



Infertility Services Clinical Coverage Criteria

Description

This policy applies to coverage for infertility services. Coverage for infertility services varies by product.

Policy

This Policy applies to the following Fallon Health products:

- Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)
- MassHealth ACO
- NaviCare HMO SNP
- NaviCare SCO
- PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- Community Care

Fallon Health requires prior authorization for infertility services. Additionally, infertility services are subject to the coverage, limitations and exclusions outlined in the Member's Evidence of Coverage/Member Handbook.

Members who have Pharmacy Benefits will not be approved for infertility drugs unless they meet criteria as defined in this policy.

No coverage will be provided for the diagnosis or treatment of infertility for individuals who are not plan members, with the exception of coverage for sperm, egg, and/or inseminated egg procurement and processing, and banking of sperm or inseminated eggs; to the extent such costs are not covered by the donor's insurer, if any.

Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for infertility services. Medicare does not have an NCD for infertility services. National Government Services, Inc. does not have an LCD or LCA for infertility services at this time (Medicare Coverage Database search 04/21/2024).

Reasonable and necessary services associated with treatment for infertility are covered under Medicare. Infertility is a condition sufficiently at variance with the usual state of health to make it appropriate for a person who normally is expected to be fertile to seek medical consultation and treatment (Medicare Benefit Policy Manual, Chapter 15, Section 20.1 B. Treatment for Infertility).

MassHealth ACO

For MassHealth members, the treatment of male or female infertility (including but not limited to laboratory tests, drugs and procedures associated with such treatment is not covered (130 CMR 433.451(B) Nonpayable Services).

MassHealth covers only the diagnosis and treatment of the underlying cause of infertility. There is no coverage for treatments, such as IUI or IVF services.

NaviCare HMO SNP, NaviCare SCO

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Definitions

ART cycle - Because ART consists of several steps over an interval of several weeks an ART procedure is more appropriately considered a cycle of treatment rather than a procedure at a single point in time. A typical ART cycle begins when a woman starts taking medication to stimulate the ovaries to develop eggs or, if no drugs are given, when the woman begins having her ovaries monitored (using ultrasound or blood tests) for natural egg production. If eggs are produced, the cycle then progresses to egg retrieval, a surgical procedure in which eggs are collected from a woman's ovaries. Once retrieved, eggs are combined with sperm in the laboratory. If fertilization is successful, one or more of the resulting embryos are selected for transfer, most often into a woman's uterus through the cervix (IVF), but sometimes into the fallopian tubes (e.g., GIFT or ZIFT). If one or more of the transferred embryos implant within the woman's uterus, the cycle then progresses to clinical pregnancy. A cycle may be discontinued at any step for specific medical reasons (e.g., no eggs are produced, the embryo transfer was not successful) or by patient choice.

Gender Descriptions - In this policy, the terms biological female and biological male are used to clarify the reproductive capacity of the member and are not meant to exclude members with other gender identities/expressions:

- The term *biological* female used in this policy refers to members with two X chromosomes (or no Y chromosome) and includes members with gender identities other than female.
- The term *biological* male used in this policy refers to members with XY chromosomes and includes members with gender identities other than male.

Fertility treatment when the prognosis is very poor or futile - Infertility services are considered to be medically necessary when policy criteria are met for the time period that fertility is naturally expected. In addition, for all members, services will no longer be covered if the treatment being requested is considered to be "futile" or has a "very poor prognosis," as defined by the American

Society for Reproductive Medicine. Futile treatments are defined as having a < 1% chance of achieving a live birth. Treatments with a very poor prognosis are defined as having a 1-5% chance of achieving a live birth. The determination of whether or not a treatment is futile or has a very poor prognosis is specific to each patient and takes into account medical history, physical exam findings, lab work, prior infertility treatments, and other factors such as population and national society of assisted reproductive techniques (SART) annual statistics.

Infertility – Infertility is medically defined as the condition of a female who is unable to conceive or a male who is unable to produce conception during a period of 1 year. The legal definition modifies this to require coverage after 1 year if the female is age 35 or younger or during a period of 6 months if the female is over the age of 35. The American Society of Reproductive Medicine (ASRM) does recommend the females 35 and older start evaluation and treatment sooner to overcome the natural subfertility¹. For purposes of meeting the Massachusetts legal criteria for infertility,^{2,3} if a person conceives but is unable to carry that pregnancy to live birth, the period of time she attempted to conceive prior to achieving that pregnancy shall be included in the calculation of the 1 year or 6-month period, as applicable. The policy presumes that the female member would be expected to conceive naturally absent a medical problem (i.e., that the insured is of normal reproductive age and a biological female). Aging is not a medical illness and treatments based on the effects of natural aging are not covered. Fallon Health acknowledges that the goal of a member is to take home a healthy baby.

