

**Medical Policy
Infertility Services**

Document Number: 002

| | *Commercial and Qualified Health Plans | MassHealth |
|----------------------------------|--|------------|
| Authorization required | X | |
| No notification or authorization | | |
| Not covered | | X |

*Not all commercial plans cover this service, please check plan’s benefit package to verify coverage.

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Overview

The purpose of this document is to describe the clinical coverage criteria that AllWays Health Partners utilizes to determine medical appropriateness for infertility services. This document does not address the coverage or criteria for the treatment of the underlying medical condition causing the infertility.

Infertility is 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 age 35. For the purposes of meeting the criteria of 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 1 year or 6-month period as applicable (M.G.L.c. 175, section 47H and 211 C.M.R 37.09).

For women without exposure to sperm, infertility is determined by the inability to conceive after six Artificial Insemination (AI)/Intrauterine insemination (IUI) cycles are performed by a qualified specialist. These AI/IUI cycles with donor sperm and associated sperm processing and infertility medications are not covered because infertility has not been established until the AI/IUI cycles have been completed.

AllWays Health Partners only provides coverage for IVF medications (Follistim AQ, Gonal-F RFF, Menopur, Novarel, Ovidrel, and Pregnyl) if the IVF or medicated IUI services have been approved.

Coverage Guidelines

AllWays Health Partners covers medically necessary expenses for the non-experimental treatment of infertility to the same extent that benefits are provided for other medically necessary services and prescription medications, when the member’s plan includes infertility treatment.

MassHealth, and Certain Custom Plans

AllWays Health Partners does not provide coverage for the treatment of infertility for MassHealth members, and members of certain Custom Plans. To determine if a Custom Plan covers infertility services, please refer to the *Summary of Benefits and Coverage* for the given plan. Infertility treatment will be listed under either “services your plan does NOT cover” or “Other Covered Services.”

The infertility treatment requested must be non-experimental, recognized as the community standard of practice in Massachusetts, and meet the criteria established by the American Society for Reproductive



Medicine, the American College of Obstetrics and Gynecology or the Society of Assisted Reproductive Technology.

Treatment must be provided by an AllWays Health Partners -contracted provider. Services must be authorized by AllWays Health Partners and delivered in accordance with medical necessity determinations.

Covered Services/Procedures

Covered services and procedures include, but are not limited to:

1. Artificial Insemination (AI)/Intrauterine insemination (IUI);
2. Conversion from IUI to In Vitro Fertilization (IVF);
3. In Vitro Fertilization (IVF);
4. Frozen embryo transfer (FET)
5. Single embryo transfer (SET)
6. Gamete Intra-Fallopian Transfer (GIFT);
7. Zygote Intrafallopian Transfer (ZIFT);
8. Intra-Cytoplasmic Sperm Injection (ICSI);
9. Donor Egg for Infertility;
10. Donor Sperm or Therapeutic Donor Insemination (TDI) Services for Infertility;
11. Donor Egg/Sperm When There is a Risk of Transmitting a Genetic Disorder for a serious genetic condition;
12. Microsurgical Epididymal Sperm Aspiration (MESA);
13. Testicular Sperm Extraction;
14. Cryopreservation of Embryos/Eggs;
15. Cryopreservation of Sperm;
16. Sperm, egg and/or inseminated egg procurement and processing, and banking of sperm, eggs, or embryos when they will be used by the member, to the extent such costs are not covered by the donor's insurer, if any;
17. Assisted Hatching; and
18. Ovulation kits: Coverage provided with prescription for up to 3 kits to support authorized AI/IUI.

General Eligibility Coverage Criteria

AllWays Health Partners covers medically necessary infertility services when a member meets all the general eligibility coverage criteria and the relevant criteria for the service-specific infertility treatment that is requested. General Eligibility criteria are as follows:

1. The member must otherwise be an individual with whom fertility would naturally be expected.
2. The member has regularly attempted to conceive but has been unable to conceive or produce conception during a one-year period, or for woman >35 years of age for a period of six months. This includes the time attempting to conceive a pregnancy that results in a miscarriage.
 - a. For women without exposure to sperm, infertility is determined by the inability to conceive after six AI/IUI cycles performed by a qualified specialist using normal quality donor sperm. These AI/IUI cycles with normal quality donor sperm and associated sperm

processing and infertility medications are not covered because infertility has not been established until the AI/IUI cycles have been completed (note: for women < 40, in order to qualify for IVF services, two of these AI/IUI cycles must be medicated cycles. See IVF Services).

