Clinical Policy: Assisted Reproductive Technology

Reference Number: CP.MP.55 Coding Implications
Last Review Date: 02/19 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Diagnostic infertility services to determine the cause of infertility and treatment is covered only when specific coverage is provided under the terms of a member's benefit plan. All coverage is subject to the terms and conditions of the plan. The following discussion is applicable only to members whose Plan covers infertility services.

Infertility is defined as the condition of an individual who is unable to conceive or produce conception during a period of 1 year if the female is age 35 or younger or during a period of 6 months if the female is over the age of 35. For purposes of meeting the criteria for infertility in this section, if a person conceives but is unable to carry that pregnancy to live birth, the period of time she attempted to conceive prior to achieving that pregnancy shall be included in the calculation of the 1 year or 6 month period, as applicable.

Assisted Reproductive Technologies (ART) encompass a variety of clinical treatments and laboratory procedures which include the handling of human oocytes, sperm or embryos, with the intent of establishing pregnancy.

The following services are considered medically necessary when performed solely for the treatment of infertility in an individual in whom fertility would naturally be expected and when meeting the accompanying ART criteria in the Policy/Criteria section.

Females:

1. FDA approved medications (including specialty injectables): clomiphene, aromatase inhibitors, estrogens, corticosteroids, progestins, metformin, and prolactin inhibitors, gonadotropin releasing hormone (GnRH) agonists, gonadotropins, and GnRH antagonists.
2. Infertility surgery: surgical laparoscopy; ovarian wedge resection or ovarian drilling; removal of myomas, uterine septa, cysts, ovarian tumors, and polyps; open or laparoscopic resection, vaporization, or fulguration of endometriosis implants; adhesiolysis; laparoscopic cystectomy; hysteroscopic adhesiolysis; removal of fallopian tubes; hysteroscopic or fluoroscopic tubal cannulation (fimbrioplasty); selective salpingography plus tubal catheterization, or transcervical balloon tuboplasty, and tubal anastomosis.
3. Sperm washing if male partner has HIV and female partner does not.
4. Artificial insemination (AI); intrauterine insemination (IUI) and intracervical insemination.
5. In vitro fertilization with embryo placement (IVF-EP).
6. Gamete intrafallopian transfer (GIFT).
7. Zygote intrafallopian transfer (ZIFT).
8. Intracytoplasmic sperm injection (ICSI) with or without assisted hatching.

9. Short duration (up to 1 year) cryopreservation of embryo(s) and mature oocytes.

Males:

1. FDA approved medications, including specialty injectables, clomiphene, corticosteroids, antiestrogens, prolactin inhibitors, cabergoline, thyroid hormone replacement, androgens, aromatase inhibitors (testolactone), GnRH, and gonadotropins.
2. Infertility surgery: varicocelectomy (spermatic vein ligation), transurethral resection of the ejaculatory ducts (TURED), orchiopexy, surgical reconstruction or repair of the vas deferens or epididymis surgery such as vasovasostomy, epididymovasostomy, epididymectomy.
3. Testicular sperm extraction (TESE), micro-TESE, and epididymal sperm extraction.
4. Sperm washing if male partner has HIV and female partner does not.
5. Impotence treatments.
6. Short duration (up to 1 year) cryopreservation of sperm.

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that ART is **medically necessary** for the following indications when the basic and treatment-specific criteria in **A** and **B** are met.

Authorized infertility benefits are covered based on the members benefit plan contract. Refer to benefit guidelines for coverage limitations.

