

Clinical Policy: Assisted Reproductive Technology

Reference Number: CP.MP.55

Date of Last Revision: 01/23

[Coding Implications](#)

[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 are covered only when specific coverage is provided under the terms of a member's/enrollee's benefit plan. *All coverage, including of a partner's infertility, if applicable, is subject to the terms and conditions of the plan.* The following discussion is applicable only to members/enrollees whose Plan covers infertility services.

For those with a female reproductive system, infertility is defined as the inability to conceive or produce conception during a period of one year if under the age of 35, or during a period of six months if they are 35 years or older.³⁷ 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 attempted to conceive prior to achieving that pregnancy shall be included in the calculation of the one year or six 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 and when meeting the accompanying ART criteria in the Policy/Criteria section.

Female Reproductive System:

1. For Food and Drug Administration (FDA) approved medications (including specialty injectables) such as clomiphene, aromatase inhibitors, estrogens, corticosteroids, progestins, metformin, and prolactin inhibitors, gonadotropin releasing hormone (GnRH) agonists, gonadotropins, and GnRH antagonists, see *CP.PHAR.131 Infertility and Fertility Preservation* and/or other applicable pharmacy policy;
2. Infertility surgery: surgical laparoscopy; 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 partner with male reproductive system has HIV and partner with female reproductive system does not;
4. Intrauterine insemination (IUI) and intracervical insemination (ICI);
5. In vitro fertilization with embryo transfer (IVF-ET);
6. Gamete intrafallopian transfer (GIFT);
7. Zygote intrafallopian transfer (ZIFT);
8. Intracytoplasmic sperm injection (ICSI);

CLINICAL POLICY

Assisted Reproductive Technology

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

Male Reproductive System:

1. For FDA approved medications (including specialty injectables) such as corticosteroids, antiestrogens, prolactin inhibitors, cabergoline, thyroid hormone replacement, androgens, aromatase inhibitors (testolactone), GnRH, and gonadotropins, see CP.PHAR.131 Infertility and Fertility Preservation and/or other applicable pharmacy policy;
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 partner with male reproductive system has HIV and partner with female reproductive system does not;
5. Impotence treatments;
6. Short duration (up to one year) cryopreservation of sperm.

Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation[®] that Assisted Reproductive Technology (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/enrollees benefit plan contract. Refer to benefit guidelines for coverage limitations.

A. Basic Criteria- meets all of the following:

1. ART is performed by a physician board-certified or board eligible in reproductive endocrinology for those with a female reproductive system and by a board-certified or board eligible urologist or reproductive endocrinologist for those with a male reproductive system;
2. There is no untreatable anatomic cause of infertility and modifiable causes of infertility not addressed within this policy have been considered and modified if possible;
3. There is documentation of an inability to conceive during a period of 12 months of cycles exposed to sperm (including intrauterine insemination (IUI)), or six months for those with female reproductive systems \geq age 35;
4. For those with female reproductive systems \geq age 40 attempting conception using their own oocytes, documentation that the treating provider has evaluated age, infertility risk factors, measure of ovarian reserve, prior treatment and response, and considers use of the member/enrollee's own oocytes a viable strategy for attempting conception;
5. 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 three 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 reanastomosis, documentation by hysterosalpingogram of unilateral or bilateral tubal patency.

B. Treatment-Specific Criteria:

1. Artificial Insemination (intracervical insemination (ICI)/intrauterine insemination (IUI))- meets all of the following:

- a. Unilateral or bilateral tubal patency, and one of the following:
 - i. Mild male reproductive system factor infertility;
 - ii. Cervical factors;
 - iii. Unexplained infertility;
 - iv. Sperm antibodies;
 - v. Endometriosis;
 - vi. Utilization of cryopreserved sperm obtained for the purpose of fertility preservation before commencing non-elective medical or surgical treatment likely to cause infertility;
 - vii. One of the following factors, which don't require treatment by a board-certified or -eligible reproductive endocrinologist or inability to conceive over six to 12 months as described in I.A.1 and I.A.3:
 - 1) Unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem and are using partner or donor sperm;
 - 2) Couples in which the partner with a male reproductive system is HIV positive and undergoing sperm washing;
 - 3) Member/enrollees with a female reproductive system and without a partner with a male reproductive system who are using donor sperm.