- b. For certain causes of known infertility, the one-year or 6-month requirement for attempted conception may be waived (e.g. bilateral Fallopian tube obstruction or ovulatory dysfunction).
3. Ovarian Reserve Assessment Criteria:
- a. Women < 40 years old must demonstrate adequate ovarian reserve by menstrual history and results from day 3 Follicle Stimulating Hormone (FSH) and Estradiol levels obtained within the last year.
 - b. Women ≥ 40 years of age must demonstrate adequate ovarian reserve evidenced by menstrual history and results from a:
 - I. Clomiphene Citrate Challenge Test (CCCT) within the past 6 months by showing a: Day 3 FSH level < 15 mIU/ml and Day 3 Estradiol Level < 80 pg/mL and a Day 10 FSH level < 15 mIU/ml; or
 - II. A CCCT within the parameters above performed within the past 12 months, and a Day 3 FSH level < 15 mIU/ml and Day 3 Estradiol Level < 80 pg/mL performed within the past 6 months.

Note: A woman ≥ 40 with any CCCT Day 10 or Day 3 FSH ≥15 mIU/ml performed at any time is not eligible for infertility services.

Note: For women who are unable to tolerate clomiphene citrate, submission of AMH level > 1.0 mg/mL or antral follicle count > 6 in addition to FSH would provide evidence of adequate ovarian reserve.

Note: For all women, any monitored, medicated-stimulated infertility treatments should demonstrate adequate ovarian response to stimulation (i.e. at least 2 follicles > 12 mm for IUI using standard medication doses, or at least 3 follicles >12 mm for IVF).

4. Anatomy Assessment:
- a. With any AI/IUI request, tubal patency and adequate uterine contours and carrying capacity must be demonstrated by either a hysterosalpingogram, definitive sono-hysterosalpingogram (e.g. FemVue) performed within the past 4 years.
 - b. With any IVF, FET or donor egg request, adequate uterine contours and carrying capacity must be documented by either by one of the tests above or by sonohysterogram or hysteroscopy performed within the past 4 years.
5. The member must be immune to rubella and varicella¹.

¹ Rubella immunity is evidenced by: a positive titer, or by evidence of at least one vaccination completed one month prior to planned infertility services. Varicella immunity is evidenced by: history of chicken pox or shingles, by a
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6. The member must have been screened for: HIV or opted out, syphilis, hepatitis C and hepatitis B antigen (even if vaccinated in the past).
7. The body mass index (BMI) of the embryo recipient should be submitted:
 - a. If the BMI is ≥ 30 , the member must be counseled to lose weight and informed of the negative impacts of obesity on fertility, infertility treatment success, obstetrical risk, anesthesia complications and poor fetal outcomes.
 - b. If the BMI is ≥ 35 , in addition to the above, there must also be documentation of nutrition consult within the past 6 months which includes a history of weight loss attempts.
8. If the member or partner was a smoker within the last year, there must be documentation of urine or serum negative cotinine levels within a month of requested service.
9. A semen analysis within the past year must be submitted if there is a male partner.
 - a. A normal fertility threshold based on WHO 5th edition 2010 (i.e. semen volume 1.5 ml, sperm concentration 15 million/ml, sperm total 40 million, 40% motility, and 4% normal morphology by Kruger classification or morphology of 30% by WHO 3rd edition classification).
 - b. If the sample is abnormal, a second sample within the past year must be obtained, and if it remains abnormal an evaluation and treatment of reversible causes undertaken including smoking cessation for at least 3 months. (AllWays Health Partners will require a urology consult for severe male factor infertility and may require for it for less severe).

Note: If the male partner has undergone a vasectomy reversal, two semen analyses in the past 3 months must be submitted to demonstrate continued success of the reversal and normal fertility threshold, in addition to meeting the service-specific criteria for Individuals who have had a Reversal of Prior Sterilization.

Note: With any infertility request, pre- and post-wash semen analyses from prior treatment cycles must be submitted.

10. With any infertility treatment request, documentation of all prior treatment and cycle details must be submitted.
11. There is a $>5\%$ probability that infertility treatment being requested will result in a live birth using the member's own eggs based on clinical history including: pregnancy history, menopausal status, diagnosis, BMI, semen analysis and response to previous cycles and infertility treatments, or the member must meet criteria for donor egg.
12. AllWays Health Partners does not cover infertility services for age-related decline, even if the member also has a medical-related cause of infertility. Women ≥ 44 years of age are generally not eligible for infertility services. Based on published research by the CDC, a woman ≥ 44 years of age utilizing their own eggs have a $\leq 5\%$ probability that in vitro fertilization will result in a live

positive titer, or by evidence of at least two vaccinations spaced one month apart and completed one month prior to planned infertility services.

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birth. The member's individual medical history is considered in any determination, but the age of the female is the most important factor affecting the live birth probability.