Fallon Health Clinical Coverage Criteria

All of the following general eligibility criteria must be met (see specific criteria sets in the treating fertility section):

1. The biological female is of normal reproductive age where fertility is expected.
2. The plan member has been diagnosed with infertility as legally defined, with 12 or 6 cycles of exposure to fresh sperm without a conception. These normally have a 20% pregnancy rate⁴. For biological females without a biological male partner, the same number of cycles of medically supervised IUIs must be documented without a conception to meet the same infertility standard. These have a 14-15% pregnancy rate.⁵
3. The live birth rate per treatment cycle started is > 5%.⁶ As part of informed consent, we expect providers have informed members of their expected live birth rate.
4. The member has not undergone surgical sterilization or had fertility suppressed by other reasons. The treatment has been shown to improve live birth rate compared to exposure to sperm.
5. A single embryo transfer leads to better infant and maternal health, so that should be done for the first cycle at least, for women under 38 years of age.⁷

¹ Practice Committee of the American Society for Reproductive Medicine. Diagnostic evaluation of the infertile female: a committee opinion. *Fertil Steril*. 2015 Jun;103(6):e44-50. Available at: <https://www.fertstert.org/action/showPdf?pii=S0015-0282%2815%2900224-1>.

² Massachusetts Regulations 211 CMR 37.00: Infertility Benefits. Available at: <https://www.mass.gov/files/documents/2017/10/23/211-37.pdf>

³ Chapter 176G Section 4:

<https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter176G/Section4>.

⁴ A Bayesian Joint Model of Menstrual Cycle Length and Fecundity Biometrics. 2016 Mar;72(1):193-203. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4761533/>

⁵ A comparison of intrauterine versus intracervical insemination in fertile single women. *Fertility and Sterility*. Vol 75, No. 4, April 2001. <https://www.fertstert.org/action/showPdf?pii=S0015-0282%2800%2901782-9>.

⁶ Ethics Committee of the American Society for Reproductive Medicine. Electronic address: asrm@asrm.org; Ethics Committee of the American Society for Reproductive Medicine. Fertility treatment when the prognosis is very poor or futile: an Ethics Committee opinion. *Fertil Steril*. 2019 Apr;111(4):659-663. Available at: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/ethics-committee-opinions/fertility_treatment_when_the_prognosis_is_very_poor_or_futile.pdf.

Normal reproductive age

Among biological females who continued to try to have children even into their 40's, the median age at last birth was 40-41, and by age 45 87% of them were not able to have more children, so all services are not covered once a biological female reaches 45⁸.

Diagnosis of infertility unrelated to natural aging

To evaluate the cause and appropriate treatment, the minimal testing must include basal (cycle days 2-4) follicular stimulating hormone (FSH) and estradiol levels, a tubal patency if intrauterine inseminations (IUIs) are to be done, a uterine cavity evaluation completed within the last year, 2 semen analyses done with 2-5 days of abstinence, as well as smoking history, body mass index (BMI), and history of alcohol usage. While a basal set of labs is sufficient for women under 40 who have a low chance of diminished ovarian reserve that comes with natural aging, prior to a fresh In Vitro Fertilization (IVF) cycle for women 40 up to 43 without documented premature diminished ovarian reserve, a clomiphene citrate challenge test (CCCT) must be done once a year and a basal FSH and estradiol repeated if 6 months have elapsed since the CCCT⁹. To confirm the clomiphene was taken properly, the basal FSH and estradiol, and then the Day 10 FSH and estradiol must be submitted. All Day 3 or Day 10 FSH must be ≤ 12 mIU/ml. The Day 3 estradiol should be < 100 pg/ml. If it is found to be > 100 without a documented medical cause, this ends coverage. If the Day 10 estradiol is not > 100 , this supports the clomiphene was not taken correctly or that there is diminished ovarian reserve. For members with a documented contraindication to clomiphene or ovulation disorder (i.e. PCOS, hypothalamic amenorrhea), we accept either the Exogenous follicle stimulating hormone ovarian reserve test (EFORT) with an Inhibin B value difference of < 78.6 between Day 3 and Day 4, OR a combination of basal FSH, estradiol, and antral follicle count (AFC) done on the same day and an anti-mullerian hormone (AMH) drawn within 1 month. Any abnormal value ends coverage, such as AMH < 1.0 ng/ml or AFC < 7 or basal FSH > 12 mIU/ml or estradiol > 100 . ASRM states a single elevated day 3 FSH value in a woman a high chance of diminished ovarian reserve connotes a poor prognosis, even when values in subsequent cycles are normal. Premature diminished ovarian reserve is therefore defined by a Day 3 FSH > 12 or Day 3 estradiol > 100 in a woman prior to age 40, not due to another condition.

