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.

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.

Definitions

Assisted reproductive technology (ART) treatment cycle - Because ART consists of several steps over an interval of several weeks to months, each treatment is more appropriately known as an ART treatment cycle. A cycle begins with starting medication to stimulate the ovaries to develop more than one egg or, if no medication is given, when monitoring the ovaries and hormone levels in the blood for natural egg production. Once egg(s) are produced and of adequate size, the cycle progresses to egg retrieval, a procedure done while sedated in which eggs are collected from a woman's ovaries through the vagina. 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 into the uterus (womb), 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 this policy's coverage criteria are met during the time/age period

that fertility is naturally expected. In addition, for all members, infertility 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 considers 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 defined as the condition of an individual who is unable to conceive or produce conception during a period of one year if the female is age 35 or younger or during a period of six months if the female is over the age of 35. For purposes of meeting these criteria, 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 (211 CMR 37.03, MGL Chapter 176G(e)). This 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 infertility 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 single healthy baby.

Fallon Health Clinical Coverage Criteria

All of the following general eligibility criteria must be met plus the service-specific criteria for the treatment requested):

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 ovulatory cycles of exposure to normal sperm without a conception. These natural attempts at pregnancy, have a 20% chance of pregnancy per ovulatory cycle (Lum et al., 2016, Wilcox et al., 2000). For biological females without a biological male partner, the same number of cycles of medically supervised donor sperm IUIs must be documented without a conception to meet the same infertility standard. These have a 14-15% chance of pregnancy per treatment cycle (Carroll and Palmer, 2001).
3. The live birth rate per treatment cycle stated is >5% (ASRM, 2019). As part of informed consent, we expect that providers have informed members of their expected live birth rate with the suggested infertility treatment.
4. The member has not undergone surgical sterilization or had fertility suppressed by other reasons. The suggested infertility treatment has been shown to improve live birth rate compared to the member continuing to try naturally to conceive.
5. Singleton pregnancy (so a single embryo transfer) leads to better infant and maternal health, so a single embryo transfer should be done for the first ART treatment cycle at least, for women under 38 years of age (Fertil Steril. 2021 Sep;116(3):651-654).

Limitations

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 (embryo) procurement and processing, and banking of sperm, eggs or embryos; to the extent such costs are not covered by the donor’s insurer, if any (211 CMR 37.05(4)).

Normal reproductive age

Age alone has an effect on fertility. Historical data suggest that, among populations that do not use contraception, fertility rates decrease with increasing age of women (Fertil Steril. 2014 Mar;101(3):633-4).

Age-related loss of fertility rises slowly until somewhere between ages 35 and 40 after which it rises rapidly. The median age at last birth for females is 40–41 years of age across a range of natural fertility populations. This suggests that there is a fairly universal pattern of age-related fertility decline (Eijkemans et al., 2014).

The decline in fertility becomes clinically relevant when women reach their mid-30s, when even assisted reproduction treatment cannot compensate for the decline in fertility associated with delaying attempts at conceiving (Baird et al., 2005). With IVF, live birth rates peak at 40% per embryo transfer for women younger than 35 years but decrease to less than 5% by age 43 years (Walter KL. 2025).

Required infertility evaluation
To evaluate the cause and if infertility treatment is appropriate and covered, the following are required:

- Baseline (cycle days 2-3) follicular stimulating hormone (FSH) and estradiol hormone levels,
- A tubal patency evaluation if intrauterine inseminations (IUIs) are to be done,
- A uterine cavity evaluation completed within the last year,
- Two semen analyses with 2-5 days of abstinence (1 is adequate if normal),
- History of smoking history, body mass index (BMI), and alcohol/drug use.