Individuals with a Sterilization Reversal

Medically necessary infertility services are authorized for members who have undergone successful reversal of previous voluntary sterilization procedures (e.g., vasectomy or tubal ligation) only when:

1. There is documentation of:
 - a. For a male reversal, a semen analysis with a normal fertility threshold (as noted in [General Eligibility Coverage Criteria](#)) to document the success of the reversal, followed by a member-age-applicable period of attempting natural conception, and then two semen analyses within 3 months of the request for infertility services to demonstrate continued success of the reversal.
 - b. For a female reversal, a post-surgical hysterosalpingogram (HSG) or chromotubation demonstrating unilateral or bilateral free spill tubal patency, followed by a member-age-applicable period of attempting natural conception, and then results of an HSG or chromotubation performed within 3 months of the request for infertility services demonstrating that post-operative scarring and tubal blockage have not occurred.
2. The member/couple otherwise meets all General Infertility Coverage Criteria;
3. The member's need for infertility services is clearly documented to be completely independent of the previous sterilization procedure

Note: ectopic pregnancy is considered evidence of a failed or failing reversal.

Note: The reversal of a voluntary sterilization is excluded from coverage.

Service—Specific Infertility Coverage Criteria

Artificial Insemination (AI)/Intrauterine Insemination (IUI)

AllWays Health Partners covers medically necessary AI/IUI when [General Eligibility Coverage Criteria](#) are met, and there is documentation of the following:

1. At least one patent Fallopian tube, normal ipsilateral ovary, and a normal endometrial cavity;
2. Spontaneous ovulation or adequate ovarian reserve testing;
3. Any one of the following:
 - a. Unexplained infertility;
 - b. Anovulation in the absence of primary ovarian insufficiency/premature ovarian failure;
 - c. Mild to moderate endometriosis;
 - d. Cervical factors;
 - e. Mild to moderate male factor infertility (i.e. with abnormal semen analysis but at least a; sperm concentration of 10 mil/ml; total sperm 20 million; motility of 20%; morphology 2% by strict Kruger classification; or morphology 20% by WHO 3rd edition classification; total motile sperm of at least 10 million, and at least 5 million on a washed sample if performed); or
 - f. Use of frozen sperm with normal fertility threshold parameters that was medically necessarily cryopreserved.



Note: Results of any prior IUI cycles must be submitted with each request to demonstrate adequate ovarian response to stimulation (i.e. at least 2 follicles >12 mm in diameter using standard medication doses) and adequate pre- and post-wash semen parameters in order to continue with IUI.

Note: In general, at most a maximum of 3 IUI cycles per lifetime will be authorized, unless an IUI has resulted in a live birth and the member <40 years old. This limit shall include cycles completed before AllWays Health Partners membership.

Conversion from IUI to In Vitro Fertilization (IVF)

AllWays Health Partners covers medically necessary conversion from IUI to IVF due to inadvertent ovarian hyperstimulation when the IUI cycle met IUI criteria and all of the following are met:

1. Current IUI cycle has resulted in estradiol level of greater than or equal to 800 pg/ml.
2. Current IUI cycle has resulted in production of at least 5 follicles greater than 13 mm in diameter.

In Vitro Fertilization (IVF) for Infertility

A. General Eligibility Coverage Criteria

AllWays Health Partners covers medically necessary IVF when General Eligibility Coverage Criteria are met and there is documentation of one of the following:

1. The member has regularly attempted to conceive but has been unable to conceive or produce conception during a one-year period, or for woman >35 years of age for a period of six months, when tubal patency and the potential for ovulation have been documented.
2. Tubal factor infertility:
 - a. Bilateral fallopian tube obstruction (excluding prior voluntary sterilization) when conventional therapy has failed;
 - b. Bilateral absence of fallopian tubes (excluding prior elective sterilization);
 - c. History of ectopic pregnancies due to prior tubal disease;
3. Stage 3 or 4 endometriosis diagnosed by laparoscopy
4. Moderate or severe male factor infertility (i.e. with a: sperm concentration less than 10 mil/ml; total sperm less than 20 million; motility of less than 20%; morphology less than 2% by strict Kruger classification; or morphology less than 20% by WHO 3rd edition classification; total motile sperm of less than 10 million, and less than 5 million on a washed sample if performed) that cannot be improved by conservative standard treatments or addressed via IUI. A urology consult is required.

B. Single Embryo Transfer (SET)

1. AllWays Health Partners requires SET for the first two IVF cycles when at least 2 good-quality embryos are available at the time of transfer for females <35 years of age;
2. AllWays Health Partners requires SET for the first IVF cycle when at least 2 good-quality embryos are available at the time of transfer for females age 35–37;
3. AllWays Health Partners does not require SET for a female over the age of 37;



Note: Members with severe premature ovarian failure characterized by: age less than 40, amenorrheic for 6 months, and a menopausal FSH level are not eligible for IVF but can be considered for donor egg.

Note: AllWays Health Partners expects that standard medication doses for stimulation be used and that all good quality embryos be frozen for future use. AllWays Health Partners covers cryopreservation up to one year for the remaining embryos.

Note: When there are at least 3 cryopreserved embryos from a female ≤ 37 , or at least 4 from a female ≥ 38 , these must be used prior to any request for further IVF cycles. A member who requests a frozen embryo transfer must meet General Infertility Coverage Criteria.