Expected live birth rate

No coverage will be provided for infertility services when the chance of achieving a live birth per cycle started is $< 5\%$. Currently, Centers for Disease Control and Prevention (CDC) data shows that women 43 and older have $< 5\%$ live birth rate per IVF cycle started using their own eggs.^{10,11,12,13,14,15}

⁷ ASRM Elective Single Embryo Transfer:

⁸ Eijkemans MJ, van Poppel F, Habbema DF, Smith KR, Leridon H, te Velde ER. Too old to have children? Lessons from natural fertility populations. Hum Reprod. 2014;29(6):1304–1312. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4389129/>

⁹ ASRM testing and interpreting measures of ovarian reserve;

¹⁰ CDC 2016 Women Aged 40 or Older: https://www.cdc.gov/art/pdf/2016-national-summary-slides/art_2016_graphs_and_charts.pdf#page=17

¹¹ CDC 2015 Women Aged 40 and Older: https://www.cdc.gov/art/pdf/2015-national-summary-slides/ART_2015_graphs_and_charts.pdf#page=17

¹² CDC 2014 Women Aged 40 and Older: https://www.cdc.gov/art/pdf/2014-national-summary-slides/art_2014_graphs_and_charts.pdf#page=16

¹³ CDC 2013 Women Aged 40 or Older: https://www.cdc.gov/art/pdf/2013-national-summary-slides/ART_2013_graphs_and_charts_final.pdf#page=15

¹⁴ SART Final National Summary Report for 2017. Live births per intended egg retrieval (all embryo transfers):

https://www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?reportingYear=2017

After 6 IVF non-donor cycles in a row without a live birth, data show a 7th cycle will have a <5% live birth rate.¹⁶

Trying IUI after failing IVF is also associated with < 5% live birth rate per cycle started.

Reduced fertility / Sterilization

When there has been a procedure to reverse elective female sterilization (e.g., microsurgical tubal anastomosis), and tubal patency on at least one side has been proven, the female plan member must then begin the period to demonstrate infertility (i.e., inability to conceive during the statutory time period). If the member has taken medications that reduce fertility, then they must be stopped completely and documented return of ovulation or return of sperm count to normal ranges to start the time period required to prove infertility. When the male partner has reversed male sterilization, the provider must submit 2 post reversal semen analyses (6 months apart) showing ≥ 20 million total motile sperm and $\geq 3\%$ normal forms, and the member had a normal semen analysis 6 months prior to the infertility service request. The semen analysis must be within 6 months of the procedure since vasectomy reversals may continue to fail at 6% per year. Voluntary male sterilization ends coverage for intracytoplasmic sperm injection (ICSI), IVF, and donor sperm based on male factor or Unexplained infertility.

Smoking reduces fertility in women and reduces the success of IVF by nearly 50%,¹⁷ even when the male smoked and the woman did not. It leads to preterm delivery, intrauterine growth restriction, placental abruption, placenta previa, premature rupture of membranes, early menopause, and perinatal mortality.¹⁸ A study showed that conception delay over 1 year was 54% higher in smokers and the impact of passive cigarette smoke exposure alone was only slightly smaller than for active smoking. Nicotine replacement is pregnancy category D or C. As many who try to quit completely find this difficult, urine or serum cotinine levels must be obtained within the month of the requested service, for all members and their partners who acknowledged smoking or nicotine usage within the past year. Coverage can be approved 2 months after the cotinine level reaches normal levels and the repeat within the month is also normal.

