



Assisted Reproductive Technologies

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Related Medical Guidelines

[Infertility Services](#)

[Recurrent Pregnancy Loss](#)

Acronyms Key

Assisted hatching	AH	Intrauterine inseminations	IUI
Artificial insemination	AI	Intracervical insemination	ICI
Assisted reproductive technologies	ART	Intrafallopian insemination	IFI
Estradiol	E2	Intra cytoplasmic sperm injection	ICSI
Embryo transfer	ET	In vitro fertilization	IVF
Follicle stimulating hormone	FSH	Luteinizing hormone	LH
Gamete intrafallopian transfer	GIFT	Luteinizing hormone releasing hormone	LHRH
Human chorionic gonadotropin	hCG	Microsurgical epididymal sperm aspiration	MESA
Human gonadotropin	HG	Pronuclear stage tubal embryo transfer	PROUST
Human menopausal gonadotropin	hMG	Testicular sperm aspiration	TESA
Gonadotropin releasing hormone	GnRH	Zygote intrafallopian transfer	ZIFT

Definitions

Infertility — when a male or female is unable to conceive or produce conception after ≥ 12 months of frequent, unprotected heterosexual sexual intercourse or ≥ 6 months of frequent unprotected heterosexual sexual intercourse if the female partner is $>$ age 35 years. (Earlier evaluation and treatment may be justified based on medical history and physical findings and is warranted after 6 months)

Artificial insemination (AI)¹ (See also [Limitations/Exclusions](#))

AI (IUI, ICI and IFI) may be utilized as follows:

1. Unstimulated AI — for infertile couples with mild male-factor infertility, unexplained infertility, minimal to mild endometriosis
2. Clomiphene-citrate-stimulated AI — for infertile women with WHO Group II ovulation disorders (i.e., polycystic ovarian syndrome) who ovulate with clomiphene citrate, but who have not achieved pregnancy post ovulation induction with clomiphene. (Stimulated AI is not offered in management of male-factor infertility because it is not more effective than unstimulated AI)
3. Human gonadotropin and IUI — often used when the member fails to become pregnant by other means

Donor insemination — for the following conditions:

1. Obstructive azoospermia
2. Nonobstructive azoospermia
3. Infectious disease in the male partner (i.e., HIV)
4. Severe rhesus isoimmunization
5. Severe semen quality deficits in couples who do not wish to undergo intracytoplasmic sperm injection
6. Where there is a high risk of transmitting a genetic disorder in the male partner to the offspring
7. When there is no male partner

Electroejaculation — used for total anejaculation secondary to neurologic impairment, e.g. spinal injury, retroperineal surgery (e.g., retroperineal lymphadenectomy) or diabetic neuropathy. (Insufficient evidence of therapeutic value for > 1 AI within a 30-day period)

Assisted hatching (AH) — implantation (for some IVF patients; including those that have embryos with thick zona) is precluded because of the inability of the embryo to hatch out of the zona. A 30-micron-size hole made in the zona at the time of transfer improves implantation. The embryo is then transferred to fresh medium and transferred into the uterus. (AH is not recommended because it has not been shown to improve pregnancy rates)

Assisted oocyte fertilization microtechnique — IVF involves the retrieval of female oocytes and the insemination of these oocytes with male-donor sperm; fertilization occurs in a test tube or petri dish. A number of micromanipulation techniques have been developed to help in cases when sperm cannot penetrate the outer envelope of the oocyte (zona pellucida). Penetration difficulties typically occur when semen quality is poor or when there is insufficient motile sperm.

Assisted reproductive technologies (ART) — consists of procedures that directly unite sperm and eggs in order to overcome some infertility factors. Various fertility drugs are used in to stimulate the growth of multiple oocytes; increasing the chance of fertilization and therefore pregnancy. ART includes:

1. IVF
2. Gamete Intrafallopian Transfer (GIFT)
3. Zygote Intrafallopian Transfer (ZIFT)

¹Although infertility may be covered, services associated with donor insemination (including semen donor recruitment, selection and screening, and cryostorage of sperm) may not be covered. In addition, semen cryopreservation is not deemed a disease treatment and is therefore not covered. Please check benefit plan descriptions for details. In addition, benefit packages may exclude AI or may limit AI to 3–6 cycles per lifetime. Please check member benefits.