Note: AllWays Health Partners covers at most, a maximum of 6 IVF cycles per lifetime, when the member continues to meet criteria. A cycle begins when a medication prescription is filled. Frozen embryo transfers and prior IVF cycles that resulted in live birth are not part of this 6-cycle limit. This limit shall include cycles completed before AllWays Health Partners membership and include IVF, Donor Egg, and canceled IVF cycles (e.g. incomplete cycle due to poor response).

In Vitro Fertilization (IVF) for Member not in Active Infertility Treatment

AllWays Health Partners covers one cycle of IVF for the purpose of egg retrieval, processing and fertilization and a single cryopreservation of eggs/embryos for up to one year, when there is documentation that a member will be undergoing medical or surgical treatment (e.g. chemotherapy, radiation, gender reassignment), that is likely to result in permanent infertility. This does not include voluntary sterilization or past voluntary sterilization. In this case the member and/or couple do not need to be already receiving AllWays Health Partners -authorized infertility services. There must be a >5% probability of a future live birth using the member's cryopreserved eggs/embryos, based on clinical history including: pregnancy history, menstrual history, applicable ovarian reserve assessment, response to any prior infertility treatments if any, menopausal status, and medical/surgical diagnoses, and partner's semen analysis if applicable.

AllWays Health Partners does not cover these services for age-related decline in fertility. Women \geq age 40 must meet ovarian reserve assessment criteria. Women ≥ 44 years of age are generally not eligible for these services.

Gamete Intra-Fallopian Transfer (GIFT), Zygote Intra-Fallopian Transfer (ZIFT)

AllWays Health Partners covers medically necessary GIFT or ZIFT when [General Eligibility Coverage Criteria](#) and IVF criteria are met, and there is documentation of at least one patent fallopian tube, and a condition that prevents visualization of the cervix (e.g. severe cervical stenosis) such that IVF is not practical.

Frozen Embryo Transfer (FET)

AllWays Health Partners covers medically necessary FET when [General Eligibility Coverage criteria](#) except for semen analysis are met, and the member has frozen embryos from a prior IVF or Donor Egg Cycle, and the request is not related to gestational carrier services.

Intra-Cytoplasmic Sperm Injection (ICSI)

AllWays Health Partners covers medically necessary ICSI when the female partner meets coverage criteria for IVF, and there is documentation of at least one of the following:

1. Severe male factor infertility (i.e. with a: sperm concentration less than 10 mil/ml; total sperm less than 20 million; motility of less than 20%; morphology less than 2% by strict Kruger classification; or morphology less than 20% by WHO 3rd edition classification; total motile sperm of less than 10 million, and less than 5 million on a washed sample if performed) when the male partner has been evaluated by urology and the condition cannot be improved by conservative treatment and cannot be overcome with IVF.
2. Total failed fertilization or near total failed fertilization (less than 50%) of mature eggs on a prior IVF cycle with standard insemination.

Note: ICSI is not authorized for any IVF cycle using donor sperm since it is expected that normal quality donor sperm will be used.

Note: ICSI is not authorized solely to perform Preimplantation Genetic Testing (PGT) when AllWays Health Partners' PGT criteria are not met.

Note: If sperm are to be used from MESA or TESE procedures, sufficient sperm quality and quantity for a successful ICSI and fertilization, and for a >5% live birth probability must be documented before a request for IVF/ICSI is evaluated and authorized. In some cases, donor sperm back-up may be encouraged.

Donor Egg Services for Infertility

AllWays Health Partners covers medically necessary donor egg services when fertility is naturally to be expected and one of the following is met:

1. Member < 40 years of age who has one of the following medical causes of infertility:
 - a. Premature ovarian failure with onset and diagnosis prior to age 40 (with either a Day 3 FSH or a random FSH if menopausal and amenorrheic of >20 mIU/ml prior to age 40);
 - b. Met [General Eligibility Coverage Criteria](#), and has failed IVF due to poor embryo quantity or quality, or in whom IVF is felt to offer not much above a 5% probability of live birth due to premature diminished ovarian reserve; or
 - c. Congenital or surgical absence of ovaries.
2. Member ≥ 40 -42 years of age who meets [General Eligibility Coverage Criteria](#), but has failed IVF due to poor embryo quantity or quality, or who meets General Eligibility Coverage Criteria but IVF is felt to offer not much above a 5% probability of live birth.

Note: Member age 43 or older who does not meet General Infertility Coverage Criteria, or who met General Infertility Coverage Criteria and has failed IVF, is experiencing age-related decline in fertility, and is one in whom fertility is not naturally expected and therefore are not authorized for donor egg.



Note: The egg donor is to be between the ages of 21 and 29 years of age with Day 3 FSH < 10 mIU/ml and E < 80 pg/ml OR AMH level > 2 ng/mL. The member must be the sole recipient of the donor eggs.