Obesity leads to an increase in spontaneous abortion after assisted reproductive treatment.¹⁹ It is 18% for normal weight and 31% for Body Mass Index (BMI) ≥ 35 . There is also increased surgical risk in oocyte retrieval. Obesity may be a sign of Polycystic Ovarian Syndrome (PCOS)

¹⁵ SART Preliminary National Summary Report for 2018. Live births per intended egg retrieval (all embryo transfers):

https://www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?reportingYear=2018

¹⁶ Smith, Andrew D A C et al. Live-Birth Rate Associated With Repeat In Vitro Fertilization Treatment Cycles. *JAMA* vol. 314,24 (2015): 2654-2662.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4934614/>

¹⁷ Practice Committee of the American Society for Reproductive Medicine. Electronic address: asrm@asrm.org; Practice Committee of the American Society for Reproductive Medicine. Smoking and infertility: a committee opinion. *Fertil Steril*. 2018 Sep;110(4):611-618. Available at: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/smoking_and_infertility.pdf.

¹⁸ American Society for Reproductive Medicine; American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice. Prepregnancy counseling: Committee Opinion No. 762. *Fertil Steril*. 2019 Jan;111(1):32-42. Available at: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/prepregnancy_counseling.pdf.

¹⁹ Practice Committee of the American Society for Reproductive Medicine. Obesity and reproduction: a committee opinion. *Fertil Steril*. 2015 Nov;104(5):1116-26. Available at: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/obesity_and_reproduction.pdf.

which may require different treatment. It has been demonstrated that weight loss can improve the fertility of obese women through the recovery of spontaneous ovulation and others will improve their response to ovarian stimulation. Live birth rate was 9% lower for women with BMI > 30 undergoing IVF. For Asians, the calculations are slightly different, and a BMI calculator can be found at <https://aadi.joslin.org/en/am-i-at-risk/asian-bmi-calculator>. Therefore, women with BMI greater than 30 must undertake a weight-reduction program, including nutrition consult, diet, exercise, and behavior modification.

A BMI of less than 18.5 (underweight) may cause irregular menstrual cycles and anovulation. The time to conception was increased 4-fold.²⁰ Women who are underweight should be counseled to achieve a BMI within the lower limits of normal. For most women, this will restore natural fertility and increase potential for a good pregnancy outcome.

Alcohol abuse and alcoholism are associated with disorders of reproductive function in both men and women. There is also a clearly established high risk of serious harm to a child associated with prenatal alcohol abuse.¹⁹ Maternal alcohol use is the leading known cause of mental retardation and is a preventable cause of birth defects. Children exposed to alcohol in utero are at risk for growth deficiencies, facial deformities, central nervous impairment, behavioral disorders, and impaired intellectual development. Consuming alcohol during pregnancy also increases the risk of miscarriage, low birth weight, and stillbirth. Women should avoid alcohol entirely while pregnant or trying to conceive because damage can occur in the earliest weeks of pregnancy, even before a woman knows that she is pregnant. Even 1-2 drinks per day is associated with decreased fertility.²⁰ Infertility services are not covered for a woman unwilling or unable to eliminate alcohol consumption.

High levels of caffeine (> 5 cups/day) are associated with decreased fertility and 2-3 cups/day may increase the risk of miscarriage in women.²⁰

Medications including anabolic steroids that reduce fertility must be stopped completely until normal function returns, then begin the required number of cycles to prove infertility.

Improved live birth rate

When there is a structural genetic abnormality causing recurrent pregnancy loss, IVF with preimplantation genetic diagnosis (PGD) had a live birth rate of 31-35% per cycle and a cumulative live birth rate of 55-74% for natural conception.²²²¹ ASRM does not list IVF as a treatment of recurrent pregnancy loss.²² Natural cycle or minimal stimulation IVF has much lower success rate, so a center may have to submit their success rates. So all treatments, including for recurrent pregnancy loss, must be shown to improve live birth rate per cycle started compared to natural conception to be covered.

²⁰ Practice Committee of the American Society for Reproductive Medicine in collaboration with the Society for Reproductive Endocrinology and Infertility. Electronic address: ASRM@asrm.org; Practice Committee of the American Society for Reproductive Medicine in collaboration with the Society for Reproductive Endocrinology and Infertility. Optimizing natural fertility: a committee opinion. *Fertil Steril.* 2017 Jan;107(1):52-58. Available at: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-members/optimizing_natural_fertility.pdf.