A. Basic Criteria- meets all of the following:

1. ART for females is performed by a physician board-certified or board eligible in reproductive endocrinology and for males is a board-certified or board eligible urologist;
2. Fertility is naturally expected of the member and there is documentation of an inability to conceive during a period of 12 menstrual cycles of exposure to sperm (including IUI), or 6 cycles for women ≥ age 35;
3. For female members ≥ 40 years attempting conception using their own oocytes, demonstration of adequate ovarian reserve. This is defined as a normal clomiphene citrate challenge test (CCCT) in the past 6 months:
   a. Cycle days 3 and/or 10 FSH levels < 15 mIU/ml and the day 3 estradiol level < 80pg/mL;
4. Infertility is unrelated to voluntary sterilization or failed reversal of voluntary sterilization of either partner. Evidence of such includes:
   a. In the case of vasectomy reversal – there must be two recent normal semen analyses within the past 3 months (sperm count > 20 million/ml; motility > 50% and normal morphology – > 14% normal forms by Krüger classification or > 30% normal forms by WHO criteria);
   b. In the case of previous tubal ligation with reanastamosis, documentation by hysterosalpingogram of unilateral or bilateral tubal patency.

B. Treatment-Specific Criteria:

1. Artificial Insemination/IUI- meets all of the following:

a. Unilateral or bilateral tubal patency, and one of the following:
   i. Mild male factor infertility;
   ii. Cervical factors;
   iii. Unexplained infertility;
   iv. Sperm antibodies;
   v. Mild endometriosis;
   vi. Unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm;
   vii. Couples in which the male partner is HIV positive and undergoing sperm washing.

2. IVF
   a. Inadequate number of frozen embryos available for transfer: < 3 for women age <35 years, or < 4 for women age ≥ 35 years; and one of the following:
      i. Barrier to fertilization, one of the following:
         a) Bilateral fallopian tube absence or obstruction due to prior tubal disease (not voluntary sterilization);
         b) Severe endometriosis which failed medical and surgical therapy;
         c) Severe male factor infertility that has failed conservative treatments (sperm concentration <10 million/mL and/or normal morphology of ≤ 1% by Krüger/≤ 5% by WHO criteria);
      ii. IUI failure, one of the following:
         a) For women ≤ 39 years old, failure of 3 cycles of IUI with gonadotropin stimulation required;
         b) For women age 40-42, failure of 1-2 cycles of IUI with gonadotropin stimulation;
      iii. High response to a medicated cycle intended for IUI, as defined by both of the following, and the cycle in question will be converted to IVF:
         a) Estradiol level of >1000 pg/ml;
         b) Production of at least 3 follicles ≥ 16mm or 4-8 follicles > 14 mm in diameter.

3. Frozen Embryo Transfers (FET)*- meets both of the following:
   a. Frozen embryos must be used prior to authorization of additional IVF cycles in one of the following circumstances:
      i. Women < 35 with at least 3 embryos available for transfer;
      ii. Women ≥ 35 with at least 4 embryos available for transfer;

      *If member continues to qualify for infertility, FET with less than this number of embryos available for transfer is considered medically necessary.

4. GIFT/ZIFT- meets all of the following:
   a. Member has at least one patent fallopian tube;
   b. IUI failure - one of the following:

i. For women ≤ 39 years old, failure of 3 cycles of IUI with gonadotropin stimulation required;
ii. For women age 40-42, failure of 1-2 cycles of IUI with gonadotropin stimulation;

c. Justification that GIFT/ZIFT is preferable to standard IVF must be provided.

5. ICSI- meets one of the following:
   a. Less than 2 million motile spermatozoa per ejaculate;
   b. Anti-spermatozoan antibodies shown to be contributing to infertility;
   c. Prior or repeated fertilization failure with standard IVF protocols (< 50% fertilization);
   d. Washed sperm limited in number and quality;
   e. Obstruction of the male reproductive tract not amenable to repair necessitating MESA or TESE (does not include obstruction due to voluntary sterilization);
   f. Abnormal morphology (≤ 1% normal forms by Kruger; ≤ 5% normal forms by WHO);
   g. Specific spermatozoan defects impairing spermatozoa-oocyte interaction;
   h. Selected types of female infertility, such as morphologic anomalies of oocytes and anomalies of the zona pellucida;
   i. Fertilization of previously frozen oocytes;
   j. HIV discordant couples.