Note: When donor egg coverage criteria are met the cycle is authorized for up to 6 months. If the donor egg procedure is not performed, a new request with updated clinical information must be submitted for authorization.

Note: Coverage for the embryo recipient (AllWays Health Partners member) includes: medications to support implantation if the member has a prescription drug benefit, egg insemination, the embryo transfer procedure, member monitoring, and cryopreservation of remaining embryos up to one year.

Note: Coverage for the egg donor is limited to: monitoring up to egg retrieval and the egg retrieval procedure, unless the embryo recipient has AllWays Health Partners prescription drug coverage in which case medications to stimulate the donor's ovaries and to induce ovulation are also covered.

Donor Sperm or Therapeutic Donor Insemination (TDI) Services for Infertility

AllWays Health Partners covers normal quality donor sperm or TDI services for an AllWays Health Partners member who meets [General Eligibility Coverage Criteria](#) and has a male partner diagnosed with moderate to severe male factor infertility as defined in the IVF section above.

Donor Egg/Sperm Services When There is a Risk of Transmitting a Genetic Disorder

AllWays Health Partners covers donor egg services for a member who meets IVF criteria for infertility, or covers normal quality donor sperm when a member meets General Eligibility Coverage Criteria for infertility in order to prevent a serious genetic condition (serious morbidity and/or mortality in childhood) in offspring when one of the following is present:

1. Both partners are known carriers of a single autosomal recessive gene (only donor sperm covered);
2. One partner is a known carrier of a single gene autosomal dominant disorder;
3. One partner is a known carrier of a single gene X-linked disorder; or
4. One of the partners is known to have a balanced translocation.

Note: The egg donor is to be between the ages of 21 and 29 years of age with Day 3 FSH < 10 mIU/ml and E < 80 pg/ml OR AMH > 2 ng/mL. The member must be the sole recipient of the donor eggs. Coverage is as listed for Donor Egg Services for Infertility.

Note: Please also see AllWays Health Partners' medical policy - Preimplantation Genetic Diagnosis.

Microsurgical Epididymal Sperm Aspiration (MESA)

AllWays Health Partners covers one MESA per lifetime for a male member with azoospermia and normal testicular function evidenced by normal testes exam, FSH, and testosterone, and who has either: congenital bilateral absence of vas deferens (CBVAD), stricture of the vas deferens, atrophy/fibrosis of the spermatic cord/vas deferens, or infertility due to extra testicular obstructive causes (excluding that

resulting from prior sterilization or sterilization reversal procedures); and whose female partner otherwise meets [General Eligibility Coverage Criteria](#).

Testicular Sperm Extraction (TESE)

AllWays Health Partners covers one TESE per lifetime for a male member with non-obstructive azoospermia that is not due to suppression of sperm production by anabolic steroids, and when the azoospermia is not amenable to other treatment such as hormonal therapy for hypogonadotropic hypogonadism. There must be a Y chromosomal microdeletion assay and karyotype prior to TESE, to eliminate the possibility of genetic traits that would predict the failure of sperm retrieval. The female partner must otherwise meet [General Eligibility Coverage Criteria](#).

Cryopreservation of Eggs/Embryos

AllWays Health Partners covers cryopreservation and storage for up to one year's storage when authorized in accordance with this policy and when one of the following criteria is met:

1. Female member is receiving AllWays Health Partners -authorized IVF or Donor Egg services and has embryos which should not be transferred into the uterus during the current cycle due to:
 - a. The high risk of multiple gestations from the transfer of an excessive number of available embryos; or
 - b. The high probability of an adverse impact on the woman's health and well-being, e.g. severe hyperstimulation syndrome;
2. Female member is receiving AllWays Health Partners -authorized IVF and there are unfertilized mature eggs due to an unexpected lack of sperm for fertilization; or
3. Female member will be undergoing medical treatment (e.g. chemotherapy, radiation, and gender reassignment) excluding voluntary sterilization that is likely to result in permanent infertility, and AllWays Health Partners has authorized an IVF cycle for stimulation and retrieval.
Cryopreservation of eggs/embryos will be covered for up to one year from the time of the egg retrieval.

Cryopreservation of Sperm

AllWays Health Partners covers cryopreservation and storage for up to one year's storage for a male member who meets one of the following criteria:

1. Male member has been diagnosed with a medical condition, not a result of previous voluntary sterilization, which requires that sperm be obtained directly via an AllWays Health Partners -authorized MESA or TESE procedure for ongoing infertility treatment.
2. Male member has a neurological or psychological condition, not a result of previous voluntary sterilization, which interferes with the ability to produce a sperm sample on the day of an AllWays Health Partners -authorized infertility procedure. The member must have a confirmed diagnosis that requires that sperm be obtained in advance and cryopreserved for ongoing infertility treatment.
3. Male member will be undergoing medical or surgical treatment (e.g. chemotherapy, radiation, gender reassignment surgery) excluding voluntary sterilization that is likely to result in permanent infertility. In this case the male member and/or couple do not need to be already



receiving AllWays Health Partners -authorized in infertility services. There must be a >5% probability of a future live birth using the member's cryopreserved sperm.