4. Embryo Transfer (ET)
5. Intracytoplasmic Sperm Injection (ICSI)
6. Assisted Hatching (AH)
7. Testicular Sperm Aspiration (TESA)
8. Microsurgical Epididymal Sperm Aspiration (MESA)

Culture and fertilization — laboratory culture and fertilization of the oocytes with sperm for a period of approximately 3–5 days.

Embryo — Embryo quantity and quality are considered adequate if an ART cycle yields ≥ 3 embryos for transfer, each of which consists of at least 6–8 cells (for day 3 transfers) of reasonable quality (grade B or equivalent) with $< 50\%$ fragmentation.

Embryo transfer (ET) — done after approximately 3–5 days of laboratory culture; the physician places the embryos (fertilized eggs) in the uterus. The embryos are aspirated into a small catheter, which is passed through the cervix and implanted into the uterus. (Mock transfers not separately reimbursed; see [Limitations/Exclusions](#))

Gamete intrafallopian transfer (GIFT) — a mixture of sperm and egg placed directly into the woman's fallopian tubes during surgical laparoscopy.

Intra cytoplasmic sperm injection (ICSI) — a technique whereby a single sperm is picked up in a micropipette and injected directly into the oocyte cytoplasm. ICSI may be utilized for severe deficits in semen quality or quantity or for couples where a previous in vitro fertilization treatment cycle has resulted in failed or poor fertilization.

Intrauterine Insemination (IUI) — see "[artificial insemination](#)".

In vitro fertilization (IVF) — the most commonly used form of ART; especially helpful in the presence of tubal problems, consists of the following 4 stages:

1. Gonadotropins are used to recruit follicles and to mature oocytes.
2. The oocytes retrieval from the ovaries
3. The oocytes lab-fertilization in dish by sperm collected from the male partner.
4. Embryos are transferred to the uterus.

A cycle is defined as 1 egg-retrieval and 1 transfer. (Note: Incomplete transfer counts towards cycle)

Microsurgical epididymal sperm aspiration (MESA) — specialized sperm retrieval technique.

Oocyte retrieval — a mature or nearly mature egg is aspirated from its follicle for IVF.

Ovarian reserve in response to gonadotropin stimulation — considered normal if ≥ 3 follicles develop and estrogen levels are > 500 mIU/ml post ovarian hyperstimulation with gonadotropins. Diminished ovarian reserve is indicated by peak estrogen levels < 500 mIU/ml or < 3 mature follicles are available at the time of stimulation and retrieval.

Testicular sperm aspiration (TESA) — minor outpatient procedure where sperm is aspirated directly from the testicles where it is produced. If successful, the sperm can then be used with IVF/ICSI.

Semen quantity and quality — for the purpose of this guideline, male infertility is considered severe if the sperm quantity is < 10 million total per ejaculate and contains $< 4\%$ normal forms (quality). (Note: Morphology parameter of 4 is representative of both the WHO and Kruger criteria sets)

Zygote intrafallopian transfer (ZIFT) — a form of IVF; eggs are harvested and fertilized in a dish in the laboratory, approximately a day later the fertilized egg is placed inside the fallopian tube.

Benefit Coverage Statement

Members between 21–44 years of age² who meet the clinical definition of infertility are eligible for [infertility services](#) commensurate with their benefit program.

[ART](#) services are authorized based upon medical necessity within the parameters of the member's benefit.

If multiple EmblemHealth contracts or riders cover a member, that member will only be eligible for the number of attempts in a lifetime listed in the contract or rider with the highest number of attempts.