2. In Vitro Fertilization with Embryo Transfer (IVF-ET)

- a. Inadequate number of frozen embryos available for transfer*: < 3 for those with a female reproductive system age < 35 years, or < 4 for those with a female reproductive system 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) Endometriosis-associated infertility which failed endometriosis treatment interventions directed by a physician;
 - c) Severe male reproductive system infertility that has failed conservative treatments (sperm concentration < 10 million/mL and/or normal morphology of ≤ 1% by Krüger/≤ 5% by WHO criteria);
 - d) Prior IVF cycle that resulted in failed or poor fertilization of eggs;
 - ii. Unexplained infertility, one of the following:
 - a) ≥ 38 years of age with a female reproductive system;
 - b) For those with a female reproductive system < age 38, failure of at least three cycles of IUI with oral agents (i.e., clomiphene or letrozole);

CLINICAL POLICY
Assisted Reproductive Technology

- 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 three follicles \geq 16mm or four to eight follicles > 14 mm in diameter;
- iv. Utilization of cryopreserved sperm and an oocyte or embryo(s) obtained for the purpose of fertility preservation before commencing non-elective medical or surgical treatment likely to cause infertility.

***Note:** Refer to Table 1 below for guidance on number of embryos to transfer per attempt at conception.

Table 1. American Society for Reproductive Medicine (ASRM) limits for quantity of embryos to transfer.⁹

Prognosis	Age (years)			
	< 35	35 to 37	38 to 40	41 to 42
Cleavage stage embryos				
Euploid	1	1	1	1
Other favorable	1	1	\leq 3	\leq 4
Embryos not Euploid or Favorable	\leq 2	\leq 3	\leq 4	\leq 5
Blastocysts				
Euploid	1	1	1	1
Other favorable	1	1	\leq 2	\leq 3
Embryos not Euploid or Favorable	\leq 2	\leq 2	\leq 3	\leq 3

- 3. Frozen Embryo Transfers (FET)- meets both of the following:
 - a. Number of embryos to transfer per attempt at conception meets the requirements in Table 1 above;
 - b. Frozen embryos must be used prior to authorization of additional IVF cycles in one of the following circumstances:
 - i. Those with a female reproductive system < 35 years of age, with at least 3 embryos available for transfer*;

- ii. Those with a female reproductive system ≥ 35 years of age, with at least 4 embryos available for transfer*;
- iii. Utilization of cryopreserved embryo(s) obtained for the purpose of fertility preservation before commencing non-elective medical or surgical treatment likely to cause infertility.

***Note:**

- If member/enrollee continues to qualify for infertility, FET with less than this number of embryos available for transfer is considered medically necessary.
4. Gamete Intra-Fallopian Transfer (GIFT)/Zygote Intra-Fallopian Transfer (ZIFT)- meets all of the following:
- a. Member/enrollee has at least one patent fallopian tube;
 - b. One of the following:
 - i. Utilization of cryopreserved sperm and an oocyte or embryo(s) obtained for the purpose of fertility preservation before commencing non-elective medical or surgical treatment likely to cause infertility;
 - ii. Unexplained infertility, one of the following:
 - a) For those with a female reproductive system < 38 years old, failure of 3 cycles of IUI with oral agents (i.e., clomiphene or letrozole);
 - b) For those with a female reproductive system age 38-42, failure of at least 1 cycle of IUI with oral agents (i.e., clomiphene or letrozole);
 - c. Justification that GIFT/ZIFT is preferable to standard IVF.
5. Intracytoplasmic Sperm Injection (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 microepididymal sperm aspiration (MESA) or testicular sperm extraction (TESE) (does not include obstruction due to voluntary sterilization);
 - f. Abnormal morphology ($\leq 1\%$ normal forms by Kruger; $\leq 5\%$ normal forms by WHO);
 - g. Specific spermatozoan defects impairing spermatozoa-oocyte interaction;
 - h. Fertilization of previously frozen oocytes;
 - i. Utilization of cryopreserved sperm and/or oocyte obtained for the purpose of fertility preservation before commencing non-elective medical or surgical treatment likely to cause infertility.
6. Donor egg cycle- member/enrollee has a female reproductive system and 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;