Surrogacy/Gestational Carrier:

AllWays Health Partners will authorize one cycle of oocyte stimulation, retrieval, and fertilization for female members who meet all of the following:

1. Members with a clear medical contraindication to pregnancy due to an uncorrectable structural uterine abnormality or a life-threatening condition (documentation required).
2. Member is using their own oocytes and self-paying for a gestational carrier.
3. Documentation of adequate ovarian reserve as outlined in General Eligibility criteria.

Note: use of donor egg and gestational carrier is not covered as the female member is not physically treated in this instance

Note: costs of implantation (transfer, pre-pregnancy costs, cryopreservation) or pregnancy-related services for the gestational carrier are not covered.

Exclusions

AllWays Health Partners does not provide coverage for infertility services for any condition/diagnosis/service not covered under this coverage criterion, including but not limited to:

1. Coverage for undocumented infertility;
2. Members who do not have an infertility benefit;
3. AI/IUI cycles, donor sperm and associated processing and infertility medications for women undergoing AI/IUI to establish a state of infertility;
4. Infertility services for women who are menopausal or perimenopausal or who are not naturally expected to be fertile, unless the woman is experiencing menopause at a premature age as noted in criteria above;
5. Services requested for the convenience, lifestyle, personal, or religious preference of the member in the absence of medical necessity;
6. Infertility treatment with $\leq 5\%$ chance of success for a live birth;
7. Donor sperm and services in the absence of a male partner;
8. Reversal of voluntary sterilization;
9. Infertility services (including but not limited to consultations, labs, radiology studies, infertility drugs, ART cycles, MESA, TESE and other services to assess and/or treat infertility in a member or a member's partner) requested as a result of a prior voluntary sterilization or unsuccessful sterilization reversal procedure;
10. Testicular Sperm Aspiration (TESA) procedure and all costs related to the procedure including but not limited to: pathology screening, and facility and anesthesia charges;
11. Monitoring of non-authorized IUI cycles;
12. IVF when it is known at the initiation of the cycle that none of the resulting embryos will be transferred during the same cycle and the sole intent is to cryopreserve all embryos for future use, unless the cycle is authorized for a member undergoing medical treatment that will render the member permanently infertile and there is no male partner;

13. IVF when it is known at the initiation of the cycle that either some or all of the resulting eggs will not be used to create embryos to be transferred during the same cycle and the sole intent is to cryopreserve eggs for future use, unless the cycle is authorized for a member undergoing medical treatment that will render the member permanently infertile and there is no male partner;
14. Cryopreservation of eggs, embryos, or sperm for convenience;
15. Cryopreservation of embryo, sperm, and eggs exceeding 1 year;
16. Cryopreservation and/or storage of ovarian tissue;
17. Cryopreservation and/or storage of testicular tissue;
18. Cryopreservation for the sole purpose of circumventing reproductive aging in healthy women;
19. Infertility services when normal embryos have been or will be discarded because of gender selection;
20. Genetic engineering;
21. Embryonic research;
22. IUI, IVF, or ICSI when using donor sperm that is not of normal quality;
23. Non-medical fees related to sperm procurement, e.g. fee to a sperm donor for donation of sperm to a sperm bank;
24. Infertility medications for anonymous donor secured via an egg bank when the eggs will be used by multiple recipients.
25. Coverage for donor egg services provided by an IVF center or other organization for use of the donor eggs or created embryos by multiple recipients.
26. Non-medical fees related to donor egg procurement: e.g. fee to a donor for donation of egg(s) to donor egg program, finder fees, broker fees, and legal fees;
27. Egg harvesting or other treatment incidental to an operative procedure required for an unrelated cause;
28. Coverage of donor eggs or donor sperm and/or services when not used by either the member or the member's partner;
29. Surrogacy/Gestational Carrier Services unless those outlined above;
30. Sperm, egg and/or inseminated egg procurement and processing, and banking of sperm or inseminated eggs, to the extent such costs are covered by the donor's insurer;
31. Infertility services when an individual or couple is using illicit substances or abusing substances known to negatively interfere with fertility or fetal development (e.g. marijuana, opiates, cocaine, or alcohol). Results of serum or urine drug screening may be requested before infertility services are authorized;
32. Infertility services for a female member who smokes or has not abstained from smoking for at least 3 months;
33. Infertility services when a partner with male factor infertility smokes or has not abstained from smoking for at least 3 months;
34. Services provided to a gestational carrier, including, but not limited to transfer, impending pregnancy costs, or cryopreservation of embryos, whether or not the gestational carrier is an AllWays Health Partners member;

35. Use of donor egg with gestational carrier even when the gestational carrier is an AllWays Health Partners member;
36. Investigational experimental procedures or treatment not based on scientific body of evidence;
37. Coverage of IVF medications if the IVF or medicated IUI services are not approved.