Clinical Criteria

I. Precertification Requirements³

(Note: It is the member's responsibility to obtain prior approval. Pre-service requests must also include a completed [Statement of Medical Necessity for ART — Appendix A](#))

1. 12 months of frequent unprotected heterosexual intercourse or 6 months if the female partner is > 35 years of age
2. Women < 35, including single female patients and same sex couples — member must have undergone a total of 6 IUI cycles (with at least 2–4 cycles of ovulation induction)
3. Women > 35, including single female patients and same sex couples — member must have undergone a total of 3 (physician-supervised) IUI cycles (with at least 2–3 cycles of ovulation induction)
4. Men with azoospermia or severe deficits in semen quality or quantity (and the couple accepts donor insemination) — number of AI attempts depends on the woman's age
5. FSH — value should be < 15 on day 3 of menstrual cycle⁴
FSH test result valid for 12 months in women < 35 years of age; result valid for 6 months in women > 35. Clomiphene challenge test or other ovarian reserve test should be done every 12 months in women > 40
6. Ovarian reserve testing — antral follicle count on day 2-5 of cycle by transvaginal ultrasound (< 4 antral follicles should preclude attempting ART)
7. Estradiol — value should be < 100; an elevated estradiol with a low FSH is still consistent with decreased ovarian reserve
8. Reversal of elective tubal ligation or vasectomy — If an elective tubal ligation or vasectomy is reversed and the reversal is successful (as shown by patent tubes or normal semen analysis) and the member is unable to conceive after meeting the clinical definition of infertility, then the member may be ART-eligible; however, the reversal of the tubal ligation or vasectomy is not a covered benefit
9. ART is indicated (per section II)

II. ART Indications

Members who do not achieve conception through less invasive treatments (i.e., medical, hormonal therapy or surgical) may be treated with an ART procedure when either of the following is met:

1. Failure of artificial insemination with gonadotropin (FSH) or clomiphene citrate ovarian hyperstimulation as noted above

OR

2. Couples for whom natural or artificial insemination would not be expected to be effective including:

² In accordance with New York Consolidated Laws, Insurance, Section 3221 (k) (6), Section 4303(s).

³ Fertilization rates are considered poor if IVF cycles result in <50% fertilization.

⁴ An elevated FSH level indicates reduced ovarian reserve, e.g. increasing age, and results in higher failure rate of ART.

- A. Men with azoospermia or severe deficits in semen quantity (< 10M) and quality (< 4% normal forms), and the couple declines donor insemination (Note: It is expected that the male have at least 2 unprocessed semen analyses with 1 week or more in between the tests)
- B. Women with tubal factor infertility:
 - Bilateral tubal disease (e.g., tubal obstruction, absence or hydrosalpinges)
 - Endometriosis stage 3 or 4
 - Failure to conceive post pelvic surgery with restoration of normal pelvic anatomy after:
 - i. Attempts to conceive for 6 months if < age 35
 - ii. Attempts to conceive for 3 months if ≥ age 35
 - Infertility resulting from ectopic pregnancy
 - Ectopic pregnancy occurring during infertility treatment
 - Unilateral tubal disease with failure to conceive after:
 - i. Attempts to conceive for ≥ 6 months if < age 35
 - ii. Attempts to conceive for 3 months if ≥ age 35
- C. Inadvertent ovarian hyperstimulation (estradiol level > 1500–2000 pg/mL and > 6 follicles > 16 mm, or 6–10 follicles > 14 mm, or a larger number of smaller follicles) during preparation for a planned stimulated IUI cycle in women < age 40 with a diagnosis other than polycystic ovarian syndrome. (In women ≥ 40, it is typically not medically necessary to convert an AI cycle to IVF due to ovarian hyperstimulation)

III. ART Utilization

An ART cycle consists of any of the following: IVF with embryo transfer, GIFT or ZIFT:

1. IVF with fresh embryo transfer.⁵

ET — it may be considered medically necessary to freeze embryos not transferred during a stimulated IVF cycle and to transfer them prior to the next stimulated treatment cycle because this will minimize ovulation induction and egg collection, both of which carry risks for the woman. Prior to proceeding to the next fresh ART cycle, ET using previously frozen embryos must be used (i.e. fertilized and transferred) if ≥ 3 cryopreserved embryos of a similar developmental stage are available (for women ≥ age 35). However, embryo storage is not covered.