6. Assisted Hatching- meets both of the following:
   a. Women ≥ 38 years old;
   b. ≥ 2 failed IVF cycles with poor quality embryos.

7. Donor egg cycle- female meets one of the following:
   a. Congenital or surgical absence of ovaries;
   b. Premature ovarian failure (menopause before age 40);
   c. Premature diminished ovarian reserve (CCCT day 3 or 10 FSH ≥ 15 in women ≤ 35);
   d. Ovarian failure following chemotherapy or radiation therapy;
   e. Previously failed IVF in a woman age ≥40;
   f. Gonadal dysgenesis including Turner Syndrome;
   g. High risk of transmitting genetic disorder from female.

8. TESE, micro-TESE and epididymal sperm extraction – applies only if the male partner is a covered member. Meets the following:
   a. Male with obstructive or non-obstructive azoospermia.

9. Donor sperm, meets one of the following:
   a. Male partner has bilateral congenital absence of the vas deferens (BCAVD);
   b. Male partner has obstructive azoospermia;
   c. Female without a male partner;
   d. High risk of transmitting an infectious disease from male partner (such as HIV);
   e. High risk of transmitting a genetic disorder in the male partner to the offspring;

f. Male partner has non-obstructive azoospermia confirmed through MESA/TESA;
g. Couples who are incompatible for red cell antigens (eg, D, Kell) associated with hemolytic disease of the newborn and with a history of a severely affected infant;
h. Male partner has had previous radiation or chemotherapy resulting in abnormal semen analysis;
i. Male partner has had two abnormal semen analyses (by Krüger or WHO classification) at least 30 days apart;
j. Failure of at least 3 cycles IVF or ICSI.

10. Cryopreservation of sperm:
    a. Short term storage of sperm during the initial year (up to 90 days approved at a time beyond the initial year, after last approved infertility treatment) for a male member already in active infertility treatment who has undergone an approved MESA or TESE procedure.

    Note: see CP.MP.130 Fertility Preservation if undergoing medical treatment that will result in infertility.

11. Cryopreservation of embryos:
    a. Short term storage of embryos during the initial year (up to 90 days approved at a time beyond the initial year, after last approved infertility treatment) if:
        i. Embryos could not be transferred due to high risk of multiple gestation, or
        ii. Embryos could not be transferred due to a potential adverse impact on maternal health (i.e., severe hyper-stimulation syndrome, etc.), or
        iii. Altered endocrine and cardiovascular profile at time of embryo transfer (elevated progesterone, hypertension, etc.), or
        iv. Fewer embryos are available at one time than are planned to be transferred (low responder), or
        v. Uterine conditions are not ideal for implantation and an approved infertility treatment is planned to increase likelihood of implantation, or
        vi. Implantation should be postponed to allow for testing and treatment of Zika virus in areas affected.

    Note: see CP.MP.130 Fertility Preservation if undergoing medical treatment that will result in infertility.

12. Cryopreservation of mature oocytes:
    a. Short-term storage during the initial year (up to 90 days approved at a time beyond the initial year, after the last approved infertility treatment) if meeting one of the indications above for cryopreservation of embryos, but is unable, or unwilling for ethical reasons, to cryopreserve embryos.

    Note: see CP.MP.130 Fertility Preservation if undergoing medical treatment that will result in infertility.

II. It is the policy of health plans affiliated with Centene Corporation® that ART is **not medically necessary** for the following indications:

- **A.** Any experimental infertility procedure, until the procedure becomes recognized as non-experimental;
- **B.** Surrogacy;
- **C.** Reversal of voluntary sterilization;
- **D.** Commercially available over-the-counter home test kits, including but not limited to ovulation prediction and pregnancy test kits;
- **E.** Infertility treatment needed as a result of prior voluntary sterilization or unsuccessful sterilization reversal procedure;
- **F.** A partner's infertility services when a partner in not a member;
- **G.** A member who is medically infertile due to natural aging (>50 years) or for women who are menopausal;
- **H.** Gender selection, chromosomal studies of donor sperm or egg.

