

Corporate Medical Policy

Infertility Diagnosis and Treatment

File Name: infertility_diagnosis_and_treatment
Origination: 1/2000
Last CAP Review: 2/2010
Next CAP Review: Not applicable
Last Review: 3/2011

Active policy, no longer scheduled for routine literature review.

Description of Procedure or Service

Infertility is the inability of a heterosexual couple to conceive a child within a 12 month period of unprotected coitus (sexual intercourse). 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 a woman's ovaries, combining them with sperm in the laboratory, and returning them to the woman's body or donating them to another woman. They do NOT include treatments in which only sperm are handled (i.e., intrauterine—or artificial—insemination) or procedures in which a woman 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 woman's ovaries, combining them with sperm in the laboratory and, if fertilized, replacing the resulting embryo into the woman's uterus. Various types of transfers may occur to replace the fertilized egg back into the female.

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 be performed as part of an IVF procedure. Such procedures include Zona "drilling" or (PZD) where the zona pellucida of the oocyte is mechanically interrupted so as to assist sperm entry, and 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, 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

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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.

*****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

Active policy, no longer scheduled for routine literature review.

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 covered, some benefit plans impose dollar limits on these services.

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], 17 Hydroxyprogesterone, total and fractionated testosterone, estradiol measurements) if clinically indicated.
 - c) Cervical mucus testing (post coital test or PCT)
 - d) LH (lutening hormone), prolactin, progesterone, and/or FSH (Follicle stimulation hormone) levels
 - e) Pelvic ultrasonography
 - f) Hysterosalpingography (HSG)
 - g) Laparoscopy

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- h) Hysteroscopy
 - i) Hormonal antisperm antibodies (should not be performed as a routine screen)
 - j) Fasting insulin
 - k) Serum Chlamydia IgG
- 2) Diagnostic tests for the **Male**:
- a) Semen analysis (two specimens at least one month apart). Normal semen analysis values include:
 - Volume (amount): 2-6 ml
 - pH (acidity): 7.2-7.8
 - Count: 20-250 million/ml
 - Motility (movement): >50% at one hour
 - Live/dead 60%
 - 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 of the sperm should have normal shaped heads.

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)
- c) Antisperm antibodies
- d) Post-ejaculatory urinalysis
- e) Urine and semen culture
- f) Vasography
- g) Scrotal ultrasonography
- h) Testicular biopsy
- i) Sperm Penetration Assay (SPA) is a laboratory test used to determine the ability of a man's sperm to penetrate a hamster egg. It is thought that this test provides evidence of the sperm's fertilizing ability. The test uses hamster eggs that have been stripped of the Zona Pellucida which is the outer membrane surrounding the oocyte that maintains species specificity for fertilization. Removal of the zona pellucida from hamster ova permits their use as a model for sperm oocyte interaction. The test is performed by incubating a number of zona-free hamster eggs with human sperm for several hours. According to the percentage of ova penetrated, the semen sample is rated as being in a potentially "fertile" or "infertile" range. A sperm penetration assay may be considered medically necessary as a technique to determine whether intracytoplasmic sperm injection should be offered as part of an in vitro fertilization technique. NOTE: Covered if used as a diagnostic technique for male infertility; if used as part of IVF, this assay would be covered only if the member has benefits for artificial means of conception.
- j) 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.

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- 1) Infertility drugs:
 - 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 annovulation secondary to polycystic ovarian disease (PCOD).
- 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)
 - 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
- 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 men with obstructive azoospermia:
 - Epidymectomy
 - 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 them 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
 - endometrial biopsies
 - postcoital testing

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- 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

Members meeting the medically necessary criteria related to female infertility listed above are eligible for 4 cycles of AI using sperm from the male partner per pregnancy attempt.