2. ICSI is medically necessary where there is azoospermia or oligospermia (obstructive or nonobstructive), severe semen quality or quantity deficits, or for couples where a previous IVF treatment cycle has resulted in failed or poor fertilization. ICSI is covered for severe male factor when at least 2 unprocessed semen analyses show < 10 million total motile sperm or 4% strict Krueger normal forms or post processing semen analyses show ≤ 3 million total motile sperm. It is expected that at least 50% of oocytes should fertilize with insemination; anything less than 40% is abnormal and is considered reduced or poor fertilization.

3. GIFT is considered a medically necessary IVF alternative⁶ for women with female-factor infertility⁶ (male factor excluded); it includes the following:

⁵ While certain benefit programs provide coverage for infertility services, they may exclude coverage of fees associated with oocyte donation (i.e., [as pertains to donors], recruitment, selection, ovarian stimulation, oocyte collection and screening and storage of donor oocytes). Please check member benefit. For members with ART benefits that contain this exclusion, medically necessary ART services are covered only once an embryo is created from the donor egg.

⁶ Female factor fertility includes, but is not limited to, morphologic anomalies of the oocyte, limited quantities of oocytes and anomalies of the zona pellucida.

- A. Laparoscope oocyte (egg) retrieval
- B. Immediate oocyte loading with sperm into a transfer catheter and insertion into the member's fallopian tube via the same laparoscope (there must have at least one patent fallopian tube for this method to be an effective infertility treatment)
- 4. ZIFT, tubal embryo transfers (TET) or pronuclear stage tubal embryo transfers (PROUST) are considered medically necessary IVF alternatives for women with female-factor infertility (male factor excluded)
 - A. Specialized sperm retrieval techniques — considered medically necessary to overcome anejaculation (e.g., vasal sperm aspiration, MESA, percutaneous epididymal sperm aspiration [PESA], electroejaculation, TESA, seminal vesicle sperm aspiration and sperm recovery from bladder or urine for retrograde ejaculation)
 - B. Oocyte donation — considered medically necessary in women for the management of infertility associated with the following conditions when the infertile member is the intended recipient of the resulting embryos:
 - Premature ovarian failure
 - Gonadal dysgenesis including Turner syndrome
 - Bilateral oophorectomy
 - Ovarian failure following chemotherapy or radiotherapy
 - IVF treatment failure
 - High risk of transmitting a genetic disorder from the female partner to the offspring
 - C. Assisted hatching — not recommended because it does not improve pregnancy rates; however, it may be indicated for women > age 38 and when any of the following are applicable:
 - ≥ 3 failed IVF attempts (failure to detect rise in HcG)
 - Thickened zona pellucida
 - Documented previous pregnancy after IVF with AH

IV. Pre-implantation genetic diagnosis (PGD)⁷

PGD is considered medically necessary when the member meets ART criteria and any of the following is applicable:

1. The test is used to improve the implantation rate of in vitro fertilization (IVF) in infertile couples who have had three prior failed attempts at IVF
2. One partner is known to have a balanced translocation or balanced inversion
3. To determine the sex of an embryo when there is a documented history of an x-linked disorder and deselection of an affected embryo can be made on the basis of sex alone
4. Deselection of embryos with genetic mutation when partners meet at least one of **Criteria A** and all of **Criteria B**
 - A. **≥ 1:**
 - Both partners are carriers of the same autosomal recessive disorder
 - One partner is a carrier of an autosomal recessive disorder, and the couple produced an offspring affected by that disorder
 - One partner is a carrier of a single gene autosomal dominant disorder
 - One partner is a known carrier of a single gene X-linked disorder
 - B. **All:**
 - The genetic disorder is identified with high degree of reliability through specific mutations
 - The genetic disorder is associated with severe disability or has a lethal natural history

⁷ PGS is not an effective treatment for recurrent miscarriage and is therefore not within the standard of care.