While a basal set of labs is sufficient for women under 40 years of age at the projected time of infertility treatment beginning (as they have a low chance of diminished ovarian reserve that comes with natural aging), women ≥40 and <44 years without documented premature diminished ovarian reserve, will require a yearly clomiphene citrate challenge test (CCCT) and basal FSH and estradiol levels repeated if 6 months have elapsed since the CCCT. Basal FSH and estradiol (typically done on cycle day 2 or 3) and then cycle day 10 FSH and estradiol levels must be submitted. All Day 3 or Day 10 FSH must be ≤12.0 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 suggests the clomiphene citrate medication 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 cycle day 3 and cycle 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 are alternate ovarian reserve tests. Any abnormal value ends infertility treatment coverage, such as AMH <1.0 ng/ml or basal AFC <7 or basal FSH >12.0 mIU/ml or estradiol > 100.0. ASRM states a single elevated day 3 FSH value in a woman with a high chance of diminished ovarian reserve (i.e. 40 years of age or older) connotes a poor prognosis with infertility treatment, even when values in subsequent cycles are normal. Premature diminished ovarian reserve is therefore defined by a cycle day 3 FSH >12.0 or cycle day 3 estradiol >100.0 in a woman prior to age 40, without a documented other reason for these values (i.e. an ovarian cyst can cause an elevated basal estradiol level) (Fertil Steril. 2020 Dec;114(6):1151-1157).

Expected live birth rate
No coverage will be provided for infertility services when the chance of achieving a live birth per any infertility treatment cycle started is <5% (Fertil Steril. 2019 Apr;111(4):659-663).

After 6 IVF treatment cycles using one's own eggs without a live birth, the medical literature shows a 7th IVF cycle will have a <5% live birth (Smith et al., 2015).

Trying IUI treatment 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 a prior elective female sterilization (e.g., tubal ligation and then tubal reanastomosis), and at least one tube has been proven to be open, the female plan member may be eligible for infertility treatment if they are defined infertile. If a member has taken medications that reduce fertility, then they must stop that medication and have documented return of ovulation or return of sperm count to normal ranges to start the time period required to define them with infertility. When the male partner has had a sterilization (i.e. vasectomy) reversed, there must be 2 post reversal semen analyses (6 months apart) showing ≥ 20 million total motile sperm and ≥3% normal forms, and the member must have a normal semen analysis 6 months prior to their planned infertility treatment requested for possible infertility

treatment coverage. The semen analysis must be within 6 months of any requested infertility treatment since sterilization/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 treatment by nearly 50% (Fertil Steril. 2018 Sep;110(4):611-618), even when the male partner smokes and the member does not. It also is associated with preterm delivery, intrauterine growth restriction, placental abruption, placenta previa, premature rupture of membranes, early menopause, and perinatal mortality (Obstet Gynecol. 2019 Jan;133(1):e78-e89). 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 smoking 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 of infertility treatment can be approved 2 months after the cotinine level reaches normal levels and the repeat within the month of expected infertility treatment is also normal.

Obesity leads to an increase in spontaneous abortion (miscarriage) with pregnancy after an assisted reproductive treatment (Fertil Steril. 2021 Nov;116(5):1266-1285). Miscarriage rate is 18% for normal weight and 31% for Body Mass Index (BMI) ≥35. There is also increased procedure risk with oocyte (egg) retrieval which is part of the IVF treatment cycle. Obesity may be a sign of Polycystic Ovarian Syndrome (PCOS) which may require different treatment (i.e. ovulation induction). It has been demonstrated that weight loss can improve fertility in obese women with restarting spontaneous ovulation or may improve the response to ovarian stimulation medications. Live birth rate was 9% lower for women with BMI > 30 undergoing IVF treatment. 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 prior to being eligible for infertility treatment coverage.

A BMI of less than 18.5 (underweight) may cause irregular menstrual cycles and anovulation, too. The time to conception was increased 4-fold (Fertil Steril. 2022 Jan;117(1):53-63). Women who are underweight should be counseled to achieve a BMI within at least the lower limits of normal. This may restore natural fertility and increase potential for a good pregnancy outcome.

Alcohol and drug use disorders are associated with disorders of reproductive function in both men and women (ASRM, 2022). There is also a clearly established high risk of serious harm to a child associated with prenatal alcohol and drug abuse (Gosdin et al., 2022). 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 (Fertil Steril. 2022 Jan;117(1):53-63). 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 (Fertil Steril. 2022 Jan;117(1):53-63).

Medications including anabolic steroids that reduce fertility and must be stopped completely until normal reproductive function returns, which would then begin the required number of natural cycles attempting pregnancy counted to be defined infertile.

