

Corporate Medical Policy

Infertility Diagnosis and Treatment – B0006

File Name: infertility_diagnosis_and_treatment
Origination: 1/2000
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Description of Procedure or Service

Infertility, as defined by American Society for Reproductive Medicine (ASRM), is a disease (an interruption, cessation, or disorder of body functions, systems, or organs) of the reproductive tract which prevents the conception of a child or the ability to carry a pregnancy to delivery. It is defined by the failure to achieve a successful pregnancy after 12 months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination. Earlier evaluation and treatment for those individuals actively looking to achieve a conception may be justified based on medical history and physical findings and is warranted after 6 months for women age 35 years or older. First, infertility must be diagnosed. Tests will determine if either partner has reduced fertility. Infertility may be related to female factors (i.e., pelvic adhesions, ovarian dysfunction, endometriosis, prior tubal ligation), male factors (i.e., abnormalities in sperm production, function, or transport or prior vasectomy), a combination of both male and female factors, or unknown causes. Once the infertility has been diagnosed, treatments for infertility may begin. The treatment of infertility begins with basic treatments. These can include advice (e.g., the timing of intercourse or reduction of stress factors), the administration of drugs to enhance the reproductive cycle, and various procedures that treat underlying causes of infertility. If the basic treatments fail, then treatment moves to more advanced techniques including assisted reproductive technologies (ART).

The definition of ART according to the Center for Disease Control (CDC) is all fertility treatments in which both eggs and sperm are handled. In general, ART procedures involve surgically removing eggs from the ovaries, combining them with sperm in the laboratory, and implanting them in the uterus. They do NOT include treatments in which only sperm are handled (i.e., intrauterine—or artificial—insemination) or procedures in which an individual takes medicine only to stimulate egg production without the intention of having eggs retrieved.

For the purpose of this policy, assisted reproductive technologies (ART) includes any means of attempting pregnancy that does not involve normal coitus (sexual intercourse) and will be referred to as "artificial means of conception". The simplest of these techniques is artificial insemination (AI). In this procedure, viable sperm is mechanically injected into the vagina, cervix, or uterus. In vitro fertilization (IVF) is a more advanced technology that involves surgically removing eggs from the ovaries, combining them with sperm in the laboratory and, if fertilized, replacing the resulting embryo into the uterus. Various types of transfers may occur to replace the fertilized egg back into the individual.

All services which are received as part of an IVF procedure are considered under the same benefit as the IVF procedure. This can include office visits, drugs, lab and pathology, surgical procedures, etc. Mechanically assisted fertilization (MAF) may also be performed as part of an IVF procedure. Such procedures may include intracytoplasmic sperm injection (ICSI).

Modifications of the IVF procedure include such procedures as GIFT (gamete intrafallopian transfer), ZIFT (zygote intrafallopian transfer), PROST (pronuclear stage transfer), TEST (tubal embryo stage transfer) and TET (tubal embryo transfer). While many of the services received during these procedures are similar to IVF, in GIFT, eggs and sperm are transferred to the fallopian tube where fertilization occurs. In ZIFT, PROST,

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TEST, and TET, fertilized embryos are transferred at various stages of development into the fallopian tube, either from the fimbrial end via laparoscopy or through catheterization of the uterine end, the latter with or without ultrasound guidance.

Artificial means of conception are frequently excluded from coverage. Please check the member benefit booklet to understand the infertility benefits available to the member.

This policy does not address procedures or treatments related to transgender services. Please see the policy “Gender Confirmation Surgery and Hormone Therapy” for information regarding transgender services.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Infertility when it is determined to be medically necessary because the criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore, member benefit language should be reviewed before applying the terms of this medical policy.

See "Family Planning" section under "Covered Services" for benefits and exclusions. Also see "What is not Covered" section of member benefit booklet.

Please refer to the member's benefit booklet for all infertility services. Some plans may provide no benefits. Some plans may provide some coverage, but exclude coverage for artificial means of conception, including, but not limited to artificial insemination, in vitro fertilization and associated services such as drugs, labs, pathology, etc. Please review the member benefit plan to understand coverage and/or limitations regarding infertility.

When Infertility Diagnosis and Treatment is covered

A) **Diagnostic Tests:**

The first stage of infertility treatment is the accurate diagnosis of the condition. **Please check the member's benefit booklet for benefit information regarding infertility.** Depending on the member of an infertile couples' unique medical situation, the following diagnostic tests may be considered medically necessary, when performed solely to establish the underlying etiology of infertility:

- 1) Diagnostic tests for the **Female**
 - a) Diagnostic tests for general medical evaluation, including complete blood count (CBC), liver function tests (LFT), rapid plasma reagin test (RPR), Human Immunodeficiency Virus (HIV), cultures for chlamydia and gonorrhea.
 - b) Diagnostic tests to rule out endocrine causes of infertility (e.g., thyroid-stimulating hormone [TSH], blood sugar, dehydroepiandrosterone [DHEA], dehydroepiandrosterone sulfate (DHEAS), 17 hydroxyprogesterone, total and fractionated testosterone, estradiol measurements) if clinically indicated.
 - c) LH (luteinizing hormone), prolactin, progesterone, and/or FSH (Follicle stimulation hormone) levels
 - d) Anti-Mullerian hormone (AMH)
 - e) Pelvic ultrasonography
 - f) Hysterosalpingography (HSG)
 - g) Saline infusion sonohysterography (SIS or SHG)
 - h) Laparoscopy
 - i) Hysteroscopy

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- j) Hormonal antisperm antibodies (should not be performed as a routine screen)
 - k) Fasting insulin
 - l) Serum Chlamydia IgG
- 2) Diagnostic tests for the **Male**:
- a) Semen analysis (two specimens at least one month apart).
Note: Semen analysis values may vary according to the reference lab used.
 - b) Endocrine evaluation **if clinically indicated**. (Minimum initial hormonal evaluation should consist of measurement of serum follicle-stimulating-hormone (FSH), luteinizing hormone (LH), testosterone, and prolactin.)
 - c) Antisperm antibodies
 - d) Post-ejaculatory urinalysis
 - e) Urine and semen culture
 - f) Vasography
 - g) Scrotal ultrasonography
 - h) Testicular biopsy
 - i) Transrectal ultrasonography of the prostate, seminal vesicles, and ejaculatory duct. This test should only be used when there is:
 - A motility of <30% in the absence of any other explanation with or without a decreased sperm count
 - Low semen volume (<1.0 ml)
 - Perineal pain associated with ejaculation
 - One of the above plus a physical exam which is suggestive of 1.) a cyst of either the seminal vesicle or prostate, or 2.) with non-palpable vas deferens or epididymides
- Note:** Only azoospermia (no sperm cells in the ejaculate) is diagnostic of male infertility. Fertility has been documented in males with values as low as 20% of normal spermatozoa or 20% motility. Clinical history should be considered in the diagnosis.

B) Basic Treatments

Once infertility has been established, the treatments for infertility begin. **Please check the member's benefit booklet for benefit information regarding the treatment of infertility.** Depending on the member of an infertile couples' unique medical situation, the following treatments for infertility may be considered medically necessary.

- 1) Infertility drugs - **Please check the member's benefit booklet for information regarding pharmacy benefit coverage for infertility treatment, which may be separate from medical infertility coverage.**
 - a) Dopamine agonists (bromocriptine and cabergoline)
 - b) Clomiphene citrate
 - c) Gonadotropins:
 - Human chorionic gonadotropin (hCG)
 - Choriogonadotropin alfa (a biosynthetic [recombinant DNA-derived] chorionic gonadotropin)
 - Human menopausal gonadotropins (hMG) (menotropins). Failure of clomiphene citrate and other techniques of inducing ovulation should be documented.
 - Urofollitropin (human follicle stimulating hormone-FSH)
 - Recombinant (biosynthetic) FSH (follitropin alpha, follitropin beta)
 - Recombinant (biosynthetic) luteinizing hormone (lutropin alfa)
 - d) Low dose glucocorticoids (dexamethasone or prednisone)
 - e) Gonadotropin-releasing hormone (GnRH). Unresponsiveness to Clomiphene Citrate should be documented.
 - f) Metformin for anovulation secondary to polycystic ovarian disease (PCOD).
 - g) Non-steroidal aromatase inhibitor for medical conditions associated with infertility i.e. polycystic ovarian disease.
- 2) Therapeutic Operative Procedures for the Female (Note: Benefits for reversal of sterilization are not covered unless otherwise stated by the member benefit booklet.)
 - a) Therapeutic operative laparoscopy (e.g., treatment of endometriosis or periadnexal adhesions)

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- b) Open surgical treatment in individuals with moderate or severe endometriosis
 - c) Salpingo-ovariolysis
 - d) Terminal salpingostomy
 - e) Fimbrioplasty
 - f) Uterotubal implantation
 - g) Tubocornual anastomosis
 - h) Balloon tuboplasty
 - i) Ovarian wedge resection
- 3) Therapeutic Operative Procedures for the Male (Note: Benefits for reversal of sterilization are not covered unless otherwise stated by the member's benefit booklet.
- a) Varicocelectomy
 - b) Transurethral resection of ejaculatory duct
 - c) Orchiopexy
 - d) Surgical correction of epididymal blockage for individuals with obstructive azoospermia:
 - Epididymectomy
 - Epididymovasostomy
 - Excision of epididymal tumors and cysts
 - Epididymostomy

C) Artificial Means of Conception

This includes any means of attempting pregnancy that does not involve normal coitus. **These services are frequently excluded from coverage. These services are only covered if the member's benefit booklet identifies Artificial insemination (AI), Intrauterine Insemination (IUI), and/or In Vitro fertilization (IVF) as covered services. Please check the member benefit language regarding the benefits for artificial means of conception.**