Background

IVF-EP

In vitro fertilization involves fertilization of an egg with sperm in a dish in a laboratory, rather than inside a women's body. The resulting embryo is placed into the uterus later. One cycle of IVF-EP includes:

- Ovulation stimulation and monitoring- the woman starts ovulation drugs to stimulate the ovaries to produce multiple eggs. Ovulation drugs are given over period of 8-14 days. During this time the woman is monitored for follicular development with frequent ultrasounds and blood tests. The eggs are retrieved before ovulation occurs.
- Oocyte (egg) retrieval is usually accomplished by ultrasound guided aspiration performed in the office.
- Sperm preparation and capacitation- sperm are placed together with eggs and stored in an incubator.
- Embryo transfer- including frozen embryo transfer (FET) involves embryo transfer to the uterus any time between one to six days after egg retrieval, or after cryopreservation in FET.

GIFT

A laparoscope is used to aspirate one or more mature oocytes from the ovaries. Oocytes are then mixed with sperm and transferred to the fallopian tube via a catheter. GIFT, although more invasive than IVF, may be an appropriate choice in patients who, for religious or personal reasons, do not wish to have embryos in the laboratory. It is also appropriate for those who have failed donor insemination or require laparoscopy for other reasons. The success rate is similar to those with IVF.

ZIFT

This procedure involves placement of fertilized eggs (zygotes) or embryos into the fallopian tube. It is analogous to GIFT in that laparoscopy is needed to place the zygotes in the fallopian tubes. Whereas overall success rates are similar to IVF, ZIFT may offer some advantages to patients with difficult trans-cervical embryo transfer, uterine abnormalities (such as those caused by DES exposure), or recurrent failure with standard IVF.

ICSI
Intra-cytoplasmic sperm injection involves injecting the sperm into the egg in a dish in the laboratory to fertilize it, rather than letting sperm penetrate the egg naturally. Embryos are then transferred to the uterus as in usual IVF.

ICSI should be available to patients with previously failed fertilization who demonstrate either abnormal or normal semen profiles and to patients with spermatozoa concentration and motility too low to expect any success with conventional IVF. Patients should be counseled carefully regarding the outcomes and potential risks of ICSI. If there is a risk of adverse neonatal outcome associated with ICSI, it appears to be small.

Assisted Hatching:
"Hatching" is a natural process in which an embryo expands and eventually breaks through the zona pellucida in order to implant on the surface of the endometrium (the lining of the uterus). "Assisted hatching" refers to a laboratory procedure whereby the zona pellucida around the day 3 embryo is mechanically or chemically opened to assist the embryo in hatching from the zona about three days later. The procedure may improve the percentage of embryos that implant in selected cases with poor prognosis (eg, 2 failed IVF cycles and poor embryo quality and older women, but its use is still controversial).

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Infertility Services Requiring Prior Authorization if a covered benefit

CPT® Codes	CPT Code Descriptions
58321	Artificial insemination; intra-cervical insemination (ICI)
58322	Artificial insemination; intra-uterine insemination (IUI)
58323	Sperm washing for artificial insemination
58970	Follicle puncture for oocyte retrieval, any method (IVF)
58974	Embryo transfer, intrauterine (IVF-ET)
58976	Gamete, zygote, or embryo intrafallopian tube transfer; any method (GIFT)
89250	Culture of oocyte(s)/embryo(s), less than 4 days;
89251	Culture of oocyte(s)/embryo(s), less than 4 days; with co-culture of oocyte(s)/ embryo(s)
89253	Assisted embryo hatching, microtechniques (any method)
89254	Oocyte identification from follicular fluid
89255	Preparation of embryo for transfer (any method)

