Clinical Policy: Assisted Reproductive Technology

Reference Number: HNCP.MP.55 Coding Implications
Date of Last Revision: 10/25 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 the purpose of this policy, 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]

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) with or without assisted hatching.
9. Frozen Embryo Transfer (FET);
10. Short duration (up to one year) cryopreservation 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 Health Net of California 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 ≥ age 35;
   4. For those with female reproductive systems ≥ 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 reanastamosis, 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*: < three for those with a female reproductive system age < 35 years, or < four 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);

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 ≥ 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	≤ 3	≤ 4
Embryos not Euploid or Favorable	≤ 2	≤ 3	≤ 4	≤ 5
Blastocysts				
Euploid	1	1	1	1
Other favorable	1	1	≤ 2	≤ 3
Embryos not Euploid or Favorable	≤ 2	≤ 2	≤ 3	≤ 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 three embryos available for transfer*;
ii. Those with a female reproductive system ≥ 35 years of age, with at least four 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 three cycles of IUI with oral agents (i.e., clomiphene or letrozole);
         b) For those with a female reproductive system age 38 to 42, failure of at least one 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 two 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 (≤ 1% normal forms by Kruger; ≤ 5% normal forms by WHO);
   g. Specific spermatozoan defects impairing spermatozoa-oocyte interaction;
   h. Fertilization of previously frozen oocytes and oocytes that have undergone in vitro maturation;
   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;
   j. HIV or hepatitis-discordant couples;
   k. Need for preimplantation genetic testing for monogenic disorders (PGT-M) of embryos in settings requiring absence of extraneous DNA contamination from

other sperm (i.e., members/enrollees with or carriers of cystic fibrosis, BRCA mutations and congenital adrenal hyperplasia);

l. Treatment of elected types of female infertility such as members/enrollees with morphologic anomalies of oocytes and/or anomalies of the zona pellucida.

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. 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;
   h. Hypergonadotropic hypogonadism.

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 ejaculatory dysfunction;
   c. Partner with male reproductive system has obstructive azoospermia, severe oligozoospermia, or other significant sperm or seminal fluid abnormalities;
   d. Those with a female reproductive system without a partner with a male reproductive system;
   e. High risk of transmitting an infectious disease from partner with a male reproductive system (such as HIV);
   f. High risk of transmitting a genetic disorder in the partner with a male reproductive system to the offspring;
   g. Partner with male reproductive system has non-obstructive azoospermia confirmed through MESA/TESA;
   h. 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;
   i. Partner with male reproductive system has had previous radiation or chemotherapy resulting in abnormal semen analysis;
   j. Partner with male reproductive system has had two abnormal semen analyses (by Krüger or WHO classification) at least 30 days apart;
   k. 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 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 Health Net of California 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 outside of the body in a laboratory. The resulting embryo is then placed into the uterus at later time. 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 the patient 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.

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 created 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 undergoing 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 allowing the sperm to penetrate the egg naturally. Embryos are then transferred to the uterus as in usual ET or cryopreserved in preparation for future FET.[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]

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 patient, 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 2023, 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 Codes that Support Medical Necessity
58321	Artificial insemination; intra-cervical
58322	Artificial insemination; intra-uterine
58323	Sperm washing for artificial insemination
58970	Follicle puncture for oocyte retrieval, any method
58974	Embryo transfer, intrauterine
58976	Gamete, zygote, or embryo intrafallopian tube transfer; any method
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)
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

HCPCS Codes	HCPCS Code Descriptions
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

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	
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	10/22	10/22

Reviews, Revisions, and Approvals	Revision Date	Approval Date
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.		
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 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.	01/23	01/23
Annual review. Added Frozen Embryo Transfer (FET) under Description with no impact to criteria. Added criteria I.B.5.h. to include "and oocytes that have undergone in vitro maturation; added criteria I.B.6.h. Hypergonadotropic hypogonadism. Added criteria I.B.8.b. Partner with male reproductive system has ejaculatory dysfunction; expanded crtieria I.B.8.c.to include severe oligozoospermia, or other significant sperm or	01/24	01/24

Reviews, Revisions, and Approvals	Revision Date	Approval Date
seminal fluid abnormalities. Background rewording with no impact to criteria. References reviewed and updated.		
Annual review. Description updated with no impact on criteria. Added criteria I.B.5.i.-I.B.5.l. to include: HIV or hepatitis-discordant couples; Need for preimplantation genetic testing for monogenic disorders (PGT-M) of embryos in settings requiring absence of extraneous DNA contamination from other sperm (i.e., members/enrollees with or carriers of cystic fibrosis, BRCA mutations and congenital adrenal hyperplasia); Treatment of elected types of female infertility such as members/enrollees with morphologic anomalies of oocytes and/or anomalies of the zona pellucida. Removed "premature" in criteria I.B.6.c. Removed criteria I.B.10. regarding cryopreservation of embryos References reviewed and updated. Reviewed by internal and external specialist.	02/25	02/25
Policy updated for Health Net of California to accommodate changes made by DMHC APL SB729. Assisted Hatching (89253) added to medically necessary procedures.	10/25	10/25

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39. Senate Bill 729 (Menjivar, 2024) amended Health and Safety Code section 1374.55[1] of the Knox-Keene Act. SB 729 as enacted required large group health contracts issued, amended,

or renewed on or after July 1, 2025, to cover the diagnosis and treatment of infertility and fertility services.

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/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.