



MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	ASSISTED REPRODUCTIVE TECHNOLOGIES FOR INFERTILITY
Policy Number	4.01.05
Category	Contract Clarification
Effective Date	10/18/01
Revised Date	10/18/01, 08/22/02, 07/24/03, 06/24/04, 08/25/05, 08/31/06, 08/23/07, 08/28/08, 04/23/09, 06/24/10, 06/24/11, 06/28/12, 06/27/13, 06/26/14, 06/25/15, 06/22/16, 10/26/17, 10/25/18, 10/24/19
Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

****Additional coverage for MEDICAID MANAGED CARE/HARP MEMBERS is addressed at the end of this document****

POLICY STATEMENT

I. **Establish Infertility Diagnosis:** Based upon our criteria and review of the peer-reviewed literature, diagnostic work-up and corresponding *infertility* treatments are **medically appropriate** for the diagnosis and *treatment of infertility*. In cases of male infertility, the male must be covered as a member under the policy to receive any services.

Prior to initiation of infertility treatment a medical history, including history related to infertility and coexisting medical conditions should be documented. Information regarding the following may be obtained:

- post coital test;
- hysterosalpingogram, hysteroscopy, sonohysterogram;
- laparoscopy;
- prior infertility treatment;
- sperm count/motility; and
- other laboratory tests as indicated (e.g., FSH, Hba_{1c} in diabetics, Prolactin, TSH, T4, etc.).

II. **Medical treatment of ovulatory dysfunction:** Based upon our criteria and review of peer-reviewed literature, treatment with FDA-approved drugs has been medically proven to be effective and therefore **medically appropriate** in the *treatment of infertility* with the following limitations:

- Infertile, anovulatory women - once the lowest dose of clomiphene citrate required to induce ovulation is established, up to 12 cycles of clomiphene treatment will be covered. If there is no pregnancy after 6 cycles of treatment, consultation with a reproductive endocrinologist before proceeding with additional treatment cycles is indicated.
- Infertile, ovulatory women receiving clomiphene citrate for superovulation – appropriate for up to six cycles of treatment. Up to six cycles of intrauterine insemination may be included with this treatment. These superovulation cycles, with or without intrauterine insemination, should be supervised by a reproductive endocrinologist or gynecologist credentialed to provide this treatment.
- After clomiphene failure, or in place of clomiphene treatment, for women in late reproductive life treatment with FDA approved gonadotropin drugs is limited to:
 - up to four (4) cycles per member per pregnancy as defined by a positive HCG determination; and

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2. prescription or administration by a reproductive endocrinologist and other physicians credentialed to provide this treatment. After two (2) successive spontaneous miscarriages, further evaluation as to the cause of the miscarriages must be performed before the use of gonadotropin drugs can be resumed.
- III. **Comprehensive services:** If the basic infertility services do not result in increased fertility, the following comprehensive infertility services are included:
- A. Ovulation induction and monitoring
 - B. Pelvic ultrasound
 - C. Artificial insemination
 - D. Hysteroscopy;
 - E. Laproscopy;and
 - F. Laparotomy.
- IV. **Surgical Treatment:**
- A. Based upon our criteria, procedures to repair the anatomical structures for the purpose of conception are **medically appropriate** when no prior procedure has been performed that has purposely interrupted the function of the structure (e.g., elective sterilization, elective Essure System for permanent birth control).
 - B. Based upon our criteria, assisted reproductive technologies are **not medically appropriate** when:
 1. the reversal of an elective sterilization does not restore fertility (e.g., a male member who remains azoospermic following the reversal of a prior elective sterilization), or
 2. either partner has undergone an elective sterilization in the past.
- V. **Contraindications:** Clinical **contraindications** to infertility treatment with FDA-approved drugs or co-morbid conditions that include:
- A. significant bilateral tubal disease:
 1. that is uncorrectable by surgery, or
 2. with ART procedure(s) where fertilization occurs within the body, or
 3. and are contraindicated for IVF/GIFT/ZIFT;
 - B. extensive pelvic adhesions;
 - C. coexisting medical conditions that place the patient and/or fetus at unacceptable risk (e.g., uncontrolled diabetes mellitus, poorly controlled hypertension, morbid obesity (clinically severe obesity) with BMI>35.0, usage of prescription medication detrimental to or contraindicated for pregnancy), or other uncontrolled medical conditions; or
 - D. baseline (day 2-day 4) FSH greater than or equal to 15 mIU/ml.
- VI. Based upon our criteria, assisted reproductive technology (ART) services that are intended to achieve conception and do not treat a correctable malformation, disease or dysfunction are **not medically appropriate** unless used in conjunction with superovulation therapy with clomiphene citrate or gonadotropins.
- VII. **Sperm Washing and Artificial Insemination:** Based upon our criteria and review of the peer-reviewed literature, sperm washing and artificial insemination are **medically appropriate** in cases of low sperm count, low sperm motility, quadriplegia or paraplegia in male members, poor sperm-mucous interaction or unexplained infertility (the inability to conceive where reproductive defects have not been able to be identified).
- VIII. **Investigational procedures:** Based upon our criteria and review of the peer-reviewed literature, the following have not been medically proven to be effective and, therefore, are considered **investigational**:
- A. Assisted hatching,
 - B. Hyaluronan binding assay (HBA),
 - C. Co-culture of embryos, and
 - D. Sperm DNA integrity tests (e.g., sperm chromatin structure assay [SCSA®], sperm chromatin dispersion test [SCD], sperm DNA fragmentation assay [SDFA™], deoxynucleotidyl transferase-mediated deoxyuridine triphosphate-biotin nick end labeling [TUNEL], single cell electrophoresis assay [COMET]).