- d. Ovarian failure following radiation or chemotherapy;
 - e. Previously failed IVF in those with a female reproductive system age ≥ 40 ;
 - f. Gonadal dysgenesis including Turner Syndrome;
 - g. High risk of transmitting genetic disorder from those with a female reproductive system.
7. TESE, micro-TESE and epididymal sperm extraction for those with a male reproductive system with obstructive or non-obstructive azoospermia.
8. Donor sperm, meets one of the following:
- a. Partner with male reproductive system has bilateral congenital absence of the vas deferens (BCAVD);
 - b. Partner with male reproductive system has obstructive azoospermia;
 - c. Those with a female reproductive system without a partner with a male reproductive system;
 - d. High risk of transmitting an infectious disease from partner with a male reproductive system (such as HIV);
 - e. High risk of transmitting a genetic disorder in the partner with a male reproductive system to the offspring;
 - f. Partner with male reproductive system has non-obstructive azoospermia confirmed through MESA/TESA;
 - g. Couples who are incompatible for red cell antigens (e.g., D, Kell) associated with hemolytic disease of the newborn and with a history of a severely affected infant;
 - h. Partner with male reproductive system has had previous radiation or chemotherapy resulting in abnormal semen analysis;
 - i. Partner with male reproductive system has had two abnormal semen analyses (by Krüger or WHO classification) at least 30 days apart;
 - j. Failure of at least three cycles IVF or ICSI.
9. Cryopreservation of sperm: 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 member/enrollee with a male reproductive system 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.

10. 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) for any of the following:
 - i. Embryos could not be transferred due to high risk of multiple gestation;
 - ii. Embryos could not be transferred due to a potential adverse impact on maternal health (i.e., severe hyper-stimulation syndrome, etc.);
 - iii. Altered endocrine and cardiovascular profile at time of embryo transfer (elevated progesterone, hypertension, etc.);

CLINICAL POLICY
Assisted Reproductive Technology

- iv. Fewer embryos are available at one time than are planned to be transferred (low responder);
- v. Uterine conditions are not ideal for implantation and an approved infertility treatment is planned to increase likelihood of implantation;
- 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.

- 11. 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;
 - 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 the partner is not a member/enrollee, unless mandated by benefits;
 - G. Those with a female reproductive system who are ≤ 54 years of age and are menopausal (unless using a donor egg for premature diminished ovarian reserve or premature ovarian failure);
 - H. Those with a female reproductive system who are > 55 years of age;
 - I. Gender selection, chromosomal studies of donor sperm or egg.

Background

In Vitro Fertilization and Embryo Transfer (IVF-ET)

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

- Ovulation stimulation and monitoring- the patient starts ovulation drugs to stimulate the ovaries to produce multiple eggs. Ovulation drugs are given over a period of eight to 14 days. During this time they are monitored for follicular development with frequent ultrasounds and blood tests. The eggs are retrieved before ovulation occurs.

CLINICAL POLICY

Assisted Reproductive Technology

- 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.

Gamete Intra-Fallopian Transfer (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.

Zygote Intra-Fallopian Transfer (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 diethylstilbestrol (DES) exposure), or recurrent failure with standard IVF.

Intra-Cytoplasmic Sperm Injection (ICSI)

ICSI 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.²⁰

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.²⁰

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 2021, 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

CLINICAL POLICY
Assisted Reproductive Technology

CPT® Codes	CPT Codes that Support Medical Necessity
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)
89254	Oocyte identification from follicular fluid
89255	Preparation of embryo for transfer (any method)
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

CLINICAL POLICY
Assisted Reproductive Technology

HCPCS Codes	HCPCS Code Descriptions
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

Reviews, Revisions, and Approvals	Revision 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.	04/16	04/16

CLINICAL POLICY
Assisted Reproductive Technology

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Took out requirement that male partner be a covered member/enrollee. 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.		
References reviewed and updated. ICD-10 codes added.	04/17	04/17
Under general female criteria 8, added cryopreservation of oocytes, and removed requirement that member/enrollee 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 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.	03/18	03/18
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

