraw-Hill, 1996.
- Yaron, Y, Amit, A, Brenner, SM, Peyser, MR, David, MP, Lessing, JB. In-vitro fertilization and oocyte donation in women 45 years of age and older. *Fertil Steril* 1995; 63:1, 71-6.