Infertility Services
Clinical Coverage Criteria

Overview

Fallon Health covers Infertility treatments as outlined by Massachusetts General Law[1,2,3,4] or Medicare[5]. In accordance with MassHealth, coverage for MassHealth ACO plan members is limited to services for the diagnosis and treatment of an underlying cause of infertility. No coverage is provided for infertility treatments, such as intrauterine insemination (IUI) or in vitro fertilization (IVF).

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 subfertility[6]. For purposes of meeting the Massachusetts legal criteria for infertility in this section, 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.

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial
☒ Medicare Advantage
☐ MassHealth ACO
☒ NaviCare
☒ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare covers reasonable and necessary services associated with the diagnosis and treatment of infertility (Medicare Benefit Policy Manual, Chapter 15, Section 20.1 B. Treatment for Infertility). Medicare does not have an NCD which specifically addresses infertility services. National Government Services, Inc. does not have an LCD or LCA for infertility services at this time (MCD search 06-25-2021).

For plan members enrolled in NaviCare and PACE plans, Fallon Health follows guidance from CMS for coverage determinations. In the event that there is no Medicare guidance or if the plan

member does not meet medical necessity criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Each PACE plan member is assigned to an Interdisciplinary Team. When there is no Medicare or MassHealth guidance, the member's Interdisciplinary Team is responsible for coverage determinations.

Fallon Health requires Prior Authorization for Infertility Services. Additionally, Infertility Services are subject to the coverage at 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.

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 rate[7]. For women 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.[8]
3. The live birth rate per treatment cycle started is > 5%.[9] 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.[10]

Normal reproductive age

Among women 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 45[11].

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 CCCT[12]. 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.[13,14,15,16,17,18]

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.[19]

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 ≥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%,[20] 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.[21] 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.[22] 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) 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.[23] 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.22[24] ASRM does not list IVF as a treatment of recurrent pregnancy loss.[25] 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.

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.[26] 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 surgery[27]
- 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.

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 unexpectantly 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.[28,29]
- 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.[30] 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
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.[31] 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.[32] 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)
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 >/= 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.[33] A study using Array Comparative Genomic Hybridization[34] 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.[35] ASRM states “At present, however, there is insufficient evidence to recommend the routine use of blastocyst biopsy with aneuploidy testing in all infertile patients.”[36] 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
- 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.

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.

Biological Male: A member born with X and Y chromosomes and includes members with gender identities other than male.

Biological Female: A member born with no Y chromosomes (usually 2 X) and includes members with gender identities other than female.

Basal follicle stimulating hormone (FSH) level: An elevated basal (done on cycle day 2, 3, or 4) FSH level predicts that the ovarian response to gonadotrophin will be reduced and conception will be less likely in IVF cycles. A single properly done elevated value is prognostic of all future cycles, so repeating it to get a lower value is an attempt to misrepresent the member's condition.

Medicare 20.1BReasonable 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.

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Policy history

Origination date:	08/1996
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, NaviCare and PACE under policy section.

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.