Recurrent Pregnancy Loss
The majority of miscarriages are sporadic and most result from genetic causes that are greatly influenced by maternal age. It is estimated that fewer than 5% of women will experience two

consecutive miscarriages, and only 1% experience three or more. Recurrent pregnancy loss (RPL) is defined by two or more failed clinical pregnancies, and up to 50% of cases of RPL will not have a clearly defined etiology. When one of the partners has a chromosomal structural rearrangement genetic abnormality, preimplantation genetic testing for structural chromosomal rearrangements (PGT-SR), amniocentesis or chorionic villus sampling (CVS) are options to detect the genetic abnormality in the offspring. Amniocentesis and CVS are prenatal tests conducted during pregnancy; PGT-SR is performed during IVF, to transfer unaffected embryos. While data are limited comparing in vitro fertilization (IVF)/PGT-SR versus medical management (defined as natural conception and observation) for couples with RPL carrying a structural genetic abnormality, two systematic reviews have summarized the success rates from the literature. In these reviews, live birth rates were estimated to be between 31%–35% per cycle for IVF/ PGT-SR and cumulative live birth rates were 55%–74% for natural conception/medical management. Therefore, there are insufficient data demonstrating that IVF/PGT-SR improves live birth rate in couples with RPL and a structural genetic abnormality (Fertil Steril. 2012 Nov;98(5):1103-11).

Natural Cycle IVF
Natural cycle or minimal stimulation IVF has much lower success rate, so a center must submit their success rates with this type of treatment to calculate likely chance of live birth for the member for this type of infertility treatment.

Single embryo transfer (SET)
Multiple births result in substantial risks to a pregnancy and mother (i.e. excess perinatal and maternal morbidity that include maternal hospitalization and neonatal intensive care and potential lifelong need for care of chronic illness, rehabilitation, and special education. Fertil Steril. 2021 Sep;116(3):651-654). To reach the goal of infertility treatment, i.e., to take home a healthy single baby, single embryo transfer is required for:

1) Members at any age, that have an euploid embryo.
2) Members < 35 years old undergoing their first IVF cycle or donor egg IVF or donor embryo FET, a single embryo transfer (SET) must be done even if PGT-A was not done .But if there are no top-quality embryos before or after thawing, then two or more embryos of any quality may be transferred.
3) For women 35 up to 37 who had a live birth from their first IVF cycle or those using donor egg and undergoing a second treatment cycle (even if the member has one or more embryos frozen), a single thawed elective embryo transfer (STEET) 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 (even if there is only a single embryo frozen that is not top quality; this is because any frozen embryo has a chance to become a live born child).

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 surgery (Fertil Steril. 2012 Sep;98(3):591-8)
- Male factor infertility as defined in this policy for biologically male partner
- 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.

Male Factor Infertility
An analysis from the CDC NASS program evaluated the use and outcomes of intracytoplasmic sperm injection (ICSI) among couples with and without male factor infertility from 1996 through 2012. 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 vs conventional IVF. 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. Overall, use of ICSI did not improve reproductive outcomes, regardless of whether male factor infertility was present (Luke et al., 2017; Boulet et al., 2015).

If using donor sperm for a diagnosis of male factor infertility, IUI is required using donor sperm prior to being eligible for IVF unless or until a diagnosis of female infertility is met.

If a member plans to use their male partner's sperm for IVF with ICSI treatment directly and if unsuccessful, the member must do donor sperm using IUI to and/or be defined with female infertility to be eligible for IVF using donor sperm.

Donor sperm is guaranteed to be normal, so would not require ICSI during IVF treatment.

Electroejaculation is covered to obtain sperm if a male member is unable to produce a sperm specimen (i.e. after a spinal cord injury) and the male member has attempted and failed treatment if available to try and correct their ejaculation condition.