²¹ M.T.M. Franssen, et al, Reproductive outcome after PGD in couples with recurrent miscarriage carrying a structural chromosome abnormality: a systematic review, *Human Reproduction Update*, Volume 17, Issue 4, July-August 2011, Pages 467–475. <https://academic.oup.com/humupd/article/17/4/467/832707>

²² Practice Committee of the American Society for Reproductive Medicine. Evaluation and treatment of recurrent pregnancy loss: a committee opinion. *Fertil Steril.* 2012 Nov;98(5):1103-11. Available at: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/evaluation_and_treatment_of_recurrent_pregnancy_loss.pdf.

Single embryo transfer (SET)

Multiple births result in substantial excess perinatal and maternal morbidity and include maternal hospitalization and neonatal intensive care and potential lifelong need for care of chronic illness, rehabilitation, and special education.²³ To help the member's desire to take home a healthy baby, for members < 38 years old undergoing their first IVF cycle or donor egg IVF or donor embryo FET, SET must be done. If there are no top-quality embryos after thawing, then two or more embryos of any quality may be transferred. For women < 35, or 35 up to 38 who had a live birth from the first IVF cycle, or those using donor egg, and undergoing a second treatment cycle. If the member has one or more embryos frozen, then a single thawed embryo transfer must be done. If there are no top-quality embryos after thawing, then two or more embryos of any quality may be transferred. If no cryopreserved embryos are available, then a fresh cycle of IVF with SET may be done.

For all treatment cycles, all frozen embryos must be used before another fresh cycle may be approved.

In Vitro Fertilization (IVF)/ Zygote Intra-Fallopian Transfer (ZIFT)/ Gamete Intra-Fallopian Transfer (GIFT)

IVF/ZIFT/GIFT is considered to be medically necessary after the member has met the criteria for infertility coverage as defined in this policy for any of the following conditions:

- Tubal factor infertility unrelated to prior sterilization
- Pelvic adhesive disease
- Endometriosis Stage III or IV who fail to conceive following conservative surgery or have a contraindication to surgery²⁴
- Male factor infertility as defined in this policy for biologically male partner
- Failure to have a live birth after 3 cycles of IUI with oral medications for unexplained infertility.
- For ovulatory disorders, failure to have a live birth after 6 months of conservation treatment, oral agents for 3 cycles, and 3 FSH IUIs.

Non-covered:

- Sperm storage/banking for biological males requesting this service for convenience or "back-up" for a fresh specimen
- For IVF cycles done for infertility, if all embryos are frozen, then a transfer must be planned for the member's next monthly cycle or that freeze-all cycle is not covered, as the live birth rate is 0%.

Male Factor Infertility

The CDC notes that "For cycles with a male factor infertility diagnosis, ICSI use was associated with reduced rates of implantation and multiple births, compared with conventional IVF. However, rates of pregnancy, miscarriage, and live birth were not different for cycles using ICSI versus conventional IVF."²⁸ Male factor infertility is defined by one of the 3 bullets below, not due to modifiable factors. IUI is required after an approved IVF cycle using the biological male partner's sperm when switching to unmedicated IUIs with donor sperm due to male factor infertility in the member's present biological male partner. Electroejaculation is covered.

²³ Practice Committee of Society for Assisted Reproductive Technology; Practice Committee of American Society for Reproductive Medicine. Elective single-embryo transfer. *Fertil Steril*. 2012 Apr;97(4):835-42. Available at: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/elective_single_embryo_transfer.pdf.

²⁴ Practice Committee of the American Society for Reproductive Medicine. Endometriosis and infertility: a committee opinion. *Fertil Steril*. 2012 Sep;98(3):591-8. Available at: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/endometriosis_and_infertility.pdf.

ICSI and IVF for Male Factor Infertility

- ICSI is covered for male factor infertility of non-donor sperm defined as followed (same type of abnormality present in each specimen):
 - At least 2 unprocessed semen analyses show <3 million total motile sperm, OR
 - At least 2 processed semen analyses show ≤1 million total motile sperm, OR
 - At least 2 unprocessed semen analyses show ≤ 2% strict Kruger normal forms and < 6 million total motile sperm
- If day of retrieval values unexpectedly meet these criteria, a retrospective authorization can be approved.
- A prior IVF cycle had less than 20% of mature oocytes fertilized with conventional insemination.
- When doing preimplantation genetic diagnosis in the absence of male factor, ICSI is covered only when contamination of extraneous sperm will affect the accuracy of the diagnosis.
- When cryopreserved oocytes are being used.