Definitions

Artificial Insemination (AI): Placement of semen into the vagina with a syringe rather than through intercourse.

Assisted Hatching (AH): Embryo hatching is initiated in the laboratory by perturbation of the cells surrounding the egg, enhancing implantation.

Anovulation: Failure to ovulate.

Clomiphene Challenge Test (CCCT): A test to assess ovarian reserve usually used in women over 35 years of age. The test measures FSH and estradiol and the FSH response to the oral administration of 100 mg of clomiphene citrate for 5 days of the cycle on cycle day 5-9 with FSH measured on cycle Days 3 and 10 and estradiol measured on cycle Day 3.

Cryopreservation: Embryos from one cycle are preserved for future transfer by storing them at very low temperatures.

Cycle: The start of menses followed by ovarian stimulation, egg retrieval, embryo transfer, and pregnancy testing.

Egg Retrieval: The removal of eggs from one or more ovarian follicles.

Embryo Transfer: The transfer of one or more embryos into the uterus or fallopian tube.

Frozen Embryo Transfer (FET): Transfer to the uterus of embryos that have been previously cryopreserved.

Gamete Intra-Fallopian Transfer (GIFT): Similar to IVF, except sperm and egg are placed inside a catheter separated by an air bubble, and then transferred to a fallopian tube. Fertilization takes place naturally.

Infertility: 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 age 35. For the purposes of meeting the criteria of 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 one year or 6-month period as applicable (211 CMR 37.00: M.G.L. chs. 175, 176A, 176B, 176D and 176G; St. 1987, c. 394.)

For women without exposure to sperm, infertility is determined by the inability to conceive after six AI/IUI cycles are performed by a qualified specialist. These AI/IUI cycles with donor sperm and

associated sperm processing and infertility medications are not covered because infertility has not been established until the AI/IUI cycles have been completed

Intrauterine Insemination (IUI): A fertility treatment that uses a catheter to place a number of washed sperm directly into a woman's uterine cavity in an effort to achieve successful fertilization.

Intra-Cytoplasmic Sperm Injection (ICSI): Injection of sperm into an egg for fertilization.

Single embryo transfer (SET): Transfer of a single embryo at either the cleavage stage (day 2 or 3 after an egg retrieval) or blastocyst stage (day 5 or 6 after an egg retrieval), that is selected from a larger number of available embryos.

Zygote Intra-Fallopian Transfer (ZIFT): Procedure similar to IVF except that the egg is fertilized in vitro and transferred to the fallopian tube before dividing.

Relevant Regulation:

Division of Insurance Infertility benefits, 211 CMR 37.00

Infertility (37.03)

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 age 35. For the purposes of meeting the criteria of 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 one year or 6 month period as applicable.

Scope of Coverage (37.04)

Insurers shall provide benefits for required infertility procedures, as described in 211 CMR 37.05, which are furnished to an insured, covered spouse and/or other covered dependent.

Insurers shall not be required to provide benefits for services furnished to a spouse or dependent if the spouse or dependent is not otherwise covered by the insurer, except as provided in 211 CMR 37.05(4).

Required Infertility Benefits (37.05)

Subject to any reasonable limitations as described in 211 CMR 37.09, insurers shall provide benefits for all non-experimental infertility procedures including, but not limited to:

- (1) Artificial Insemination (AI) and Intrauterine Insemination (IUI).
- (2) *In Vitro* Fertilization and Embryo Transfer (IVF-ET).
- (3) Gamete Intrafallopian Transfer (GIFT).
- (4) 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.
- (5) Intracytoplasmic Sperm Injection (ICSI) for the treatment of male factor infertility.
- (6) Zygote Intrafallopian Transfer (ZIFT).
- (7) Assisted Hatching.
- (8) Cryopreservation of eggs.

Prescription Drugs (37.06)



Insurers shall not impose exclusions, limitations, or other restrictions on coverage for infertility-related drugs that are different from those imposed on any other prescription drugs.

Optional Infertility Benefits (37.07)

No insurer shall be required to provide benefits for:

- (1) Any experimental infertility procedure, until the procedure becomes recognized as non-experimental;
- (2) Surrogacy;
- (3) Reversal of Voluntary Sterilization;

Prohibited Limitations on Coverage (37.08)

- (1) No insurer shall impose deductibles, copayments, coinsurance, benefit maximums, waiting periods, or any other limitations on coverage for required infertility benefits which are different from those imposed upon benefits for services not related to infertility.
- (2) No insurer shall impose pre-existing condition exclusions or pre-existing condition waiting periods on coverage for required infertility benefits. No insurer shall use any prior diagnosis of or prior treatment for infertility as a basis for excluding, limiting, or otherwise restricting the availability of coverage for required infertility benefits.
- (3) No insurer shall impose limitations on coverage based solely on arbitrary factors, including but not limited to number of attempts or dollar amounts.