ICSI for Non-Male-Factor Infertility
Intracytoplasmic sperm injection (ICSI), while typically effective for overcoming low or absent fertilization in couples with a clear abnormality of semen parameters, is frequently used in combination with assisted reproductive technologies for other etiologies of infertility in the presence of semen parameters that meet the World Health Organization (WHO) 2010 normative reference values. The ASRM Committee Opinion provides a critical review of the literature, where available, to identify situations where ICSI may or may not be of benefit. This document replaces the previously published document of the same name, last published in 2012 (Fertil Steril 2012;98:1395–9). Proposed indications for the use of ICSI where there is no identifiable male factor include unexplained infertility, poor-quality oocytes, low oocyte yield, advanced maternal age, prior fertilization failure with conventional insemination, preimplantation genetic testing (PGT), fertilization after in vitro maturation (IVM), and fertilization of cryopreserved oocytes. Some practitioners have even proposed routine use of ICSI in all IVF cases without an indication (Fertil Steril. 2020 Aug;114(2):239-245).

The 2020 Committee Opinion concludes:
- ICSI without male factor infertility may be of benefit for select patients undergoing IVF with preimplantation genetic testing for monogenic disease and previously cryopreserved oocytes.

The additional cost burden of ICSI for non–male factor indications, where data on improved live-birth outcomes over conventional insemination are limited or absent, must be considered.

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.
- If on the day of egg retrieval during an IVF treatment cycle, semen values unexpectedly meet these criteria, a retrospective authorization can be approved for ICSI.
- A prior IVF cycle had less than 20% of mature oocytes fertilized with conventional insemination.
- When doing preimplantation genetic testing (PGT) in the absence of male factor, ICSI is covered only when contamination of extraneous sperm will affect the accuracy of the PGT.

- When cryopreserved oocytes are being used.
- When using testicular derived sperm.

Non-covered:
- In cases where semen parameters are otherwise good but fewer than 5% of the sperm have normal shape, studies indicate ICSI does not improve live birth rates with IVF treatment.
- Sperm penetration assay to determine whether ICSI should be offered for fertilization during an IVF treatment cycle.
- For IVF cycles without male factor infertility.
- 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 ("Rescue ICSI") on an IVF cycle when low fertilization rate is discovered at the time of IVF, has not been proven to improve live birth rate in a prospective, randomized trial.
- Treatment to reverse or based on results from a voluntary sterilization with or without a reversal.

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 (i.e. if the member and their male partner both are carriers of a disease).
1) at least 2 processed semen analyses show ≤ (less than or equal too) 1 million total motile sperm, OR
2) at least 2 unprocessed semen analyses show <3 million total sperm, OR
3) at least 2 semen analyses show ≤ 2% strict Kruger normal forms.

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
Embryo cryopreservation and storage is covered for up to 24 months for embryos that are created during an approved IVF cycle through Fallon Health, except when intended for a gestational carrier.

If there are excess eggs harvested during an approved IVF cycle, with an inadequate amount of sperm available during the same treatment cycle then excess egg cryopreservation is covered.

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 treatment cycle, OR
- Embryos were created while a patient under an insurer other than Fallon Health, AND member meets Fallon Health infertility criteria in this policy (either at time at freezing or prior to transfer), OR
- Member was approved for donor egg/embryo IVF treatment 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 3 consecutive embryo transfers and no prior pregnancy with IVF with embryo transfer(s) (failure to detect rise in HCG).

Non-covered:
- Assisted hatching if PGT is done, as the PGT embryo biopsy 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 >12.0 and or baseline estradiol >100.0 without a documented medical reason, prior to age 40.

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

Fresh or frozen donor eggs are 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
- The egg donor is known to the member, OR
- Infertility medications for anonymous donors if the member is sole recipient of the unknown donor's eggs.

Cryopreservation of donor eggs or embryos is covered up to 24 months when created during an approved donor egg 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 (polycystic Ovarian Syndrome) 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 (Thessaloniki ESHRE/ASRM, 2007). 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 (Shamonki et al., 2003). 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
Where a disease or the necessary treatment of that disease has a likely side effect of loss of fertility, this Plan will provide coverage for a single cycle of IVF with egg or embryo

cryopreservation if the member is <44 years of age, or sperm collection at any age, with storage. Storage of a member's eggs, embryos, or sperm will be covered for up to 24 months.

A semen analysis showing sperm are present is needed to be eligible for sperm cryopreservation.