These services include:

- 1) Artificial insemination (AI) for Female Infertility: AI may be considered medically necessary when all of the following criteria are met.
 - a) Complete evaluation of the following must be considered prior to the initiation of Intrauterine Insemination (IUI):
 - ovulatory disorders
 - tubal abnormalities
 - cervical abnormalities
 - immunologic factors
 - b) Prior to AI, the following routine diagnostic tests must be performed or deemed inappropriate:
 - Basal body temperature records
 - laparoscopy
 - documentation of tubal patency and normal configuration of the uterine cavity (e.g., hysterosalpingography)
 - testing for chlamydia, gonorrhea, syphilis, and Acquired Immune Deficiency Syndrome (AIDS)
 - c) Final diagnosis includes any of the following:
 - anatomic defects of the vagina
 - defects of ovaries
 - cervical mucus abnormalities
- 2) Artificial Insemination for Male Infertility: AI for male factor infertility may be considered medically necessary when all of the following criteria are met:
 - a) Complete evaluation of the following must be performed or deemed inappropriate prior to initiating AI:
 - comprehensive urological evaluation
 - two semen analyses which are separated by an interval of at least 3 months
 - b) Final diagnosis includes any of the following:
 - anatomic defects of the penis

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- low sperm count (<20 million/ml)
 - antisperm antibodies
 - oligoasthenospermia
 - retrograde ejaculation
 - seminal fluid liquefaction defect
 - teratospermia
 - aspermia
- c. Benefits for artificial insemination using donor sperm are allowed only when the male partner is a covered member and has been diagnosed with male infertility.
- Note:** Sperm washing is considered eligible for coverage when in preparation for a covered procedure.
- 3) In Vitro Fertilization (IVF): Benefits for IVF are available only if specified in the member contract.
- a) IVF services may include the following:
- stimulation of ovulation
 - monitoring of ovulation stimulation
 - oocyte retrieval
 - laboratory studies
 - embryo assessment and transfer
 - luteal phase support
 - thawing of cryopreserved embryos
- b) All services which are received as part of an IVF procedure are considered under the same benefit as the IVF procedure. This can include:
- drugs
 - lab
 - pathology
 - surgical procedures
 - radiology (ultrasound)
- c) The following procedures may be performed in conjunction with IVF:
- (i) Intracytoplasmic Sperm Injection (ICSI);
 - (ii) Microscopic epididymal sperm aspiration (MESA);
 - (iii) Percutaneous epididymal sperm aspiration (PESA);
 - (iv) Testicular sperm aspiration (TESA);
 - (v) Testicular sperm extraction (TESE)
 - (vi) Assisted hatching.
- d) Current American Society for Reproductive Medicine (ASRM) and Society for Assisted Reproductive Technology (SART) guidelines regarding limits to the number of embryos transferred should be followed. (see Policy Guidelines)

When Infertility Diagnosis and Treatment is not covered

- A) For the treatment of normal physiologic causes of infertility**, such as menopause, or infertility resulting from voluntary sterilization (vasectomy or tubal ligation/occlusion) unless otherwise stated by the member's benefit plan.
- B) Diagnostic tests**
- 1) The following diagnostic tests are considered investigational. BCBSNC does not cover investigational procedures.
 - a) Assessment of sperm movements, including the use of videomicrography, cinematography, time-exposure photography, computer assisted sperm analysis (CASA), etc.
 - b) Analysis of ATP concentration (Adenosine triphosphate) in ejaculate
 - c) Tubalscopy
 - d) Anti-zona pellucida antibodies
 - e) Sperm hyaluronan binding assay (HBA)
 - f) Tests of sperm DNA integrity, including, but not limited to, sperm chromatin assays and sperm DNA fragmentation assays