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IX. Exclusions and Limitations:

- A. In vitro fertilization (IVF), Gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), cryopreservation services and other forms of ART: are **contract dependent**.
- B. The following services are generally excluded by contract, and are **ineligible for coverage** if excluded by contract:
 - 1. Procurement of donor sperm or ova;
 - 2. Cloning services and procedures.
 - 3. Reversal of tubal ligations.
 - 4. Reversal of vasectomies.
 - 5. Travel expenses

All services must be provided by Providers who are qualified to provide such services in accordance with the guidelines established and adopted by the American Society for Reproductive Medicine.

Refer to the FLRx Prescription Drug Policies: Infertility Medications.

POLICY GUIDELINES

- I. **All** ART, including but not limited to, in-vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), ~~and~~ artificial insemination, and cryopreservation services are **contract dependent**. Inclusive with ART are but not limited to:
 - A. Surgical procedures, including retrieval of eggs or sperm from the Member and transfer of a fertilized egg to a female Member.
 - B. Members are eligible for In Vitro Fertilization and Assisted Reproductive Technology: when the couple has been unable to achieve a pregnancy after 12 months of unprotected intercourse, or six (6) months for Members age 35 and older; and after other reasonable, less expensive and medically appropriate infertility treatments have not resulted in a successful pregnancy.
 - C. Cryopreservation services, including freezing, storage and thawing, associated with IVF, GIFT and ZIFT are contract dependent and may be eligible for coverage. (Refer to Description VII-H).
- II. The diagnosis and treatment for infertility services must be prescribed by a physician in a plan of care.
- III. Benefits will not be provided for infertility services unless there has been a diagnosis of infertility. *Infertility* is defined as a disease or condition characterized by the failure or incapacity to impregnate another person or conceive, defined as a failure to establish a clinical pregnancy after twelve months or more of regular unprotected intercourse or therapeutic donor insemination or after six months of regular, unprotected sexual intercourse or therapeutic donor insemination for a female thirty-five years of age or older. Earlier evaluation and treatment may be justified based on medical history and physical findings.
- IV. ART consists of several steps over an interval of approximately 2 weeks and is considered a cycle of treatment rather than a procedure at a single point in time. The start of an ART cycle is when a woman begins taking drugs to stimulate production of ova or starts ovarian monitoring with the intent of having embryos transferred. The cycle continues through all necessary steps until after the time sperm is transferred during insemination or embryo(s) are transferred during IVF/GIFT/ZIFT.
- V. Peer-reviewed, published studies and professional society guidelines do not provide data concerning the appropriate number of cycles. Therefore, based upon specialty clinician input, when coverage is available for ART services and cycle limitations are not stipulated in the member's subscriber contract, the following will be considered medically appropriate:
 - A. Artificial insemination is limited to a lifetime maximum of 6 cycles, and
 - B. IVF, GIFT, and/or ZIFT are limited to a lifetime maximum of 3 cycles. A "cycle" is considered all treatment that starts when: preparatory medications are administered with the intent of undergoing IVF with either a fresh or frozen embryo transfer.