Permissible Limitations on Coverage (37.09)

Limitations on coverage shall be based on clinical guidelines and the insured’s medical history. Clinical guidelines shall be maintained in written form and shall be available to any insured upon request. Standards or guidelines developed by the American Society for Reproductive Medicine, the American College of Obstetrics and Gynecology or the Society for Assisted Reproductive Technology may serve as a basis for these clinical guidelines.

CPT/HCPC Codes

| Authorized CPT/HCPCS Codes | Code Description |
|-----------------------------------|--|
| S4011 | In vitro fertilization; including but not limited to identification and incubation of mature oocytes, fertilization with sperm, incubation of embryo(s), and subsequent visualization for determination of development |
| S4013 | Complete cycle, gamete intrafallopian transfer (GIFT), case rate |
| S4014 | Complete cycle, zygote intrafallopian transfer (ZIFT), case rate |
| S4015 | Complete in vitro fertilization cycle, not otherwise specified, case rate |
| S4016 | Frozen in vitro fertilization cycle, case rate |
| S4017 | Incomplete cycle, treatment cancelled prior to stimulation, case rate |
| S4018 | Frozen embryo transfer procedure cancelled before transfer, case rate |

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|-------|--|
| S4020 | In vitro fertilization procedure cancelled before aspiration, case rate |
| S4021 | In vitro fertilization procedure cancelled after aspiration, case rate |
| S4022 | Assisted oocyte fertilization, case rate |
| S4023 | Donor egg cycle, incomplete, case rate |
| S4025 | Donor services for in vitro fertilization (sperm or embryo), case rate |
| S4026 | Procurement of donor sperm from sperm bank |
| S4027 | Storage of previously frozen embryos |
| S4028 | Microsurgical epididymal sperm aspiration (MESA) |
| S4030 | Sperm procurement and cryopreservation services; initial visit |
| S4031 | Sperm procurement and cryopreservation services; subsequent visit |
| S4035 | Stimulated intrauterine insemination (IUI), case rate |
| S4037 | Cryopreserved embryo transfer, case rate |
| S4040 | Monitoring and storage of cryopreserved embryos, per 30 days |
| S4042 | Management of ovulation induction (interpretation of diagnostic tests and studies, nonface-to-face medical management of the patient), per cycle |

Effective Date/ Approval History

July 2018: Annual review. Added ovulatory dysfunction under General Eligibility Coverage Criteria 2 b. Added second note under General Eligibility Coverage Criteria. Added Hepatitis C to the #6 General Eligibility Coverage Criteria. Added “documentation of urine or serum negative cotinine levels within a month of requested service” under # 8 General Eligibility Coverage Criteria. Added unilateral or bilateral in 1.b. under Individuals with a Sterilization Reversal. Added “and prior IVF cycles that resulted in live birth” under Single Embryo Transfer (SET) within the fourth note. Added language regarding coverage for gender reassignment under IVF For Member Not in Active Infertility Treatment, Cryopreservation of Eggs/Embryos, and Cryopreservation of Sperm. Added section Surrogacy and Gestational Carrier. Updated references.

July 2017: Removed the restriction “Infertility services for female member with a BMI ≥ 40 , or has not had a BMI < 40 for the past 3 months”

April 2017: Added coverage criteria indicating IVF/IUI medications are only covered if the IVF services are covered. Also added criteria for Single Embryo Transfer. Added definition of Single Embryo Transfer. Added exclusion.

November 2016: Annual review.

November 2015: Removed the condition that the intention is to transfer the eggs/embryos back to the member in order to meet IVF for members not in active infertility treatment but are undergoing medical treatment that renders them infertile.

July 2015: Added to general eligibility criteria that partners to be counseled re smoking risks, those with male factor to demonstrate smoking cessation of 3 months; and screening for infectious diseases. Added



criteria for TESE; criteria for persons undergoing medical treatment that will render them permanently infertile. Clarified criteria for reversal of sterilization procedure and ICSI as well as made note that AllWays Health Partners expects with IVF that standard medication does be used and all good quality embryos be frozen.

July 2014: Added “This document does not address treatment of underlying medical condition causing infertility” to overview; reversal of sterilization general eligibility criteria; IUI cycle limit, notes to IVF section regarding premature ovarian failure; cryopreservation up to 1 year and lifetime maximum of 6 cycles; criteria for MESA; exclusions for TESE, illicit substances, BMI > 40 and smoking; and regulation language. Changed: general eligibility criteria: added anatomy assessment, BMI, smoking and semen analysis and donor egg for infertility criteria.

February 2013: Modified definition of infertility, modified general infertility criteria, changed cryopreservation to be up to two years & minor edits for clarification.

January 2012: Added IUI conversion criteria; Amended Benefit Coverage documentation, converted to criteria.

March 2004: Effective date.

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