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- g) Hemizona assay
 - h) Hypo-osmotic swelling test
- C) Basic Treatments**
- 1) Benefits for reversal of sterilization are not covered unless otherwise stated by the member benefit plan.
 - 2) The following treatments are considered investigational. BCBSNC does not cover investigational procedures.
 - a) Administration of tamoxifen
 - b) Administration of cyclofenil
 - c) Pulsatile administration of human menopausal gonadotropins (hMG)
 - d) Administration of growth hormone
 - e) Administration of anastrozole
- D) Artificial Insemination (AI), Intrauterine Insemination (IUI), Intracervical Insemination (ICI)**
- 1) Contraindications for AI in Females include, but are not limited to the following:
 - a) infection such as acute cervicitis, salpingo-oophoritis
 - b) tubal obstruction
 - c) pregnancy
 - d) unexplained uterine bleeding
 - e) presence of sexually transmitted disease
 - 2) Contraindications for AI in Males include, but are not limited to the following:
 - a) infection such as prostatitis or epididymitis
 - b) presence of sexually transmitted disease
 - 3) When contraindicated as above, AI would be considered to be not medically necessary and therefore non-covered.
- E) In Vitro Fertilization (IVF) and services associated with IVF, except as specifically included in the member's benefit plan.**
- 1) Modifications of the IVF procedure are considered investigational, and are also excluded under most standard plans. Modifications include, but are not limited to, such procedures as:
 - a) GIFT (gamete intrafallopian transfer)
 - b) ZIFT (zygote intrafallopian transfer)
 - c) PROST (pronuclear stage transfer)
 - d) TEST (tubal embryo stage transfer)
 - e) TET (tubal embryo transfer)
 - f) Zona "drilling" (PZD)
 - 2) Charges related to cryopreservation of embryos are not covered under standard medical benefits or under infertility benefits unless otherwise stated in the member's benefit booklet.
 - 3) Charges related to cryopreservation of reproductive tissue, including sperm and oocytes, are not covered under standard medical benefits or under infertility benefits unless otherwise stated in the member's benefit booklet.
 - 4) Associated charges related to cryopreservation of embryos or reproductive tissue, including testing, transport fees and storage, are not covered under standard medical benefits or under infertility benefits unless otherwise stated in the member's benefit booklet.
 - 5) Sperm washing is not eligible for coverage when used in preparation for a noncovered procedure.
 - 6) Charges related to oocyte or sperm donation or storage (including donor and recipient charges) are not covered under standard medical benefits or infertility benefits unless otherwise stated in the member's benefit booklet.
 - 7) The following techniques related to IVF are considered investigational and are not covered:
 - a) Co-culture of embryos,
 - b) Sperm selection with hyaluronan for intracytoplasmic sperm injection (ICSI).
- F.) Uterine transplant is considered investigational as a treatment of infertility.**

Policy Guidelines

Please check the member's benefit booklet to understand the infertility benefits available to the member. Infertility benefits are frequently excluded from the individual member benefit plan.

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When benefits are available for in vitro fertilization, [current ASRM/SART guidelines](#) should be followed regarding limits to the number of embryos transferred. In most cases, single embryo transfer is indicated. Medical record documentation must include a statement of individual conditions justifying transferring fewer or more embryos than guideline recommended limits. IVF programs are encouraged to monitor their own data on embryo transfer, pregnancy rates, and pregnancy outcomes.

Preimplantation genetic testing is not covered except when benefits are available for IVF, unless otherwise stated in the member's benefit booklet.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable Codes: 0664T-0670T, 54900, 54901, 55300, 55400, 55870, 58321, 58322, 58323, 58340, 58345, 58350, 58660, 58672, 58673, 58740, 58750, 58752, 58760, 58770, 58970, 58974, 58976, 74740, 76830, 76831, 76856, 76857, 76942, 76948, 76998, 89250, 89251, 89253, 89254, 89255, 89257, 89258, 89259, 89260, 89261, 89264, 89268, 89272, 89280, 89281, 89290, 89291, 89300, 89310, 89320, 89321, 89322, 89325, 89329, 89330, 89331, 89335, 89337, 89342, 89343, 89344, 89346, 89352, 89353, 89354, 89356, 89398, G0027, Q0115, S3655, S4011, S4013, S4014, S4015, S4016, S4017, S4018, S4020, S4021, S4022, S4023, S4025, S4026, S4027, S4028, S4030, S4031, S4035, S4037, S4040, S4042

Please refer to the member's benefit booklet for all infertility services. Some plans may provide no benefits. Some plans may provide some coverage, but exclude coverage for in vitro fertilization and similar services. Please review the member benefit plan to understand coverage and/or limitations regarding infertility.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

From Policy Entitled: Infertility

Textbook of Gynecology, L. Copeland, W.B. Saunders Co., 1993.

Consultant Review 12/97

"The Insulin Sensitizing Agent Troglitazone Improves Metabolic and Reproductive Abnormalities in the Polycystic Ovary Syndrome" from The Journal of Clinical Endocrinology and Metabolism. Volume 81, No. 9, June 1996

Consultant Review 5/98

Blue Cross Blue Shield Pharmacist 5/98

Medical Policy Advisory Group recommendations 5/28/98

From Policy Entitled: Artificial Insemination

PCP medical policy dated 12/2/91

MedPoint medical policy dated 7/1/93

The American Fertility Society - Guideline for Practice - Intrauterine Insemination

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Consultant Review 6/97

Consultant Review 3/98

Medical Policy Advisory Group 11/98

From Policy Entitled: Sperm Penetration Assay

Blue Cross Blue Shield Association 12/95, policy 4.02.01

Medical Policy Advisory Group 11/98

New Policy Entitled: Infertility, Diagnosis and Treatment

Specialty Matched Consultant Advisory Panel 11/1999

Medical Policy Advisory Panel 12/2/1999

Specialty Matched Consultant Advisory Panel - 9/2001

BCBSA Medical Policy Reference Manual, 10/8/02; 4.02.04

BCBSA Medical Policy Reference Manual, 7/17/03; 4.02.01

Specialty Matched Consultant Advisory Panel - 8/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.02.01, 11/9/04

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.02.04, 3/15/05

Specialty Matched Consultant Advisory Panel - 8/25/05

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.02.01, 12/14/05

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.02.01, 2/15/07

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.02.04, 4/25/06

American Society for Reproductive Medicine (ASRM). Patient's Fact Sheet: Diagnostic Testing for Male Factor Infertility.