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- VI. All obese patients (BMI > 30 kg/2) should be counseled on lifestyle and behavioral modifications, such as appropriate diet and exercise. For counseling of morbid obesity (clinically severe obesity) as a coexisting medical conditions that places the patient and/or fetus at unacceptable risk see: <https://www.acog.org/Patients/FAQs/Obesity-and-Pregnancy#does>.
- VII. Only a male member's primary care physician, an in-plan urologist (when required by contract), or the female member's OB/GYN or reproductive endocrinologist may perform the male member's infertility evaluation, referral for semen analysis and appropriate follow-up treatment.
- VIII. A contracted laboratory (when required by contract) must perform semen analysis in conjunction with female infertility evaluations.
- IX. Experimental, nonstandard, and/or unevaluated infertility treatments and drugs approved by the FDA that are not specifically approved to treat infertility are considered **investigational**.
- According to the American Society for Reproductive Medicine (ASRM), "Procedures (including tests, treatments, or other interventions) for the diagnosis or treatment of infertility will be considered experimental or investigational until the published medical evidence regarding their risks, benefits, and overall safety and efficacy is sufficient to regard them as established medical practice."
- X. Diagnostic work-up and infertility treatments for a partner who is not a member is **ineligible for coverage**.
- XI. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

According to the American Society of Reproductive Medicine, *infertility* is defined as a disease* or condition characterized by the failure or incapacity to impregnate another person or conceive, defined as a failure to establish a clinical pregnancy after twelve months or more of regular unprotected intercourse or therapeutic donor insemination or after six months of regular, unprotected sexual intercourse or therapeutic donor insemination for a female thirty-five years of age or older. Earlier evaluation and treatment may be justified based on medical history and physical findings..

* Disease is "any deviation from or interruption of the normal structure or function of any part, organ, or system of the body as manifested by characteristic symptoms and signs; the etiology, pathology, and prognosis may be known or unknown." (Dorland's Illustrated Medical Dictionary, 31st edition, 2007:535)

- I. There are many *causes* of infertility and these causes can be attributed to either female or male factors or both.
- A. Female factors of infertility include:
1. ovulatory dysfunctions such as: amenorrhea, oligoovulation, oligomenorrhea, or hyperprolactinemia;
 2. uterine anomalies and abnormalities such as: unicornate, septate or bicornate uteri, endometrial polyps, submucous myomas, or synechiae;
 3. peritoneal factors such as: endometriosis or pelvic/adnexal adhesions;
 4. anatomic tubal damage or disease; or
 5. cervical factors such as: abnormal cervical mucus production or poor sperm-mucous interaction.
- B. Male factors of infertility include:
1. azoospermia - the absence of spermatozoa/sperm;
 2. oligospermia - low sperm count;
 3. low sperm motility; and/or
 4. teratospermia - abnormal semen morphology.
- II. The *treatment* of infertility may include a variety of diagnostic procedures, therapeutic drugs and ART procedures. The services involved in evaluation and treatment of infertility vary and may include the following:
- A. Complex infertility work-ups;
- B. Hormonal treatments;