Non-covered:

- In cases where semen parameters are otherwise good but fewer than 5% of the sperm have normal shape, the better-run studies indicate ICSI does not improve live birth rates. A team from the University of Utah concluded in their recent meta-analysis that in this population ICSI is ineffective.^{25,26}
- Sperm penetration assay to determine whether ICSI should be offered for fertilization during an IVF treatment cycle.
- For cycles without male factor infertility, ICSI use was associated with decreased rates of implantation, pregnancy, live birth, and multiple live births compared with conventional IVF.²⁷ It is then not covered and providers who offer this anyway must provide this data as part of informed consent.
- Donor sperm from cryobanks are guaranteed to be normal, so IVF or ICSI based on poor quality of these specimens is not covered
- Emergency ICSI on an IVF cycle when low fertilization rate is discovered at the time of IVF, as this is not proven to improve live birth rate in a prospective, randomized trial.
- Treatment to reverse voluntary sterilization

Donor Sperm

Donor sperm is covered (up to 2 vials per IVF/IUI cycle) when the biological male partner's sperm meets the criteria below. If there is no proven female factor requiring IVF, then IUIs will be approved with the donor sperm until female factor/unexplained infertility is proven by sufficient failures to conceive. Donor sperm is not covered to correct genetic factors. In order to receive coverage for infertility services, male members must have at least 2 processed semen analyses show <1 million total motile sperm OR at least 2 unprocessed semen analyses show ≤ 2% strict Kruger normal forms AND < 6 million total motile sperm.

Non-covered:

- Donor sperm without documented biological male factor infertility proven with 2 abnormal semen analyses with the same defect
- Donor sperm for biological males with genetic sperm defects

Cryopreservation after IVF Cycle

²⁵ Keegan, Brian Robert et al. Isolated teratozoospermia does not affect in vitro fertilization outcome and is not an indication for intracytoplasmic sperm injection. *Fertility and Sterility*, Volume 88, Issue 6, 1583 – 1588. [https://www.fertstert.org/article/S0015-0282\(07\)00211-7/fulltext](https://www.fertstert.org/article/S0015-0282(07)00211-7/fulltext)

²⁶ Hotaling, James M. et al. The relationship between isolated teratozoospermia and clinical pregnancy after in vitro fertilization with or without intracytoplasmic sperm injection: a systematic review and meta-analysis. *Fertility and Sterility*, Volume 95, Issue 3, 1141 – 1145. [https://www.fertstert.org/article/S0015-0282\(10\)02590-2/fulltext](https://www.fertstert.org/article/S0015-0282(10)02590-2/fulltext)

²⁷ CDC Key Findings using ICSI: <https://www.cdc.gov/art/key-findings/icsi.html>

Embryo cryopreservation and storage is covered for up to 24 months for embryos that are created during an approved IVF cycle through Fallon, except when intended for a gestational carrier. If there are excess eggs harvested compared to the small number of sperm harvested for severe male factor, then the eggs may be cryopreserved.

Non-covered:

- Embryo/Egg cryopreservation and storage exceeding 24 months
- Cryopreservation after approved IVF cycle if the egg/embryo is intended for a gestational carrier.

Frozen Embryo Transfer (FET)

Frozen embryo transfer (FET) is covered when the following criteria are met:

- Embryos were created during a Fallon Health approved IVF cycle, OR
- Embryos were created while a patient under an insurer other than Fallon Health, AND member meets infertility criteria on this policy (either at time at freezing or prior to transfer), OR
- Member was approved for donor egg/embryo and will be using donor egg/embryo for FET.

Assisted Embryo Hatching

Assisted embryo hatching is covered under the following circumstances:

- Documented prior pregnancy following IVF with assisted hatching, OR
- 3 or more failures to implant after each embryo transfer cycle (failure to detect rise in HCG).

Non-covered:

- Assisted hatching if PGD is done, as PGD process includes opening the zona.

Donor Egg/Donor Embryo

Donor egg/embryo* is covered for medical illness which causes unnatural loss of egg quantity:

- At least two IVF treatment cycles where <6 eggs were retrieved with maximum ovarian stimulation prior to age 40, OR
- Absent ovaries prior to age 40, OR
- FSH >12 prior to age 40, not due to other disorders.