American Society for Reproductive Medicine (ASRM). Medications for Inducing Ovulation - A Guide for Patients.

American Society for Reproductive Medicine (ASRM). Infertility: An Overview - A Guide for Patients.

Shaban, Stephen F. Male Infertility Overview: Assessment, Diagnosis, and Treatment. Retrieved on July 12, 2007 from Georgia Reproductive Specialists website at <http://www.ivf.com/shaban.html>

Management of Male Infertility. Retrieved from <http://www.urologyhealth.org/search/index.cfm?topic=129&search=male%20AND%20infertility&searchtype=and>

American Urological Association (AUA). Report on optimal evaluation of the infertile male. Retrieved on July 12, 2007 from http://www.auanet.org/guidelines/main_reports/optimizevaluation.pdf

Specialty Matched Consultant Advisory Panel - 8/29/2007

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.02.04, 5/14/2009

Specialty Matched Consultant Advisory Panel – 2/2010

American Society for Reproductive Medicine (ASRM). Patient's Fact Sheet: Diagnostic Testing for Male Factor Infertility. Retrieved on October 3, 2014 from http://www.asrm.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/Testing_Male-Fact.pdf

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American Society for Reproductive Medicine (ASRM). Medications for Inducing Ovulation - A Guide for Patients. Retrieved on October 3, 2014 from http://www.asrm.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/ovulation_drugs.pdf

American Society for Reproductive Medicine (ASRM). Infertility: An Overview - A Guide for Patients. Retrieved on October 3, 2014 from http://www.asrm.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/infertility_overview.pdf

Male Infertility: Management. Retrieved on October 3, 2014 from <http://www.urologyhealth.org/urology/index.cfm?article=29&display=1>

American Urological Association (AUA). Report on optimal evaluation of the infertile male. Retrieved on October 3, 2014 from <http://www.auanet.org/education/guidelines/male-infertility-d.cfm>

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.02.04, 4/10/2014

Specialty Matched Consultant Advisory Panel – 9/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.02.04, 4/23/2015

American Society for Reproductive Medicine (ASRM). Diagnostic evaluation of the infertile male: a committee opinion. Retrieved on September 9, 2015 from [http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Committee_Opinions/optimal_evaluation_of_the_infertile_male\(1\).pdf](http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Committee_Opinions/optimal_evaluation_of_the_infertile_male(1).pdf) .

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.02.04, 8/11/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.02.04, 8/10/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.02.04, 8/9/2018

The Practice Committee of the American Society for Reproductive Medicine, and the Practice Committee of the Society for Assisted Reproductive Technologies, Guidance on the Limits to the Number of Embryos to Transfer: A Committee Opinion, 107(4) FERTILITY & STERILITY 901 (2017), https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/guidance_on_the_limits_to_the_number_of_embryos_to_transfer.pdf

Infertility workup for the women’s health specialist. ACOG Committee Opinion No. 781. American College of Obstetricians and Gynecologists. Obstet Gynecol 2019;133:e377–84.

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.02.04, 8/8/2019

Specialty Matched Consultant Advisory Panel – 9/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.02.04, 9/2020

Specialty Matched Consultant Advisory Panel – 9/2021

Medical Director Review 9/2021

The American College of Obstetricians and Gynecologists. Infertility Workup for the Women’s Health Specialist. Vol 133, No. 6, June 2019

Specialty Matched Consultant Advisory Panel 9/2022

Medical Director Review 9/2022

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Specialty Matched Consultant Advisory Panel 9/2023

Medical Director Review 9/2023

Definition of infertility: A committee opinion (2023). American Society for Reproductive Medicine. (n.d.). <https://www.asrm.org/practice-guidance/practice-committee-documents/denitions-of-infertility/>

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Policy Implementation/Update Information

From Policy Entitled: Infertility

- 3/98 Original Policy developed
- 5/98 Reviewed: Added to Policy section that Troglitazone (Rezulin) in conjunction with Clomid for patients with polycystic ovarian syndrome, when initial Clomid therapy has failed as another treatment modality.
- 5/98 Reviewed: Changed Artificial Reproductive Technologies to Assisted Reproductive Technologies. Added Human Growth Hormone to Assisted Reproductive Technologies and removed from Investigational list.