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- C. Laparoscopy;
 - D. Hysteroscopy;
 - E. Endometrial biopsy;
 - F. Fallopian tube catheterization and recannulization;
 - G. Hysterosalpingogram;
 - H. Ultrasound/sonography;
 - I. Laboratory studies (e.g., Semen analysis, Hormone level studies, appropriate blood tests);
 - J. Follicular stimulation with medications (e.g., Clomid, Gonal-f);
 - K. Monitoring ovulation via ultrasound and endocrine studies;
 - L. Post coital tests;
 - M. Semen analysis;
 - N. Retrieval of ova by various methods under general or local anesthesia; and
 - O. Varicocele repair, testicular biopsy, or epididymal aspiration.
- III. ART *procedures* include the laboratory handling of human ova, sperm and embryos. ART procedures include, but are not limited to, the following:
- A. Procedures in which fertilization takes place within the human body:
 - 1. *Artificial Insemination (AI)* - a process involving the non-coital introduction of sperm into the cervical canal (intracervical) or uterine cavity (intrauterine) in order to produce conception.
 - 2. *Direct Intra-Peritoneal Insemination (DIPI)* - a process attempting fertilization by introducing sperm into the uterus via injection through the abdomen.
 - B. Procedures in which fertilization takes place outside the human body:
 - 1. *In-Vitro Fertilization (IVF)* - a process in which mature ova are removed from the ovaries by various methods, placed in a laboratory medium with sperm, and incubated for 48-72 hours. The fertilized ova are then placed into the uterus through the cervix. The fertilization procedure takes 2-3 days. The actual fertilization takes place outside the body (in-vitro).
 - 2. *Cryopreserved Embryo Transfer (CET)* - the transfer of fertilized embryos that were previously cryopreserved (frozen) in the laboratory, thawed and then transferred into the uterus.
 - 3. *Gamete Intrafallopian Transfer (GIFT)* - a process in which mature ova are aspirated from the ovary by various methods, introduced into a catheter with sperm, and immediately transferred into the fallopian tubes.
 - 4. *Zygote Intrafallopian Transfer (ZIFT)* - a variation of the GIFT procedure that combines sperm and ova in a laboratory medium resulting in zygote(s) which are then transferred into the fallopian tubes.
 - 5. *Intracytoplasmic Sperm Injection (ICSI)* - the micromanipulation of sperm performed in a laboratory, and involves injection of a single sperm directly into the cytoplasm of a mature ovum using a microinjection pipette. After fertilization, the embryo is inserted into the uterus or fallopian tube using IVF, GIFT or ZIFT procedures.
 - C. *Natural oocyte retrieval (NORIVF)* - the harvesting of ova from the ovary following natural ovulation (ovulation without hormone therapy).
- IV. Sperm may be obtained from ejaculate, including electro-ejaculate when necessary (e.g., males with spinal cord injury or peripheral neuropathy), cryopreserved specimens, or surgical procedures including, but not limited to, the following techniques:
- A. Microsurgical Epididymal Sperm Aspiration (MESA),
 - B. Microsurgical Testicular Sperm Extraction (MicroTESE),
 - C. Percutaneous Epididymal Sperm Aspiration (PESA),
 - D. Percutaneous Testicular Biopsy (PercBiopsy),
 - E. Testicular Fine Needle Aspiration (TEFNA),
 - F. Testicular Sperm Aspiration (TESA), or
 - G. Testicular Sperm Extraction (TESE).

An American Urological Association recommendation addressing the management of azoospermia states “the choice of sperm retrieval by either percutaneous or open surgery from either the testis or epididymis should be based upon

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local preferences and expertise since there is no evidence that the site or method of sperm retrieval affects outcome of in vitro fertilization with intracytoplasmic sperm injection for patients with obstructive azoospermia. Open surgical testicular sperm retrieval with or without microscopic magnification is recommended for patients with nonobstructive azoospermia.”

V. Laboratory sperm testing:

- A. The *hyaluronan binding assay (HBA)* is a qualitative assay of sperm maturity in which mature sperm bind to hyaluronan. A low level of sperm binding to hyaluronan suggests there is a low proportion of mature sperm in the specimen. HBA has been proposed for standard analysis of semen to diagnose suspected male infertility and to determine if ICSI is needed as part of an ART procedure.
- B. *Sperm DNA integrity* has emerged as a potential cause of idiopathic male infertility. Commercially available flow cytometry tests of DNA integrity include the sperm chromatin structure assay (SCSA®) and the sperm DNA fragmentation assay (SDFATM). Other laboratory tests for sperm integrity, such as the terminal deoxynucleotidyl transferase-mediated nick end-labeling (TUNEL) and single-cell gel electrophoresis (COMET) assays, require microscopic analysis and can, therefore, only assess a limited number of sperm. Tests of sperm DNA integrity have been proposed for evaluation of failed pregnancy or spontaneous abortions, in unassisted pregnancy, after failed IVF attempts or in selecting sperm samples for cryopreservation.

VI. *Co-culture of embryos* involves an effort to improve the culture media for embryos so that a greater proportion of embryos will reach the blastocyst stage and hopefully improve the implantation and pregnancy rate. Co-culture can be referred to the procedure whereby “helper” cells are grown along with the developing embryo. A variety of co-culture techniques have been investigated, involving the use of feeder cell layers derived from a range of tissues (e.g., human oviducts, fetal bovine uterine or oviduct cells) to established cell lines.