- Testing is accompanied by genetic counseling
5. Pre/post-test genetic counseling is required to inform decision-making

Limitations/Exclusions

1. Coverage exclusions:
 - A. Less than 12 months of frequent unprotected heterosexual intercourse or 6 months if the female partner is > age 35 years
 - B. Cryopreservation and storage procedures of the sperm or egg (other than short-term cryopreservation of embryos that are necessary for contemporaneous use in infertile persons currently under active fertility treatment)
Note: Cryopreservation of mature oocytes and sperm is considered medically necessary for members facing iatrogenic infertility due to chemotherapy, pelvic radiotherapy, other gonadotoxic therapy or ovarian/testicular removal for treatment of disease. Some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary. If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern.
 - C. Embryo storage
 - D. All donor services and fees including sperm, egg and surrogacy
 - E. Reversal of elective sterilization procedures (i.e., tubal ligation, vasectomy)
 - F. Cloning
 - G. Ovulation predictor kits or devices
 - H. Frozen embryo transportation
 - I. Sex preselection
2. Pre-implantation genetic screening is not considered medically necessary when any of the following is applicable:
 - A. The selection of embryos with specific HLA typing to provide a match for an individual in need of an allogenic transplant
 - B. The selection of embryos with the sole purpose of determining the gender of the resultant offspring.
 - C. When ART criteria are not met
3. Mock embryo transfer is not a covered procedure, as such planning, performed in anticipation of embryo transfer, is considered to be inclusive to the evaluation and management service provided
4. Infertility services are not considered medically necessary once pregnancy is established. (Member will have to re-qualify for ART services)
5. Requests for fertility preservation services (e.g., embryo, egg or ovarian tissue cryopreservation) for iatrogenic infertility (i.e., secondary to chemotherapy, etc.), as well as storage procedures, will not be considered, as these services are excluded from coverage.
6. The following laboratory services/treatments are not considered medically necessary because they are ineffective or investigational:
 - A. Aromatase inhibitors (testolactone) for idiopathic male infertility (i.e., for men without documented hypogonadotropic hypogonadism)
 - B. GIFT for male factor infertility or unexplained infertility problems
 - C. Leukocyte immunization (immunizing female partner with male partner leukocytes)
 - D. FSH manipulation of women with elevated FSH levels as an effort to reduce FSH level
 - E. Growth hormone administration during ovulation
 - F. Intravenous immunoglobulins administration

- G. Fine needle aspiration (mapping) of testes
- H. For male infertility evaluation, the following laboratory services: Seminal alpha-glucosidase, zinc, citric acid and acid phosphatase
- I. ZIFT for male factor infertility or unexplained infertility problems
- J. The following sperm function tests:
 - Sperm chromatin assay
 - Sperm DNA fragmentation assay
 - Hemizona assay
 - In vitro testing of sperm penetration
 - Hypoosmotic swelling test
 - Sperm nucleus maturation
 - Hyaluronan binding assay

Revision History

4/21/2017	Communicated that a balanced inversion, within PGD criteria, is clinically acceptable alternative to balanced translocation
2/10/2017	Added antral follicle count testing prerequisite for assessing ovarian reserve Added language to Limitations/Exclusions section communicating that cryopreservation of mature oocytes and sperm is considered medically necessary for members facing iatrogenic infertility due to chemotherapy, pelvic radiotherapy, other gonadotoxic therapy or ovarian/testicular removal for treatment of disease. (Member benefit supersedes)
12/10/2015	Clarified preimplantation genetic diagnostic testing (PGD) criteria and added eligibility for the testing if one partner is a carrier of an autosomal recessive disorder and the couple produced an offspring affected by that disorder.
10/9/2015	Removed urological evaluation prerequisite for men with azoospermia and clarified that mock transfers are considered incidental to embryonic transfers and not separately reimbursable.

[Provider Qualifications — APPENDIX B](#)

[Procedure Codes — APPENDIX C](#)

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- Specialty-matched clinical peer review.