From Policy Entitled: Artificial Insemination

- 3/96 Original policy issued
- 3/97 Reaffirmed
- 6/97 Archived old policy.
- 3/98 New policy developed which addresses male and female infertility and the use of donor sperm
- 8/98 Reviewed: Changed number of IUI cycles eligible for coverage in female infertility from a range of 4-6 to 4. Changed low sperm volume to low sperm count. From Policy Entitled: Sperm Penetration Assay
- 4/86 Evaluated: Investigational
- 6/96 Reaffirmed: National Association reviewed 12/95. No changes.
- 9/98 Reaffirmed: No changes in BCBSA policy. Added PCP and MedPoint indicators

New Policy entitled: Infertility, Diagnosis and Treatment

- 10/99 Combined Infertility, Artificial Insemination, and Sperm Penetration Assay to form new policy entitled Infertility, Diagnosis and Treatment. Reformatted.
- 12/99 Approved, Medical Policy Advisory Group
- 10/00 Typographical errors corrected. No change in criteria.
- 5/01 Changed criteria for low semen volume to "Low semen volume (<1.0 ml)", Coding format change.
- 9/01 Specialty Matched Consultant Advisory Panel review. Description of artificial insemination changed to include injection of sperm into the uterus. When Infertility Diagnosis and Treatment are covered changed to include endocrine tests as diagnostic tests for women,

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Metformin for annovulation secondary to polycystic ovarian disease, deleted 6 cycles of Clomiphene needed for documentation of clomiphene citrate unresponsiveness, Clomiphene removed from end of B. 7. Criteria. When Infertility Diagnosis and Treatment are not covered was changed to delete testing for luteal phase defect (LPD). Resulin was removed from the policy. Description clarified as needed.

- 12/03 Specialty Matched Consultant Advisory Panel review. No changes in criteria. Benefits Application and Billing/Coding sections revised.
- 4/04 Individual CPT codes listed for CPT code ranges 58321-58350, 58740-58770, 58970- 58976, 89250-89255, 89258-89259, 89300-89330 under Billing/Coding section.
- 8/12/04 HCPCS codes added to Billing/Coding section; S4011, S4013, S4014, S4015, S4016, S4017, S4018, S4020, S4021, S4022, S4023, S4025, S4026, S4027, S4028, S4030, S4031, S4035, S4036, S4040, S8055.
- 9/15/05 Description section revised. Note: The following are dependant on the individual certificate language re: infertility and IVF: Under "When Covered" section: A.2.- Diagnostic tests for the Male/ Semen analysis - testicular biopsy listed as a separate entity, not as part of semen analysis; sperm penetration assay added as medically necessary to determine whether ICSI should be offered as part of an IVF technique. Under "When not Covered" section: B. Diagnostic tests/sperm penetration assay moved to covered section; assessment of sperm movements-added computer assisted sperm analysis (CASA) to the end of the statement; assessments of the ability of sperm to interact with heterologous or homologous oocytes removed; Hyaluronan binding assay (HBA) added as investigational; D. Assisted Reproductive Technologies/AI/Contraindications in Fe-tubal obstruction listed as a separate bullet; endometriosis listed as a separate bullet and revised to "severe endometriosis (Stage IV)"; D.3. added thawing; D.4. now reads: "Charges related to the testing and transport fees or any other charges incurred due to cryopreservation, storage and thawing of sperm/semen and testicular tissue are not covered under standard medical benefits or under infertility benefits unless otherwise stated in the individual certificate."; added D.7."Charges related to co-culture of embryos are considered investigational and are not covered; added D.8.-"Charges related to cryopreservation, storage and thawing of ovarian tissue or oocytes are considered investigational and are not covered." Reference sources and medical term definitions added. Specialty Matched Consultant Advisory Panel (CAP) review 8/25/05. Based on CAP recommendations, under When Covered section: A.1.- Diagnostic tests for the Female, added fasting insulin and serum Chlamydia IgG. Notification given 9/15/05. Effective date 11/17/05.
- 11/17/05 Under Billing/Coding section: Added codes 55870, 58660, 58672, 58673, 89264, 89568, 89272, 89280, 89281, 89335, 89342, 89343, 89344, 89346, 89352, 89353, 89354, 89356, 0058T, 0059T, 0087T, G0027, S3655, S4037, S4042. Removed codes 56343, 56344, 58346, 82670, 83001, 83002, 89310, 89320, S8055.
- 10/8/07 Under Benefits Application section, changed "Some plans may provide some coverage, but exclude coverage for in vitro fertilization and similar services." To read "Some plans may provide some coverage, but exclude coverage for artificial means of conception, including, but not limited to artificial insemination, in vitro fertilization and associated services such as drugs, labs, pathology, etc."