For egg cryopreservation and for embryo freezing, all members ≥40 and <44 years of age must have ovarian reserve testing (CCCT vs alternative testing noted in this policy). If testing demonstrates diminished ovarian reserve is already present, prior to any medical treatment that is likely to render them infertile, IVF cycle and cryopreservation are not covered services.

Frozen embryo transfer, or egg thaw with insemination and embryo transfer or then freezing of embryos, is covered only when the transfer of the embryo(s) is back to the member only (not to a gestational carrier).

If during an approved IVF cycle, all embryos were frozen, then a transfer of a frozen thawed embryo must be planned for the member's next monthly cycle or that freeze-all cycle will not be paid.

Ovarian transposition is covered when a localized treatment (i.e. radiation therapy for cancer) that is likely to damage the ovaries and render a fertile member infertile, as moving the ovaries out of the treatment area (transposing the ovaries) would not result in damage to the ovaries.

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 embryo transfer or other services related/done to a gestational carrier, including, but not limited to embryo 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)
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 is covered 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.

Superovulation IUI
Where the goal of gonadotropin IUI is to obtain two or three mature follicles (16 to 18 mm in size) at the time of hCG administration.

Conversion from IUI to IVF 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 >/= 1,000 pg/ml on the day of hCG administration

It is not covered for situations where monofollicular ovulation induction was the goal and stimulation medication did not follow standard protocols for ovulation induction (Fertil Steril. 2021 Sep;116(3):651-654; Fertil Steril. 2012 Apr;97(4):835-42).

Preimplantation Genetic Testing for Aneuploidy
The value of preimplantation genetic testing for aneuploidy (PGT-A, previously known as preimplantation genetic screening or PGS) as a routine screening test for all patients undergoing in vitro fertilization has not been demonstrated, according to a Committee Opinion published by the American Society for Reproductive Medicine (ASRM). Although some earlier single-center studies reported higher live-birth rates after PGT-A in favorable-prognosis patients, recent multicenter, randomized control trials in women with available blastocysts concluded that the overall pregnancy outcomes via frozen embryo transfer were similar between IVF with PGT-A and conventional IVF. The value of PGT-A to lower the risk of clinical miscarriage is also unclear, although these studies have important limitations. This American Society for Reproductive Medicine (ASRM) Committee Opinion replaces the document of the same name, last published in 2018 (Fertil Steril. 2024;122: 421–34).

Currently, routine preimplantation embryo aneuploidy screening is not justified (Fertil Steril. 2012 Nov;98(5):1103-11), therefore, is a non-covered service.

Medicare Variation

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 06/22/2025).

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 Variation

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.

Exclusions

- Treatment to reverse voluntary sterilization (or needed as a result of a 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
- 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
- Home kits to evaluate sperm and/or freeze sperm (i.e. cryochoice kit)
- 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.
- Preimplantation genetic testing for aneuploidy (PGT-A, previously known as preimplantation genetic screening or PGS)
- More than one cycle of IVF, for members who will undergo treatment that is expected to render them infertile.
- Storage of cryopreserved sperm, eggs or embryos for more than 24 months.
- Advanced Sperm Selection Techniques (i.e. PICSI, Zeta potential, sorting by X or Y chromosome, magnetic activating cell sorting, etc.)
- Sperm hyperactivation processing/techniques
- Embryo toxic factor test (ETFL) or Natural killer cell assay
- IVIG (Intravenous Immunoglobulin)
- Granulocyte Colony Stimulating Factor (G-CSF)
- Intralipid infusion
- Endometrial Scratching
- Embryo Glue (hyaluronic acid)
- Human chorionic gonadotropin (hCG) infusion into the uterine cavity
- Uterine artery vasodilation (i.e. sildenafil)

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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 to coverage criteria), 06/24/2025, 7/22/2025 (annual review, updated Fertility Preservation pursuant to Chapter 140 of the Acts of 2024; updated criteria for single embryo transfer; added new sections for Medicare and MassHealth variation; updated Exclusions and References).
Utilization Management Committee: 07/15/2022, 08/19/2025 (annual review, approved with update to the following: Fertility Preservation pursuant to Chapter 140 of the Acts of 2024, criteria for single embryo transfer, Exclusions and References).

Instructions for Use

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).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follows 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.

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.

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.