* The egg donor must be less than 34 years of age.

Fresh or frozen donor egg is covered when criteria are met. Frozen donor embryo is covered when criteria are met.

Medication for donor egg IVF is covered for the donor under the following conditions:

- Recipient is a member with Fallon pharmacy benefits, AND
- Donor is known to the member, OR
- Infertility medications for anonymous donors if the member is sole recipient of unknown donor eggs.

Cryopreservation of donor eggs or embryos is covered up to 24 months when created during an approved IVF cycle.

Non-covered:

- Donor eggs/donor embryos for biological females with genetic egg defects
- Donor eggs/donor embryos for age-related decline in egg quantity or quality, even if the member also has a medical cause of infertility which is normally treated by IVF
- Infertility medication for anonymous donors who do not meet above criteria
- Fees related to the payment of the egg donor; donor identification; legal services; or selection, purchase and transportation of frozen donor eggs/embryos, including the purchase of donated frozen eggs or donated frozen embryos.

- Coverage for services related to achieving pregnancy through a surrogate. Use of donor egg and gestational carrier is not covered, as the female member is not physically treated in this situation and is effectively a surrogate service.

Special conditions

Ovulatory Disorders

WHO Class I (hypogonadotropic hypogonadal anovulation) often respond to lifestyle modification and WHO Class II (normogonadotropic normoestrogenic anovulation) such as PCOS often respond to weight loss. For obese women with PCOS, the loss of just 5 to 10 percent of body weight is often sufficient to restore ovulation in 55% to 100% of these women within six months.²⁸ Various ovulation-inducing agents (e.g., clomiphene citrate, aromatase inhibitors, gonadotropins), insulin-sensitizing drugs (e.g., metformin) have been used to treat those who still need intervention. PCOS members are very sensitive to gonadotropins, but the step-up protocol has been shown to be successful with a low rate of multiples.²⁹ The goal of treatment of ovulatory disorders is to restore normal monofollicular development, not superovulation. A stepwise approach of medications (oral and then injectable) must be used.

Fertility Preservation

When a member is facing permanent loss of fertility that currently exists, in medical conditions that fit the Patient Protection and Affordable Care Act (ACA) for treatment of cancer or another life-threatening illness, a single cycle of IVF with egg or embryo cryopreservation (if the member is < 43 years of age) or sperm collection and storage. The storage will be covered for up to 24 months. Frozen embryo transfer, or egg thaw with insemination and transfer, is covered back to the member only, not to a gestational carrier. For IVF cycles done for infertility, if all embryos are frozen, then a transfer must be planned for the member's next monthly cycle or that freeze-all cycle is not covered, as the live birth rate is 0%. Ovarian transposition is covered when a localized treatment would permanently harm the ovaries.

Non-covered:

- Freeze all cycles with a delay of more than 1 cycle before transferring the embryo.

Gestational Carrier

For women with a clear medical contraindication to pregnancy who are using their own oocytes and self-paying for a gestational carrier, we do pay for our member's infertility evaluation, stimulation, retrieval, and fertilization. We do not cover for implantation or other services related to a gestational carrier, including, but not limited to transfer, impending pregnancy costs or cryopreservation of embryos.

Non-covered:

- Coverage for services related to achieving pregnancy through a surrogate. Use of donor egg and gestational carrier is not covered, as the female member is not physically treated in this situation and is effectively a surrogate service.

Microepididymal Sperm Aspiration (MESA)

MESA is covered only for congenital absence or congenital obstruction of the vas deferens (typically diagnosed by the absence of fructose in semen) and confirmed by exam.

Non-covered:

- Testicular sperm aspiration (TESA) or Percutaneous Epididymal Sperm Aspiration (PESA) which can lead to no sperm retrieval

Microdissection- Testicular Excisional Sperm Extraction (TESE)

²⁸ ASRM/ESHRE Consensus on Infertility Treatment Related to PCOS:
<https://academic.oup.com/humrep/article/23/3/462/2915005>

²⁹ Shamonki, Mousa I. et al. Low-dose gonadotropin step-up protocol is highly successful for the PCOS patient. *Fertility and Sterility*, Volume 80, 171, September 1, 2003.
[https://www.fertstert.org/article/S0015-0282\(03\)01354-2/fulltext](https://www.fertstert.org/article/S0015-0282(03)01354-2/fulltext)

Microdissection-TESE is covered for non-obstructive azoospermia and spinal cord injury resulting in inability to ejaculate.