VII. *Assisted hatching* involves a procedure intended to thin or perforate the zona pellucida that has been investigated as a method of improving the implantation and subsequent pregnancy rates following IVF. Several techniques have been used to mechanically or chemically weaken the zona pellucida, including drilling, dissection, application of acid solutions or proteinases, and laser energy.

VIII. New York State Insurance Law § 4303 mandates the following benefits for treatment of infertility, under most managed care and health insurance policies.

A. Policies that provide coverage of hospital or, surgical and medical care must cover the following services:

1. Services in relation to surgical and medical procedures to ***correct malformation, disease or dysfunction*** resulting in infertility; and
2. Services in relation to diagnostic tests and procedures necessary:
 - a. to determine infertility; or
 - b. in connection with any surgical or medical treatments or prescription drug coverage included in the mandate.

These services include, but are not limited to: hysterosalpingogram, hysteroscopy, endometrial biopsy, laparoscopy, sono-hysterogram, post coital tests, testis biopsy, semen analysis, blood tests, ultrasound.

- B. Policies providing coverage for prescription drugs that also cover hospital or medical/surgical benefits must provide coverage for FDA approved drugs for the diagnosis and treatment of infertility.
- C. Diagnosis and treatment of infertility in connection with: IVF, GIFT, ZIFT, reversal of elective sterilizations, sex change procedures, and cloning are excluded from this mandate, except that three cycles of IVF must be covered under large group policies that provide medical, major medical or similar comprehensive-type coverage.
- D. Medical or surgical services or procedures that are deemed experimental are excluded from the mandate; in accordance with the guidelines and standards of the American College of Obstetricians and Gynecologists (ACOG) and the American Society for Reproductive Medicine (ASRM) which state: “A procedure for the

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treatment of infertility is considered experimental until there is adequate scientific evidence of safety and efficacy from appropriately designed, peer-reviewed, published studies by different investigator groups.”

- E. The diagnosis and treatment for infertility must be prescribed by a physician in a plan of care.
- F. The determination of appropriate candidates for the treatment of infertility and the identification of the required training, experience and other standards for health care providers who wish to diagnose and treat infertility must be in accordance with the standards and guidelines adopted by ACOG and ASRM.
- G. In 1991, the National Institutes of Health defined morbid obesity as a BMI of ≥ 35 kg/m² and severe, obesity related comorbidity as a BMI of ≥ 40 kg/m².

ACOG: Being overweight is defined as having a body mass index (BMI) of 25–29.9. Obesity is defined as having a BMI of 30 or greater. Within the general category of obesity, there are three levels that reflect the increasing health risks that go along with increasing BMI:

- Lowest risk is a BMI of 30–34.9.
- Medium risk is a BMI of 35.0–39.9.
- Highest risk is a BMI of 40 or greater.

- H. In 2020 New York State Insurance Law § 4303 expanded to cover the following benefits for fertility preservation, under most managed care and health insurance policies
 - 1. Standard fertility preservation services when a medical treatment to ***correct malformation, disease or dysfunction*** that may directly or indirectly cause iatrogenic infertility, an impairment of fertility by surgery, radiation, chemotherapy or other medical treatment affecting reproductive organs or processes. Standard fertility preservation services include:
 - a. Oocyte procurement and cryopreservation services
 - b. Embryo cryopreservation and storage
 - 2. Fertility preservation services solely for the purpose of delaying reproduction are not eligible for coverage.

RATIONALE

Assisted hatching - has been utilized by clinicians, but this practice is not strongly supported by the evidence. An update of a 2009 Cochrane systematic review and meta-analysis on assisted hatching (AH) was undertaken to determine the effect of assisted hatching of embryos from assisted conception on live birth and multiple pregnancy rates was published in 2012 (Carney, et al). Randomised controlled trials of AH (mechanical, chemical or laser disruption of the zona pellucida prior to embryo replacement) versus no AH that reported live birth or clinical pregnancy were reviewed for quality assessments and data extraction. Thirty-one trials reported clinical pregnancy data, including 1992 clinical pregnancies in 5728 women. The authors concluded that while AH does appear to offer a significantly increased chance of achieving a clinical pregnancy, the extent to which it may do so only just reaches statistical significance; the 'take home' baby rate was still not proven to be increased by AH; and the included trials provided insufficient data to investigate the impact of AH on several important outcomes and most trials still failed to report on live birth rates. The current data do not support the use of assisted hatching as a routine practice to improve IVF outcomes.