Under When Covered section: A. Diagnostic Tests, introductory paragraph: deleted "to diagnose infertility" and added at the end "when performed solely to establish the underlying etiology of infertility"; A.2.a. Semen analysis-added (two specimens at least one month apart), Volume-added (amount), pH-added (acidity), Motility-added (movement) and > 50% at one hour, added "Morphology (size and shape of the sperm): According to World Health Organization criteria at least 30% of the cells should be of normal shape. According to Kruger (strict) morphology criteria which examines the shape and size of the sperm head, 14% or more

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of the sperm should have normal shaped heads." And "Note: Semen analysis values may vary according to the reference lab used." A.2.b,c & d are now A.2. h,i & j; Inserted the following: A.2.b. "Endocrine evaluation if clinically indicated. (Minimum initial hormonal evaluation should consist of measurement of serum follicle-stimulating-hormone)." A.2.c. "Antisperm antibodies" A.2.d. "Post-ejaculatory urinalysis" A.2.e. "Urine and semen culture" A.2.f. "Vasography" A.2.g. "Scrotal ultrasonography" A.2.i. (now Sperm Penetration Assay), added "NOTE: Covered if used as a diagnostic technique for male infertility; if used as part of IVF, this assay would be covered only if member has benefits for artificial means of conception." B. Basic Treatments reformatted into 1. Infertility Drugs 2. Therapeutic Operative Procedures for the Female and 3. Therapeutic Operative Procedures for the Male: B.1. Infertility Drugs: a. Dopamine agonists (bromocriptine and cabergoline) b. Clomiphene citrate c. Gonadotropins: i. Human chorionic gonadotropin (hCG); ii. Choriogonadotropin alfa (a biosynthetic [recombinant DNA-derived] chorionic gonadotropin; iii. Human menopausal gonadotropins (hMG) (menotropins). Failure of clomiphene citrate and other techniques of inducing ovulation should be documented. iv. Urofollitropin (human follicle stimulating hormone-FSH; v. Recombinant (biosynthetic) FSH (follitropin alpha, follitropin beta); vi. Recombinant (biosynthetic) luteinizing hormone (lutropin alfa). B.2. Therapeutic Operative Procedures for the female (Note: Benefits for reversal of sterilization are not covered unless otherwise stated by the member certificate.): a. Therapeutic operative laparoscopy (e.g., treatment of endometriosis or periaidnexal adhesions); b. Open surgical treatment in women with moderate or severe endometriosis; c. Salpingo-ovariolysis; d. Terminal salpingostomy; e. Fimbrioplasty; f. Uterotubal implantation; g. Tubocornual anastomosis; h. Balloon tuboplasty; i. Ovarian wedge resection. B.3. Therapeutic Operative Procedures for the Male (Note: Benefits for reversal of sterilization are not covered unless otherwise stated by the member certificate.): a. Varicocele; b. Transurethral resection of ejaculatory duct; c. Orchiopexy; d. Surgical correction of epididymal blockage for men with obstructive azoospermia: i. Epidymectomy; ii. Epididymovasostomy; iii. excision of epididymal tumors and cysts; iv. Epididymostomy. C. Assisted Reproductive Technology: 3.d. added the following "percutaneous epididymal sperm aspiration (PESA), testicular sperm aspiration (TESA) or testicular sperm extraction (TESE) may be used in conjunction with IVF." deleted C.3.e. "Human Growth Hormone administration in connection with assisted reproductive technologies".

Under When not Covered section: A. clarified voluntary sterilization (vasectomy or tubal ligation/occlusion); B. Diagnostic tests, added B.f. "Tests of sperm DNA integrity, including, but not limited to, sperm chromatin assays and sperm DNA fragmentation assays; added B.g. Hemizona assay; added B.h. Hypo-osmotic swelling test. C. Basic Treatments, added C.2.d. Administration of growth hormone, C.2.e. Administration of letrozole C.2.f. Administration of anastrozole.

Medical Term Definitions and Reference sources added.

Notification given 10/8/07. Effective date 12/17/07. (pmo)

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| 12/17/07 | Under Billing/Coding section, added codes 76948, Q0015, 89322 and 89331. Codes 89322 and 89331 will be effective 1/1/08. Removed code S4036 which was deleted in 2006. Reference Sources added. (pmo) |
| 1/05/09 | Under Billing/Coding section removed CPT codes 0058T and 0059T - codes will be deleted as of 12/31/08. (pmo) |
| 3/16/10 | Specialty Matched Consultant Advisory Panel review 2/11/2010. Description section revised. No change to policy intent. Changed references to "Certificate" to "Benefit Booklet" or "Benefit Plan" as appropriate. Changed wording in the "When Covered" section, from "C. Assisted Reproductive Technology" to " <u>Artificial Means of Conception</u> ". In the "When Not Covered Section", changed E. from "Assisted reproductive technologies" to " <u>In Vitro Fertilization (IVF)</u> ". Removed deleted code 0087T. Added 89398. References added. (btw) |