Reviews, Revisions, and Approvals	Revision Date	Approval Date
References reviewed and updated.	01/20	01/20
Under description of policy, added reference to CP.PHAR 131. Under basic criteria, added reproductive endocrinologist as an acceptable provider for males. Under treatment specific criteria for females, I.B.2. IVF, added “unexplained infertility” for clarification; changed age criteria in ii.a, from ≤ 39 to < 38 ; changed requirement of gonadotropic stimulation to oral agents (i.e., clomiphene or letrozole); Changed age criteria in ii.b. from 40-42 to 38-42; changed requirement of failure of 1-2 cycles of IUI with gonadotropic stimulation to failure of at least 1 cycle of IUI with oral agents (i.e., clomiphene or letrozole). Under treatment specific criteria for I.B.4. GIFT/ZIFT, added “unexplained infertility” to 4b for clarification; made the same criteria changes as noted for IVF. Replaced “member” with “member/enrollee” in all instances. References reviewed and updated.	11/20	12/20
Annual review. References reviewed, updated, and reformatted. Changed “review date” in the header to “date of last revision” and “date” in the revision log header to “revision date.” Changed all instances of “female”/ “male” to “female reproductive system”/“male reproductive system”. In II.A, removed “until the procedure becomes recognized as non-experimental” from the statement “Any experimental infertility procedure.” Specialist reviewed.	12/21	12/21
Edited IUI criteria: Added an indication for member/enrollees with a female reproductive system and without a partner with a male reproductive system; noted that couples needing IUI and donor sperm for a psychosexual problem, sperm washing for HIV positive couples, and donor sperm for members with a female reproductive system and without a partner with a male reproductive system don’t have to demonstrate inability to conceive over 6 to 12 months or require treatment by a reproductive endocrinologist.	10/22	10/22
Annual review. Description updated to include additional coverage information, updated age limits, and updates to reproductive system sections. Added criteria I.A.2., revised verbiage in I.A.3., and replaced clomiphene citrate challenge test in criteria I.A.4. with provider evaluation verbiage. Added “factor” to male reproductive system infertility in I.B.1.a.i. Removed “mild” from I.B.1.a.v. Added "with embryo transfer" to I.B.2. Updated I.B.2.a.i.b) for clarity. Added criteria I.B.2.a.i.d). Revised requirements in criteria I.B.2.a.ii.a) and b). Added new criteria I.B.2.a.iv., note and Table 1 for guidance on number of embryos to transfer. Updated policy statement in I.B.3., added criteria I.B.3.a. "number of embryos to transfer..." and removed this reference from the "Note" under I.B.3. Added it to I.B.3.b.i and I.B.3.b.ii. Added new indication I.B.3.a.iii. Added indication to I.B.4.b. and reformatted criteria. Removed “must be provided” from I.B.4.c. Removed I.B.5.h., “selected types of female reproductive system infertility...” and added	01/23	01/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
I.B.5.i., “utilization of cryopreserved sperm and/or oocyte....” Criteria I.B.5.j. regarding HIV discordant couples removed. Previous Criteria I.B.6. regarding assisted hatching removed. Criteria I.B.6.c. updated to remove CCCT and FSH criteria. Minor wording reorder to Criteria I.B.6.d. Criteria I.B.7. removed “applies only if the partner with male reproductive system is a covered member/enrollee and meets the following.” Criteria II.F. updated to include, “unless mandated by benefits.” Criteria II.G. updated to state, “those with a female reproductive system who are ≤ 54 years of age and are menopausal (unless using a donor egg for premature diminished ovarian reserve or premature ovarian failure).” Criteria II.H. added regarding those with a female reproductive system who are > 55 years of age. Background updated with no impact on criteria. CPT Code table updated with header. CPT code 89253 removed from table of CPT Codes that Support Medical Necessity. ICD-10 codes removed. References reviewed and updated. Reviewed by internal specialist and external specialist.		