A 2014 guideline from the American Society of a Reproductive Medicine that addresses assisted hatching states “There is good evidence that assisted hatching (AH) slightly improves clinical pregnancy rates, particularly in poor prognosis patients, including those with prior failed in vitro fertilization (IVF) cycles. Due to a limited number of studies, there is insufficient evidence to conclude that AH improves live-birth rates” and “AH should not be recommended routinely for all patients undergoing IVF”.

Co-culture of embryos - There is no standardized method of co-culture and few clinical trials have evaluated outcomes. Most studies have not found improved implantation or pregnancy rates after co-culture. One 2015 RCT reported on a novel co-culture method and an interim analysis of the trial found a higher clinical pregnancy rate with co-culture than

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with standard practice control group. Additional studies are needed to evaluate this novel co-culture technique. No studies have reported on the impact of co-culture on live birth rates.

Hyaluronan binding assay -In the published 2016 study of 98 patients to evaluate the correlation of HBA with other semen parameters listed, Rashki et al concluded: The HBA is sensitive to morphological integrity, high progressive motility and nuclear maturation. Nonetheless, HBA is not a reliable test for prediction of sperm intracellular ROS, DF and MMP risks and healthy spermatozoa selection.

Sperm DNA integrity tests - Tests of sperm DNA integrity and fragmentation have been an important research tool to further explore the etiologies of infertility. Several studies have reported that poor sperm DNA integrity is an independent risk factor for male infertility. However, there are inadequate published data to permit scientific conclusions about tests of sperm DNA integrity as a diagnostic test used in the management of infertility. A March 2013 practice committee opinion of the American Society for Reproductive Medicine addressing *The Clinical Utility of Sperm DNA Integrity Testing* states “Existing data do not support a consistent relationship between abnormal DNA integrity and reproductive outcomes. At present, the results of sperm DNA integrity testing alone do not predict pregnancy rates achieved through natural conception or with IUI, IVF, or ICSI. However, further research may lead to validation of the clinical utility of these tests. There is insufficient evidence to recommend the routine use of sperm DNA integrity tests in the evaluation and treatment of the infertile couple”. In the ASRM 2013 guideline, *The clinical utility of sperm DNA integrity testing: a guideline*, they state: Sperm DNA damage is more common in infertile men and may contribute to poor reproductive performance. However, current methods for assessing sperm DNA integrity do not reliably predict treatment, outcomes and cannot be recommended routinely for clinical use

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.*
- ***CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.***
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
55400	Vasovasotomy, vasovasorrhaphy (not for reversal of an elective sterilization)
58321	Artificial insemination; intra-cervical
58322	intra-uterine
58323	Sperm washing for artificial insemination
58750	Tubotubal anastomosis
58752	Tubouterine implantation
58760	Fimbrioplasty
58970	Follicle puncture for oocyte retrieval, any method
58974	Embryo transfer, intrauterine
58976	Gamete, zygote, or embryo intrafallopian transfer, any method
89250	Culture of oocyte(s)/embryo(s), less than 4 days
89251 (E/I)	Culture of oocyte(s)/embryo(s), less than 4 days; with co-culture of oocyte(s)/embryos
89253 (E/I)	Assisted embryo hatching, microtechniques (any method)
89254	Oocyte identification from follicular fluid
89255	Preparation of embryo for transfer (any method)
89256	Preparation of cryopreserved embryos for transfer (includes thaw)
89257	Sperm identification from aspiration (other than seminal fluid)