CPT® Codes	CPT Code Descriptions
89257	Sperm identification from aspiration (other than seminal fluid)
89258	Cryopreservation; embryo(s)
89259	Cryopreservation; sperm
89260	Sperm isolation; simple prep (eg, sperm wash and swim-up) for insemination or diagnosis with semen analysis
89261	Sperm isolation; complex prep (eg, Percoll gradient, albumin gradient for insemination or diagnosis with semen analysis
89264	Sperm identification from testis tissue, fresh or cryopreserved
89268	Insemination of oocytes
89272	Extended culture of oocyte(s)/embryo(s), 4-7 days
89280	Assisted oocyte fertilization, microtechnique, less than or equal to 10 oocytes
89281	Assisted oocyte fertilization, microtechniques; greater than 10 oocytes.
89290	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); less than or equal to 5 embryos
89291	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); greater than 5 embryos
89337	Cryopreservation, mature oocyte(s)
89352	Thawing of cryopreserved; embryo(s)
89353	Thawing of cryopreserved; sperm/semen, each aliquot
89356	Thawing of cryopreserved; oocytes, each aliquot

HCPCS Codes	HCPCS Code Descriptions
S4011	In vitro fertilization; including but not limited to identification and incubation of mature oocytes, fertilization with sperm, incubation of embryo(s), and subsequent visualization for determination
S4013	Complete cycle, gamete intrafallopian transfer (GIFT), case rate
S4014	Complete cycle, zygote intrafallopian transfer (ZIFT), case rate
S4015	Complete in vitro fertilization cycle, not otherwise specified, case rate
S4016	Frozen in vitro fertilization cycle, case rate
S4017	Incomplete cycle, treatment canceled prior to stimulation, case rate
S4018	Frozen embryo transfer procedure canceled before transfer, case rate
S4020	In vitro fertilization procedure canceled before aspiration, case rate
S4021	In vitro fertilization procedure canceled after aspiration, case rate
S4022	Assisted oocyte fertilization, case rate
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
S4028	Microsurgical epididymal sperm aspiration (MESA)
S4035	Stimulated intrauterine insemination (IUI), case rate
S4037	Cryopreserved embryo transfer, case rate

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10 Codes	ICD-10 Code Descriptions
B20	Human immunodeficiency virus (HIV) disease
E28.310	Symptomatic premature menopause
E89.40	Asymptomatic postprocedural ovarian failure
E89.41	Symptomatic postprocedural ovarian failure
N46.01	Organic azoospermia
N46.021	Azoospermia due to drug therapy
N46.022	Azoospermia due to infection
N46.023	Azoospermia due to obstruction of efferent ducts
N46.024	Azoospermia due to radiation
N46.025	Azoospermia due to systemic disease
N46.029	Azoospermia due to extratesticular causes
N46.11	Organic oligospermia
N46.121	Oligospermia due to drug therapy
N46.122	Oligospermia due to infection
N46.123	Oligospermia due to obstruction of efferent ducts
N46.124	Oligospermia due to radiation
N46.125	Oligospermia due to systemic disease
N46.129	Oligospermia due to extratesticular causes
N80.0-N80.4	Endometriosis (uterus, fallopian tube, pelvic peritoneum, rectovaginal septum and vagina)
N97.0	Female infertility associated with anovulation
N97.1	Female infertility of tubal origin
N97.2	Female infertility of uterine origin
N97.8	Female infertility of other origins
Q50.01	Congenital absence of ovary, unilateral
Q50.02	Congenital absence of ovary., bilateral
Q50.6	Other congenital malformations of fallopian tube and broad ligament
Q55.3	Atresia of vas deferens
Q96.0-Q96.8	Turner’s syndrome
Z31.0	Encounter for reversal of previous sterilization
Z31.41	Encounter for fertility testing
Z31.430	Encounter of female for testing for genetic disease carrier status for procreative management
Z31.440	Encounter of male for testing for genetic disease carrier status for procreative management
Z31.441	Encounter for testing of male partner of patient with recurrent pregnancy loss
Z31.448	Encounter for other genetic testing of male for procreative management