References

1. American College of Obstetricians and Gynecologists Committee on Gynecologic Practice and Practice Committee. Female age-related fertility decline. Committee Opinion No. 589. *Fertil Steril.* 2014;101(3):633 to 634. doi:10.1016/j.fertnstert.2013.12.032
2. Practice Committee of the American Society for Reproductive Medicine. Diagnostic evaluation of the infertile male: a committee opinion. *Fertil Steril.* 2015;103(3):e18 to e25. doi:10.1016/j.fertnstert.2014.12.103
3. Practice Committee of the American Society for Reproductive Medicine. Effectiveness and treatment for unexplained infertility. *Fertil Steril.* 2006;86(5 Suppl 1):S111 to S114. doi:10.1016/j.fertnstert.2006.07.1475
4. Practice Committee of the American Society for Reproductive Medicine. Evaluation and treatment of recurrent pregnancy loss: a committee opinion. *Fertil Steril.* 2012;98(5):1103 to 1111. doi:10.1016/j.fertnstert.2012.06.048
5. Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Electronic address: asrm@asrm.org. Intracytoplasmic sperm injection (ICSI) for non-male factor indications: a committee opinion. *Fertil Steril.* 2020;114(2):239 to 245. doi:10.1016/j.fertnstert.2020.05.032
6. Practice Committee of the American Society for Reproductive Medicine. Electronic address: ASRM@asrm.org; Practice Committee of the American Society for Reproductive Medicine. Removal of myomas in asymptomatic patients to improve fertility and/or reduce miscarriage rate: a guideline. *Fertil Steril.* 2017;108(3):416 to 425. doi:10.1016/j.fertnstert.2017.06.034
7. Practice Committee of the American Society for Reproductive Medicine. Electronic address: asrm@asrm.org; Practice Committee of the American Society for Reproductive Medicine. Testing and interpreting measures of ovarian reserve: a committee opinion. *Fertil Steril.* 2020;114(6):1151 to 1157. doi:10.1016/j.fertnstert.2020.09.134
8. Practice Committee of the American Society for Reproductive Medicine. Electronic address: ASRM@asrm.org. Role of tubal surgery in the era of assisted reproductive technology: a

- committee opinion. *Fertil Steril*. 2021;115(5):1143 to 1150.
doi:10.1016/j.fertnstert.2021.01.051
9. Practice Committee of the American Society for Reproductive Medicine and the Practice Committee for the Society for Assisted Reproductive Technologies. Electronic address: ASRM@asrm.org. Guidance on the limits to the number of embryos to transfer: a committee opinion. *Fertil Steril*. 2021;116(3):651 to 654. doi:10.1016/j.fertnstert.2021.06.050
 10. Practice Committee of the American Society for Reproductive Medicine; Practice Committee of the Society for Assisted Reproductive Technology. Role of assisted hatching in in vitro fertilization: a guideline. *Fertil Steril*. 2022;117(6):1177 to 1182.
 11. Basile N, Garcia-Velasco JA. The state of "freeze-for-all" in human ARTs. *J Assist Reprod Genet*. 2016;33(12):1543 to 1550. doi:10.1007/s10815-016-0799-9
 12. Backeljauw P. Management of turner syndrome in adults. UpToDate. www.uptodate.com. Published June 30, 2022. Accessed November 04, 2022.
 13. Centers for Disease Control and Prevention. 2017 Assisted Reproductive Technology National Summary Report. US Dept of Health and Human Services; 2021.
 14. Forti G, Krausz C. Clinical review 100: Evaluation and treatment of the infertile couple. *J Clin Endocrinol Metab*. 1998;83(12):4177 to 4188. doi:10.1210/jcem.83.12.5296
 15. Ginsburg ES, Walker ZW. Donor insemination. UpToDate. www.uptodate.com. Published October 25, 2022. Accessed November 04, 2022.
 16. Ginsburg ES. Procedure for intrauterine insemination (IUI) using processed sperm. UpToDate. www.uptodate.com. Published September 14, 2021. Accessed November 09, 2022.
 17. Hannoun A, Abu-Musa A. Gamete intrafallopian transfer (GIFT) in the treatment of severe male factor infertility. *Int J Gynaecol Obstet*. 1998;61(3):293 to 295. doi:10.1016/s0020-7292(98)00026-5
 18. Hornstein MD, Gibbons WE. Unexplained infertility. UpToDate. www.uptodate.com. Published August 9, 2021. Accessed November 09, 2022.
 19. Kuohung W, Hornstein MD. Treatments for female infertility. UpToDate. www.uptodate.com. Published July 22, 2021. Accessed November 07, 2022.
 20. Rosen M. Intracytoplasmic sperm injection. UpToDate. www.uptodate.com. Published March 16, 2022. Accessed November 07, 2022.
 21. National Collaborating Centre for Women's and Children's Health (UK). *Fertility: Assessment and Treatment for People with Fertility Problems*. London: Royal College of Obstetricians & Gynaecologists; February 2013.
 22. Ho J. In vitro fertilization: Overview of clinical issues and questions. UpToDate. www.uptodate.com. Published October 19, 2022. Accessed November 07, 2022.
 23. Salem W. Assisted reproductive technology: Pregnancy and maternal outcomes. UpToDate. www.uptodate.com. Published October 24, 2022. Accessed November 07, 2022.
 24. Anawalt BD, Page ST. Treatments for male infertility. UpToDate. www.uptodate.com. Published February 28, 2020. Accessed November 09, 2022.
 25. Weiss NS, Nahuis M, Bayram N, Mol BW, Van der Veen F, van Wely M. Gonadotrophins for ovulation induction in women with polycystic ovarian syndrome. *Cochrane Database Syst Rev*. 2015;(9):CD010290. Published 2015 Sep 9. doi:10.1002/14651858.CD010290.pub2
 26. Kuohung W, Hornstein MD. Overview of infertility. UpToDate. www.uptodate.com. Published July 18, 2022. Accessed November 09, 2022.