- 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
 - low sperm count (<20 million/ml)
 - antisperm antibodies
 - oligoasthenospermia
 - retrograde ejaculation
 - seminal fluid liquefaction defect
 - teratospermia
 - aspermia
- c) Indications for AI related to male infertility are eligible for 4 cycles of AI per pregnancy attempt.
- 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
- 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) Mechanically assisted fertilization (MAF) may be performed as part of an IVF procedure. Such procedures include Zona "drilling" or (PZD) where the zona pellucida of the oocyte is mechanically interrupted so as to assist sperm entry, and intracytoplasmic sperm injection (ICSI).
- d) Microscopic epididymal sperm aspiration (MESA), percutaneous epididymal sperm aspiration

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(PESA), testicular sperm aspiration (TESA) or testicular sperm extraction (TESE) may be used in conjunction with IVF.

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
 - 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 letrozole
 - f) Administration of anastrozole
- D) **Artificial Insemination (AI)**
- 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) severe endometriosis (Stage IV)
 - d) pregnancy
 - e) unexplained uterine bleeding
 - f) presence of venereal disease
 - g) AIDS
 - 2) Contraindications for AI in Males include, but are not limited to the following:
 - a) infection such as prostatitis or epididymitis
 - b) presence of venereal disease
 - c) AIDS
 - 3) When contraindicated as above, AI would be considered to be not medically necessary and therefore non-covered.
- E) **In Vitro Fertilization (IVF)** except as specifically included in the member's benefit plan.
- 1) Services performed as part of IVF can include
 - a) stimulation of ovulation
 - b) monitoring of ovulation stimulation
 - c) oocyte retrieval
 - d) laboratory studies
 - e) embryo assessment and transfer
 - f) luteal phase support.

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- 2) All services which are received as part of an IVF procedure are considered under the same benefit as the IVF procedure. This can include:
 - a) drugs
 - b) lab
 - c) pathology
 - d) surgical procedures
 - e) radiology (ultrasound)
- 3) Mechanically assisted fertilization (MAF) may be performed as part of an IVF procedure. Such procedures include Zona "drilling" or (PZD) where the zona pellucida of the oocyte is mechanically interrupted so as to assist sperm entry, and intracytoplasmic sperm injection (ICSI).
- 4) Modifications of the IVF procedure 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) 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, 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.
- 5) Charges related to cryopreservation, thawing and storage of embryos are not covered under standard medical benefits or under infertility benefits unless otherwise stated in the member's benefit booklet.
- 6) Charges related to 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 member's benefit booklet.
- 7) Sperm washing is not eligible for coverage when used in preparation for a noncovered procedure.
- 8) 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.
- 9) The following techniques related to IVF are considered investigational and are not covered:
 - a) Assisted hatching,
 - b) Co-culture of embryos,
 - c) Cryopreservation of ovarian tissue or oocytes; cryopreservation of testicular tissue in prepubertal boys; storage and thawing of ovarian tissue, oocytes or testicular tissue,
 - d) Sperm selection with hyaluronan for intracytoplasmic sperm injection (ICSI).

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

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: 54900, 54901, 55300, 55400, 55870, 58321, 58322, 58323, 58340, 58345, 58350, 58660, 58672, 58673, 58740, 58750, 58752, 58760, 58770, 58970, 58974, 58976, 76948, 89250, 89251,

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89253, 89254, 89255, 89257, 89258, 89259, 89260, 89261, 89264, 89268, 89272, 89280, 89281, 89300, 89321, 89322, 89325, 89329, 89330, 89331, 89335, 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, 0058T, 0059T

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.

When covered, some benefit plans impose dollar limits on these services.

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

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

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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. Retrieved on July 12, 2007 from http://www.asrm.org/Patients/FactSheets/Testing_Male-Fact.pdf

American Society for Reproductive Medicine (ASRM). Medications for Inducing Ovulation - A Guide for Patients. Retrieved on July 12, 2007 from http://www.asrm.org/Patients/patientbooklets/ovulation_drugs.pdf

American Society for Reproductive Medicine (ASRM). Infertility: An Overview - A Guide for Patients. Retrieved on July 12, 2007 from http://www.asrm.org/Patients/patientbooklets/infertility_overview.pdf

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

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

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- 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, 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

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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 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 periadnexal 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

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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)

- 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 "Artificial Means of Conception". In the "When Not Covered Section", changed E. from "Assisted reproductive technologies" to "In Vitro Fertilization (IVF)". Removed deleted code 0087T. Added 89398. References added. (btw)
- 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)

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