APPENDIX A
Statement of Medical Necessity for ART
FAX: GHI IVF CM @ 212 -946-7516

Date: _____

Practice name: _____ Age: _____

Address: _____

Tel: _____ FAX: _____

Member name: _____ Subscriber: _____

Certificate#: _____ Phone# (H): _____ (W): _____ (C) _____

Diagnosis: _____ ICD-9: _____ Duration of infertility: _____ years

Previous infertility treatment: (Indicate the number of times treatment was initiated; i.e., 3 cycles of IUI [as evidenced by treatment documentation that includes IUI and stimulation sheets])

_____ cycles of Clomid/Serophene _____ cycles of IUI

_____ cycles of human gonadotropin _____ cycles of IVF

Procedures requested:

Cycle #: (Please circle)

_____ IVF/DIVF _____ ICSI

1st 2nd 3rd

_____ GIFT/ZIFT _____ AH

Note: If requesting 2nd or 3rd cycle, circle the # above. Fill out member name and certificate # and fax with FSH/E2 report. (DO NOT complete the remainder of this form)

_____ ET

Enclosed documents:

_____ Day 3 FSH/E2 (required on all patients regardless of age)

_____ Annual uterine cavity evaluation

_____ Semen analysis (SA) (if diagnosis is a male factor or if requesting ICSI) — 2 separate SA reports required

_____ Other clinical information pertinent to diagnosis

Physician: _____

(Print name)

(Signature)

Note: This document is accepted in lieu of a narrative medical necessity letter. Please provide all requested information to expedite precertification. Incomplete/unsigned forms will be returned to the physician's office for completion.

APPENDIX B

Provider Qualifications

Board Certification with documented experience in ART, reproductive endocrinology or urology/andrology

1. Board Certification with documented experience in the necessary areas of endocrinology, gynecological or urology procedures
2. Society of ART (SART) member and adopts SART standards and criteria to track data
3. Has an infertility counseling service available
4. Is prepared to consult education and advise both partners
5. Is knowledgeable regarding the effectiveness, adverse effects and costs of diagnosis and treatment of infertility
6. Is knowledgeable about the pre-requisites for successful reproduction

APPENDIX C**Applicable Procedure Codes**

55870	Electroejaculation
58321	Artificial insemination; intra-cervical
58322	Artificial insemination; intra-uterine
58323	Sperm washing for artificial insemination
58825	Transposition, ovary(s)
58970	Follicle puncture for oocyte retrieval, any method
58974	Embryo transfer, intrauterine
58976	Gamete, zygote, or embryo intrafallopian transfer, any method
76948	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation
89250	Culture of oocyte(s)/embryo(s), less than 4 days;
89251	Culture of oocyte(s)/embryo(s), less than 4 days; with co-culture of oocyte(s)/embryos
89253	Assisted embryo hatching, microtechniques (any method)
89254	Oocyte identification from follicular fluid
89255	Preparation of embryo for transfer (any method)
89257	Sperm identification from aspiration (other than seminal fluid)
89258	Cryopreservation; embryo(s)
89260	Sperm isolation; simple prep (eg, sperm wash and swim-up) for insemination or diagnosis with semen analysis
89261	Sperm isolation; complex prep (eg, Percoll gradient, albumin gradient) for insemination or diagnosis with semen analysis
89264	Sperm identification from testis tissue, fresh or cryopreserved
89268	Insemination of oocytes
89272	Extended culture of oocyte(s)/embryo(s), 4-7 days
89280	Assisted oocyte fertilization, microtechnique; less than or equal to 10 oocytes
89281	Assisted oocyte fertilization, microtechnique; greater than 10 oocytes
89290	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); less than or equal to 5 embryos
89291	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); greater than 5 embryos
89300	Semen analysis; presence and/or motility of sperm including Huhner test (post coital)
89310	Semen analysis; motility and count (not including Huhner test)
89320	Semen analysis; volume, count, motility, and differential
89321	Semen analysis; sperm presence and motility of sperm, if performed
S4028	Microsurgical epididymal sperm aspiration (MESA)