Reviews, Revisions, and Approvals	Date	Approval Date
Under basic criteria, clarified that men were to be treated by board-certified urologist Added IVF, Conversion from IUI to IVF and FET criteria Restructured sections to more closely resemble other Centene clinical policy Removed Authorization Protocols section	03/14	
Added TESE, micro-TESE, and epididymal sperm extraction Added "board eligible" on page 3 under requirements for treatment provided by board certified physician	04/14	05/14
Clarified criteria language to indicate number of criteria required for each procedure	11/14	
Additional language clarification to aid in conversion to Interqual Custom Content	12/14	
Combined inability to conceive for females with and without partners into one bullet point under I.B Removed FSH requirements from II.B.3 as this is covered in basic criteria	04/15	04/15
Added clomiphene and aromatase inhibitors to FDA approved medications for female infertility. IUI- added "unable to have vaginal intercourse" and male partner is HIV positive as indications, per NICE guidelines. IVF- clarified wording in 2.a. Donor egg cycle- added indications for ovarian failure post chemo/radiation, gonadal dysgenesis, and high risk of transmitting genetic disorder from female partner. Donor sperm: added following indications: obstructive azoospermia, high risk of transmitting infectious disease from male partner, female without a male partner, high risk of transmitting genetic disorder from male partner, rhesus isoimmunization and female without male partner. Took out requirement that male partner be a covered member. Added indication for cryopreservation of oocytes per ASRM guidelines. Background- added "or after cryopreservation in FET" to the last bullet in the IVF section. Added CPT codes for oocyte cryopreservation and thawing. Reviewed by specialist.	04/16	04/16
References reviewed and updated. ICD-10 codes added.	04/17	04/17
Under general female criteria 8, added cryopreservation of oocyctes, and removed requirement that member be undergoing active infertility treatment, as that is mentioned in the indication-specific criteria. Added cryopreservation of sperm to general male criteria. Added **"**sperm washing if male partner has HIV and female partner does not" to list of medically necessary services. In I.A.2., changed "member is presumably fertile" to "fertility is naturally expected of the member." In basic criteria I.A.3, clarified that demonstration of adequate ovarian reserve is necessary in women attempting conception using their own oocytes. GIFT/ZIFT: Replaced referral to IVF criteria for required number of failed IUI cycles	03/18	03/18

Reviews, Revisions, and Approvals	Date	Approval Date
with specific criteria regarding failure of IUI cycles. ICSI: added indications for selected types of female infertility, previously frozen oocytes, and HIV discordant couples. Donor Sperm: added indication after 3 cycles of failed IVF or ICSI. Sperm cryopreservation: clarified initial duration of 1 year, with option of 90 days past last fertility treatment; removed medical treatment as indication, instead referring to CP.MP.130 Fertility Preservation. Embryo cryopreservation: changed wording of cryopreservation of eggs to "cryopreservation of mature oocytes;" clarified that 90 day short-term storage is in addition to the 1 year allowed in general female criteria; removed medical treatment as indication, instead referring to CP.MP.130 Fertility Preservation. Oocyte cryopreservation: removed medical treatment as indication, instead referring to CP.MP.130 Fertility Preservation; added indication for inability to cryopreserve embryos.		
Removed from I.A.2 the statement: "Or, for females without male partners….using normal quality sperm;" as it is duplicative in this criteria point. Reworded criteria for clarity in IUI conversion to IVF section, and combined with IVF criteria. Corrected definition of severe male factor infertility in IVF section to say sperm concentration <10 million/mL instead of TMS <10 million. Clarified in donor sperm section which indications apply to the male partner. Removed redundant statement in donor egg cycle that the female has an approved ART cycle.	04/18	
References reviewed and updated. Under policy/criteria, change paragraph regarding benefit limitations of 6 cycles for any procedure to referring to benefit plan contract for coverage limitations. Under basic criteria, A.3, changed age requiring documentation of adequate ovarian reserve from ≥ 35 to ≥ 40. Under treatment specific criteria B.7.e., removed age limit of 42. Specialist reviewed.	02/19	02/19

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and

regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.