CLINICAL POLICY

Assisted Reproductive Technology

27. Anawalt BD, Page ST. Approach to the male with infertility. UpToDate. www.uptodate.com. Published October 04, 2022. Accessed November 04, 2022.
28. Morris ME. Evaluation and management of infertility in females of advancing age. UpToDate. www.uptodate.com. Published February 18, 2022. Accessed November 07, 2022.
29. Practice Committees of the American Society for Reproductive Medicine and Society for Reproductive Endocrinology and Infertility. Electronic address: asrm@asrm.org. Use of exogenous gonadotropins for ovulation induction in anovulatory women: a committee opinion. *Fertil Steril*. 2020;113(1):66 to 70. doi:10.1016/j.fertnstert.2019.09.020
30. Infertility Workup for the Women's Health Specialist: ACOG Committee Opinion, Number 781. *Obstet Gynecol*. 2019;133(6):e377 to e384. doi:10.1097/AOG.0000000000003271
31. Schlegel PN, Sigman M, Collura B, et al. Diagnosis and Treatment of Infertility in Men: AUA/ASRM Guideline Part I. *J Urol*. 2021;205(1):36 to 43. doi:10.1097/JU.0000000000001521
32. Schlegel PN, Sigman M, Collura B, et al. Diagnosis and treatment of infertility in men: AUA/ASRM guideline part II. *Fertil Steril*. 2021;115(1):62 to 69. doi:10.1016/j.fertnstert.2020.11.016
33. Practice Committee of the American Society for Reproductive Medicine. Electronic address: asrm@asrm.org; Practice Committee of the American Society for Reproductive Medicine. Evidence-based treatments for couples with unexplained infertility: a guideline. *Fertil Steril*. 2020;113(2):305 to 322. doi:10.1016/j.fertnstert.2019.10.014
34. Moseson H, Zazanis N, Goldberg E, et al. The Imperative for Transgender and Gender Nonbinary Inclusion: Beyond Women's Health. *Obstet Gynecol*. 2020;135(5):1059 to 1068. doi:10.1097/AOG.0000000000003816
35. Ethics Committee of American Society for Reproductive Medicine. Access to fertility treatment by gays, lesbians, and unmarried persons: a committee opinion. *Fertil Steril*. 2013;100(6):1524 to 1527. doi:10.1016/j.fertnstert.2013.08.042
36. ACOG Committee Opinion No. 749: Marriage and Family Building Equality for Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual, and Gender Nonconforming Individuals. *Obstet Gynecol*. 2018;132(2):e82 to e86. doi:10.1097/AOG.0000000000002765
37. Practice Committee of the American Society for Reproductive Medicine. Definitions of infertility and recurrent pregnancy loss: a committee opinion. *Fertil Steril*. 2020;113:533 to 5.
38. Ethics Committee of the American Society for Reproductive Medicine. Oocyte or embryo donation to women of advanced reproductive age: an Ethics Committee opinion. *Fertil Steril*. 2016;106:e3 to 7.

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

CLINICAL POLICY

Assisted Reproductive Technology

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/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees 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/enrollees 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/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, 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/enrollees, 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.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.

