MEDICAL POLICY

SUBJECT: ASSISTED REPRODUCTIVE TECHNOLOGIES FOR INFERTILITY

POLICY NUMBER: 4.01.05
CATEGORY: Contract Clarification

EFFECTIVE DATE: 10/18/01
REVISED DATE: 07/02/01, 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
Updated: 03/15/16
Retrospective effective date: 01/01/16
PAGE: 1 OF: 13

• If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.
• Medical policies apply to commercial and Safety Net products only when a contract benefit for the specific service exists.
• Medical policies only apply to Medicare products when a contract benefit exists and where there is no national or local Medicare coverage decision for the specific service.

POLICY STATEMENT:

I. 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 correctable malformations, disease and/or dysfunction.

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:
A. post coital test;
B. hysterosalpingogram, hysteroscopy, sonohysterogram;
C. laparoscopy;
D. prior infertility treatment;
E. sperm count/motility; and
F. other laboratory tests as indicated (e.g., FSH, Hba1c in diabetics, Prolactin, TSH, T4, etc.).

II. 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).

III. Based upon our criteria, contractually covered assisted reproductive technologies are not medically appropriate when:
A. 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
B. either partner has undergone an elective sterilization in the past.

IV. 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:
A. 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.
B. Infertile, ovulatory women receiving clomiphene citrate for superovulation – appropriate for up to six cycles of treatment. Up to six cycles of intrauterine insemination will be covered in conjunction 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.
C. After clomiphene failure, or in place of clomiphene treatment, for women in late reproductive life treatment with FDA approved gonadotropin drugs is limited to:
   1. up to four (4) cycles per member per pregnancy as defined by a positive HCG determination; and
   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.
V. Clinical **contraindications** to infertility treatment with FDA-approved drugs 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, or usage of prescription medication detrimental to or contraindicated for pregnancy); and
   D. baseline (day 2-4) FSH greater than or equal to 15 mIU/ml.

VI. Based upon our criteria, contractually covered 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. 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. 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™], deoxyribonucleotidyl transferase-mediated deoxyuridine triphosphate-biotin nick end labeling [TUNEL], single cell electrophoresis assay [COMET]).

IX. Based upon our criteria, the following services are generally excluded by contract and are **ineligible for coverage**:
   A. procurement of donor sperm or ova;
   B. in vitro fertilization, gamete intrafallopian tube transfers or zygote intrafallopian tube transfers;
   C. ovulation predictor kits;
   D. tubal ligation reversal;
   E. vasectomy reversal;
   F. services of and relating to surrogate motherhood;
   G. cryopreservation or storage of sperm, ova, and/or embryos; or
   H. cloning services and procedures.

*Refer to the FLRx Prescription Drug Policies regarding:
Infertility Medications, and
Gonadotropin Releasing Hormone Analogs.*

**POLICY GUIDELINES:**

I. All assisted reproductive technologies, including but not limited to, in-vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), and zygote intrafallopian transfer (ZIFT), are contract dependent.

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 artificial insemination for a woman who has not been diagnosed with infertility. A woman without a male partner will be considered infertile after 12 months (or 6 months depending on the woman’s age) of failed attempts to become pregnant.
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 apply:
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.

VI. 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.

VII. A contracted laboratory (when required by contract) must perform semen analysis in conjunction with female infertility evaluations.

VIII. Experimental, nonstandard, and/or unevaluated infertility treatments and drugs approved by the FDA that are not specifically approved to treat infertility are ineligible for coverage.

IX. Diagnostic work-up and infertility treatments for a partner who is not a member is ineligible for coverage.

X. 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 a disease*, defined by the failure to achieve pregnancy after 12 months or more of appropriate, timed regular unprotected intercourse or therapeutic donor insemination. Earlier evaluation and treatment may be justified based on medical history and physical findings and is warranted after 6 months for women over age 35 years. In addition, a woman without a male partner who has been unable to conceive after 12 months of artificial donor insemination (or 6 months if over age 35 years) will be considered infertile.