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- 6/22/10 Policy Number(s) removed (amw)
- 1/04/11 CPT codes 0058T and 0059T reinstated. Added to Billing/Coding section. (adn)
- 3/29/11 No change to coverage/non-coverage criteria. Policy status changed to “Active policy, no longer scheduled for routine literature review.” (adn)
- 11/26/13 Policy returned to active review. Senior Medical Director review. AIDS removed from list of contraindications to AI in both females and males. Statement related to dollar limits removed. Added the statements that “Indications for AI related to male infertility are eligible for 3 cycles of AI per pregnancy attempt” and “Members meeting the medically necessary criteria related to female infertility listed above are eligible for 3 cycles of AI using sperm from the male partner per pregnancy attempt”. (sk)
- 10/14/14 Specialty Matched Consultant Advisory Panel review 9/30/14. Senior Medical Director review. First sentence of service description reworded for better clarity. Cervical mucus testing and sperm penetration assay removed from list of diagnostic tests. Endometrial biopsies and postcoital testing removed from the list of procedures that must be performed prior to AI. References updated and added. (sk)
- 12/30/14 Added new codes 0357T and 89337 effective 1/1/2015. Deleted code 0059T effective 12/31/2014. (sk)
- 7/1/15 Reference added. (sk)
- 10/30/15 Reference added. Specialty Matched Consultant Advisory Panel review 9/30/15. (sk)
- 11/22/16 Specialty Matched Consultant Advisory Panel review 9/28/2016. No change to policy statement or guidelines. (an)
- 1/27/17 Minor changes to Description section. No change to policy statement. (an)
- 10/27/17 Added codes 89290 and 89291 to Billing/Coding section. Specialty Matched Consultant Advisory Panel review 9/27/2017. No change to policy statement. (an)
- 10/12/18 Reference added. Specialty Matched Consultant Advisory Panel review 10/3/18. No change to policy statement. (an)
- 10/1/19 Specialty Matched Consultant Advisory Panel review 9/18/2019. No change to policy statement. (eel)
- 12/31/19 Coding section updated by removing deleted code 0357T. (eel)
- 4/14/20 Description section updated. When covered section updated to allow “Saline infusion sonohysterography (SIS or SHG)”, “Anti-Mullerian hormone (AMH)”, and endocrine evaluation to include “luteinizing hormone (LH), testosterone, and prolactin.” Added “**Please check the member’s benefit booklet for information regarding pharmacy benefit coverage for infertility treatment, which may be separate from medical infertility coverage.**” to When covered section. “Non-steroidal aromatase inhibitor for medical conditions associated with infertility i.e. polycystic ovarian disease.” Added to basic treatments under When covered section. Reference values for semen analysis removed from When covered section. When covered section clarified Artificial Means of Conception with “**Artificial insemination (AI), Intrauterine Insemination (IUI), and/or In Vitro fertilization (IVF).**” Added “thawing of cryopreserved embryos” and “Assisted hatching” to Artificial Menas of Conception in When

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covered section. Mechanically assisted fertilization (MAF) clarified to Intracytoplasmic Sperm Injection (ICSI) in When covered section. “Current American Society for Reproductive Medicine (ASRM) and Society for Assisted Reproductive Technology (SART) guidelines regarding limits to the number of embryos transferred should be followed. (see Policy Guidelines)” added to When covered section. Removed “Administration of letrozole” from When not covered section. When not covered section relating to **In Vitro Fertilization (IVF) and services associated with IVF** rewritten to include “Charges related to cryopreservation of reproductive tissue, including sperm and oocytes, are not covered under standard medical benefits or under infertility benefits unless otherwise stated in the member’s benefit booklet.” Policy Guidelines section updated. References added. Coding section updated. Medical Director review 2/2020. Notification given 2/11/2020 for effective date 4/14/2020. (eel)

- 10/13/20 Specialty Matched Consultant Advisory Panel review 9/29/2020. References updated. No change to policy statement. (eel)
- 12/31/20 Coding section updated by removing deleted code 0058T effective 1/1/2021. (bb)
- 7/1/21 Added codes 0664T-0670T to Billing/Coding section effective 7/1/2021. Medical Director review 6/2021. Added investigational statement F. under “When Covered” section: “Uterine transplant is considered investigational as a treatment of infertility.” Notification given 7/1/21 for effective date 9/7/21. (lpr)
- 10/19/21 Description updated to reflect changes to infertility definition - Infertility is a disease characterized by the failure to establish a clinical pregnancy after 12 months of regular, unprotected sexual intercourse or therapeutic donor insemination for an individual under age 35 or after 6 months for an individual aged 35 or older. References updated. Specialty Matched Consultant Advisory Panel review 9/2021. Medical Director review 9/2021. (tt/jd)
- 5/3/22 Codes 0664T-0670T from Billing/Coding section and investigational statement F. under “When not Covered” section: “Uterine transplant is considered investigational as a treatment of infertility” inadvertently removed during 10/19/21 update. Codes and statement re-added. (tt)
- 10/18/22 References updated. Specialty Matched Consultant Advisory Panel review 9/2022. Medical Director review 9/2022. No change to policy statement. (tt)
- 9/29/23 References updated. Specialty Matched Consultant Advisory Panel review 9/2023. Medical Director review 9/2023. No change to policy statement. (tt)
- 4/1/24 Description updated to define infertility as defined by American Society for Reproductive Medicine (ASRM). References updated. Specialty Matched Consultant Advisory Panel review 3/2024. Medical Director review 3/2024. No change to policy statement. (tt)

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