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Code	Description
89258	Cryopreservation; embryo
89259	Cryopreservation; sperm
89261	complex prep (e.g. 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	greater than 10 oocytes
89300	Semen analysis, presence and/or motility of sperm including Huhner test
89310	motility and count (not including Huhner test)
89320	volume, count, motility, and differential
89321	Sperm presence and motility of sperm, if performed
89322	volume, count, motility, and differential using strict morphologic criteria (eg, Kruger)
89325	Sperm antibodies
89329	Sperm evaluation; hamster penetration test
89330	cervical mucus penetration test, with or without spinnbarkeit test
89331	Sperm evaluation, for retrograde ejaculation, urine (sperm concentration, motility, and morphology, as indicated)
89337	Cryopreservation, mature oocyte(s)
89342	Storage, (per year); embryo(s)
89346	Storage, (per year); oocyte(s)
89352	Thawing of cryopreserved; embryo(s)
89356	Thawing of cryopreserved; oocytes, each aliquot
Non-covered codes (if used for the purpose of delaying reproduction):	
0058T NCB	Cryopreservation; reproductive tissue, ovarian
0357T NCB	Cryopreservation, immature oocyte(s)
89335 NCB	Cryopreservation, reproductive tissue, testicular
89343 NCB	Storage, (per year); sperm/semen
89344 NCB	Storage, (per year); reproductive tissue, testicular/ovarian
89353 NCB	Thawing of cryopreserved; sperm/semen, each aliquot
89354 NCB	Thawing of cryopreserved; reproductive tissue, testicular/ovarian
89398 NCB	Unlisted reproductive medicine laboratory procedure

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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

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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
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
S4028	Microsurgical epididymal sperm aspiration (MESA)
S4035	Stimulated intrauterine insemination (IUI), case rate
S4037	Cryopreserved embryo transfer, case rate
S4042	Management of ovulation induction (interpretation of diagnostic tests and studies, non-face-to-face medical management of the patient), per cycle
Non-covered codes (if used for the purpose of delaying reproduction):	
S4023 (NCB)	Donor egg cycle, incomplete, case rate
S4025 (NCB)	Donor services for in vitro fertilization (sperm or embryo), case rate
S4026 (NCB)	Procurement of donor sperm from sperm bank
S4027 (NCB)	Storage of previously frozen embryo
S4030 (NCB)	Sperm procurement and cryopreservation services; initial visit
S4031 (NCB)	Sperm procurement and cryopreservation services; subsequent visit
S4040 (NCB)	Monitoring and storage of cryopreserved embryos, per 30 days

ICD10 Codes

Code	Description
E23.0	Hypopituitarism
N46.01-N46.9	Male infertility (code range)
N97.0-N97.9	Female infertility (code range)

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*Key Article

KEY WORDS

Artificial insemination, COMET assay, Direct intra-peritoneal insemination (DIPI), Gamete intrafallopian transfer (GIFT), Hyaluronan binding assay (HBA), Infertility, Intracytoplasmic sperm injection (ICSI), In-vitro fertilization (IVF), Microsurgical epididymal sperm aspiration (MESA), Microsurgical Testicular Sperm Extraction (MicroTESE), Sperm chromatin dispersion test [SCD], Sperm DNA integrity, Sperm chromatin structure assay (SCSA®), Sperm DNA fragmentation assay (SDFA™), Testicular sperm extraction (TESE), TUNEL assay, Zygote intrafallopian transfer (ZIFT).

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Category III CPT® Codes. Please refer to the following LCD website for Medicare Members: <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33392&ver=98&Date=07%2f01%2f2019&DocID=L33392&SearchType=Advanced&bc=KAAA&BABAAA&>

COVERAGE FOR NYS MEDICAID MANAGED CARE/HARP PRODUCT MEMBERS

Effective October 1, 2019, Medicaid Managed Care (MMC) and Health and Recovery Plan (HARP) benefits will include medically necessary ovulation enhancing drugs and medical services related to prescribing and monitoring the use of such drugs for individuals 21 through 44 years of age experiencing infertility.

For Medicaid purposes, infertility is a condition characterized by the incapacity to conceive, defined by the failure to establish a clinical pregnancy after:

1. Twelve months of regular, unprotected sexual intercourse for individuals 21 through 34 years of age, or
2. Six months for individuals 35 through 44 years of age.

Infertility benefits include:

1. Office visits
2. Hysterosalpingograms
3. Pelvic ultrasounds
4. Blood testing
5. Ovulation enhancing drugs.

The ovulation enhancing drugs included in the Medicaid formulary are:

1. Bromocriptine
2. Clomiphene Citrate
3. Letrozole
4. Tamoxifen.

Benefits will be limited to coverage for three (3) cycles of treatment per lifetime.

June 2019 Medicaid Update Bulletin:

https://www.health.ny.gov/health_care/medicaid/program/update/2019/2019-06.htm#ovulation