* 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. Hormonol treatments;
   C. Laparoscopy;
   D. Laparotomy
   E. Hysteroscopy;
   F. Endometrial biopsy;
   G. Fallopian tube catheterization and recannulization;
   H. Hysterosalpingogram;
   I. Ultrasound/sonography;
   J. Laboratory studies (e.g., Semen analysis, Hormone level studies, appropriate blood tests);
   K. Follicular stimulation with medications (e.g., Clomid, Gonal-f);
   L. Monitoring ovulation via ultrasound and endocrine studies;
   M. Post coital tests;
   N. Semen analysis;
   O. Retrieval of ova by various methods under general or local anesthesia; and
   P. 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, 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 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 (SDFA™). 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. 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.

On September 1, 2002, New York State Law mandated the following benefits for treatment of infertility, for persons age 21 to 44 years, under most managed care and health insurance policies.

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

A. Services in relation to surgical and medical procedures to correct malformation, disease or dysfunction resulting in infertility; and
B. Services in relation to diagnostic tests and procedures necessary:
   1. to determine infertility; or
   2. 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-hysterosogram, post coital tests, testis biopsy, semen analysis, blood tests, ultrasound, and artificial insemination (including intracervical and intrauterine insemination).
II. 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, including induction of pregnancy.

III. IVF, GIFT, ZIFT, reversal of elective sterilizations, sex change procedures, and cloning are excluded from this mandate.

IV. Experimental services 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 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.”

V. The diagnosis and treatment for infertility must be prescribed by a physician in a plan of care.

VI. 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.

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 - no standardized method of co-culture has emerged and no controlled studies have evaluated an improved implantation or pregnancy rate associated with co-culture. No studies, published within the past 5 years, have been identified that address embryo co-culturing.

Hyaluronan binding assay - published scientific data are inadequate to permit conclusions regarding these indications. No studies have been identified that establish the diagnostic performance of the test or examined its clinical role.

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”.

Proprietary Information of YourCare Health Plan
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.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

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<th>CPT</th>
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*Proprietary Information of YourCare Health Plan*
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<td>oocytes, each aliquot</td>
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<td>89398</td>
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**HCPCS:**

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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:
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 embryo
S4030 Sperm procurement and cryopreservation services; initial visit
S4031 Sperm procurement and cryopreservation services; subsequent visit
S4040 Monitoring and storage of cryopreserved embryos, per 30 days

ICD9:
606.0 Infertility, male, azospermia
606.1 Infertility, male, oligospermia
606.8 Infertility, male, due to extratesticular causes
606.9 Infertility, male, unspecified
628.0 Infertility, female, associated with anovulation
628.1 Infertility, female, of pituitary hypothalmic origin
628.2 Infertility, female, of tubal origin
628.3 Infertility, female, of uterine origin
628.4 Infertility, female, of cervical or vaginal origin
628.8 Infertility, female, of other specified origin
628.9 Infertility, female, of unspecified origin

ICD10:
E23.0 Hypopituitarism
N46.01-N46.9 Male infertility (code range)
N97.0-N97.9 Female infertility (code range)

REFERENCES:

American Society of Reproductive Medicine [http://www.asrm.org/Guidelines/] accessed 01/01/2016:
- Blastocyst culture and transfer in clinical-assisted reproduction. 2013 Mar.
- Criteria for number of embryos to transfer. 2013 Jan.
- Definition of experimental procedures. 2013 Apr.
- Diagnostic evaluation of the infertile male. 2015 Mar.
- *Effectiveness and treatment for unexplained infertility. 2006 Nov.
- Elective single-embryo transfer. 2012.
- Female age-related fertility decline. 2014 Mar.
- Intracytoplasmic sperm injection (ICSI) for non-male factor infertility. 2012 Dec.
- In vitro maturation. 2013 Mar.
- Revised minimum standards for practices offering assisted reproductive technologies. 2014 Sep.
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*key articles
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

Based on our review, Assisted Reproductive Technologies for Infertility is not addressed in National or Local CMS coverage determinations or policies.