Cryopreservation of Sperm or Testicular Tissue for Members in Active Infertility Treatment

Sperm storage/banking is covered for members who have undergone covered MESA or microdissection-TESE for up to 24 months.

Cryopreservation of testicular tissue/sperm in adult biological males with azoospermia in conjunction with the testicular biopsy to identify sperm in preparation for an intracytoplasmic sperm injection procedure, if sperm are found.

Conversion from IUI to IVF

Where the goal of gonadotropin IUI is to obtain two or three follicles of 16 to 18 mm at the time of hCG administration, conversion from IUI to IVF-ET is considered medically necessary for women less than 35 years of age and:

- ≥ 4 follicles ≥ 15 mm on the day of hCG administration, or
- E2 level $\geq 1,000$ pg/ml on the day of hCG administration

It is not covered for situations where monofollicular ovulation was the goal and stimulation medication did not follow international protocols.^{23,24}

Preimplantation genetic screening

Preimplantation genetic screening (PGS) refers to techniques where embryos from presumed chromosomally normal genetic parents are screened for aneuploidy (such as trisomy 21). PGS is not covered. When done with FISH method of testing, it was proven to reduce live birth rate per cycle started.³⁰ A study using Array Comparative Genomic Hybridization³¹ had 21.66% live birth rate per cycle started and 22.52% per cycle started with PGS. There is an ongoing clinical trial using next generation sequencing for PGS.³² ASRM states "At present, however, there is insufficient evidence to recommend the routine use of blastocyst biopsy with aneuploidy testing in all infertile patients."³³ All services related to an uncovered service are also not covered, so IVF done with PGS is also not covered.

Exclusions

- Treatment to reverse voluntary sterilization
- Gender selection
- In vitro maturation of oocytes
- Mock transfer
- Reciprocal IVF unless otherwise specified in the member's subscriber certificate
- Selective fetal reduction

³⁰ Mastenbroek, et al., "In Vitro Fertilization with Preimplantation Genetic Screening", *N Engl J Med* 2007; 357:9-17. <https://www.nejm.org/doi/full/10.1056/NEJMoa067744>

³¹ Feichtinger, Michael et al. "Increasing live birth rate by preimplantation genetic screening of pooled polar bodies using array comparative genomic hybridization." *PloS one* vol. 10,5 e0128317. 29 May. 2015. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4449032/>

³² Cumulative Live Birth Rate With eSET After Preimplantation Genetic Screening Versus Conventional In-vitro Fertilization (CESE-PGS): <https://clinicaltrials.gov/ct2/show/NCT03118141>

³³ Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Electronic address: ASRM@asrm.org; Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. The use of preimplantation genetic testing for aneuploidy (PGT-A): a committee opinion. *Fertil Steril*. 2018 Mar;109(3):429-436. Available at: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/use_of_pgt-a.pdf .

- Human zona binding assay (hemizona test)
- Serum anti-sperm antibody testing
- Sperm acrosome reaction test
- Co-culture of embryos
- Embryo toxic factor test (ETFL)
- Ovulation kits
- Post-coital testing
- Direct intraperitoneal insemination (DIPI)
- Peritoneal ovum and sperm transfer (POST)
- Genetic engineering
- Egg harvesting or other infertility treatment performed during an operation not related to an infertility diagnosis
- Elective egg freezing for fertility preservation.

Policy history

Origination date: 08/1996
 Review/Approval(s): Benefit Oversight Committee: 11/01/2006, 06/26/2009
 Technology Assessment Committee: 08/28/2013, 10/22/2014 (updated references, consolidated language, and updated template) 10/28/2015 (updated references) 10/26/2016 (updated references), 12/06/2017 (updated references), 06/27/2018 (added age specific FSH requirements for gonadotropins treatment with IUI, updated references, added language regarding pharmacy benefits, and peer to peer reviews), 10/23/2019 (revised criteria sets, added links, reformatted policy), 07/22/2020 (updated references), 06/25/2021 (Added clarifying language related to Medicare Advantage, MassHealth ACO, NaviCare and PACE under policy section), 04/23/2024 (annual review, no changes).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.