

POLICY TITLE	REPRODUCTIVE TECHNIQUES
POLICY NUMBER	MP-7.002

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I. POLICY

The following reproductive techniques are considered **medically necessary**:

- cryopreservation of testicular tissue in adult men with azoospermia as part of an intracytoplasmic sperm injection procedure;
- intracytoplasmic sperm injection for male factor infertility;
- blastocyst transfer

The following reproductive techniques are considered **investigational** there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures;

- assisted hatching;
- co-culture of embryos;
- cryopreservation of ovarian tissue, or oocytes;
- cryopreservation of testicular tissue in prepubertal boys;
- storage and thawing of ovarian tissue, oocytes or testicular tissue
- intracytoplasmic sperm injection in the absence of male factor infertility.

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

CHIP (aka Capital Cares 4Kids)*	PPO*	HMO*
POS*	Indemnity*	SpecialCare SM *
FEP PPO*	BlueJourney HMO**	BlueJourney PPO**

* Benefit determinations for assisted fertilization and infertility treatment should be based in all cases on the applicable contract exclusions and limitations. Individual group benefits should be reviewed to determine coverage.

** Refer to Centers for Medicare and Medicaid Services (CMS) [Medicare Benefit Policy Manual, Publication 100-02, Chapter 15, Sec.20.1](#) for treatment for infertility. Reasonable and

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necessary services associated with treatment for infertility are covered under Medicare. Any treatment leading to or in connection with assisted fertilization such as, but not limited to, artificial insemination, in vitro fertilization (IVF), gamete intra-fallopian transfer (GIFT), and zygote intra-fallopian transfer (ZIFT) are excluded from coverage.

III. DESCRIPTION/BACKGROUND

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The policy addresses a variety of techniques available to establish a viable pregnancy for couples who have been diagnosed with infertility and for whom assisted insemination is insufficient.

Infertility can be due either to female factors (i.e., pelvic adhesions, ovarian dysfunction, endometriosis, prior tubal ligation), male factors (i.e., abnormalities in sperm production, function, or transport or prior vasectomy), a combination of both male and female factors, or unknown causes. Various reproductive techniques are available to establish a viable pregnancy; different techniques are used depending on the reason for infertility.

Assisted reproductive technologies (ART), as defined by the Centers for Disease Control (CDC) and other organizations, refers to fertility treatments in which both the eggs and sperm are handled. Not included in ART is assisted insemination (artificial insemination) using sperm from either a woman’s partner or a sperm donor. In most instances ART will involve in vitro fertilization (IVF), a procedure in which oocytes harvested from the female are inseminated in vitro with sperm harvested from the male. Following the fertilization procedure, the zygote is cultured and ultimately transferred back into the female’s uterus or fallopian tubes. In some instances, the oocyte and sperm are collected, but no in vitro fertilization takes place, and the gametes are reintroduced into the fallopian tubes. Examples of ART include, but are not limited to, gamete intrafallopian transfer (GIFT), transuterine fallopian transfer (TUFT), natural oocyte retrieval with intravaginal fertilization (NORIF), pronuclear state tubal transfer (PROST), tubal embryo transfer (TET), zygote intrafallopian transfer (ZIFT), gamete and embryo cryopreservation, oocyte and embryo donation, and gestational surrogacy.

The various components of ART and implantation into the uterus can be broadly subdivided into oocyte harvesting procedures, which are performed on the female partner; sperm collection procedures, which are performed on the male partner; and the in vitro component, i.e., the laboratory procedures, which are performed on the collected oocyte and sperm. The final step is the implantation procedure.

Most CPT codes describing the various steps in ART procedures are longstanding techniques. This includes codes for oocyte retrieval, sperm isolation, culture and fertilization of the oocyte, and embryo; zygote; or gamete transfer into the uterus or fallopian tubes. Only the relatively new reproductive techniques (i.e., intracytoplasmic sperm injection, assisted hatching, co-culture of embryos) and cryopreservation of reproductive tissue (i.e., testicular, ovarian, or oocytes) will be considered.

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Regulatory Status

There are no medical devices or diagnostic tests related to assisted reproductive techniques that require FDA approval or clearance.

IV. RATIONALE

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Summary of Evidence

For individuals who have infertility who receive in vitro fertilization with assisted hatching, the evidence includes randomized controlled trials (RCTs), a systematic review and a large observational study. Relevant outcomes are health status measures, resource utilization, and treatment-related morbidity. RCTs have not shown that assisted hatching improves the live birth rate compared with standard care. Findings on clinical pregnancy rate after assisted hatching were mixed but RCTs generally did not find improvement with assisted hatching versus standard care. A large observational study found that assisted hatching was associated with worse outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have infertility who receive in vitro fertilization with co-culture, the evidence includes a RCTs and case series. Relevant outcomes are health status measures, resource utilization, and treatment-related morbidity. Most clinical trials did not find improved implantation or pregnancy rate after co-culture, and studies have not reported the live birth rate. Moreover, co-culture techniques have not been standardized and 1 RCT that found a higher clinical pregnancy rate with co-culture than a standard practice control group used a novel technique that has not been otherwise evaluated. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have cancer who will undergo treatment that may lead to infertility who receive cryopreservation of ovarian tissue, the evidence includes case series. Relevant outcomes are health status measures, resource utilization, and treatment-related morbidity. The technique has not been standardized and there is a lack of controlled studies on health outcomes following cryopreservation of ovarian tissue. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have cancer who will undergo treatment that may lead to infertility who receive cryopreservation of oocytes, the evidence includes RCTs and a systematic review on the technique in related populations. Relevant outcomes are health status measures, resource utilization, and treatment-related morbidity. The systematic review found that fertilization rates ranged from 71% to 79%, and the clinical pregnancy rates per transfer ranged from 36% to 61%. The available studies are conducted in highly selected populations and may not be generalizable to the population of interest, women with cancer. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have infertility who receive in vitro fertilization with blastocyst transfer, the evidence includes RCTs and meta-analyses. Relevant outcomes are health status measures, resource utilization, and treatment-related morbidity. RCTs and meta-analyses have found that blastocyst transfer is associated with higher live birth rates compared with cleavage stage

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transfer. One meta-analysis found a significantly higher rate of preterm birth after blastocyst stage versus cleavage stage transfer, but not find increased risks of other outcomes such as low birth rate and perinatal mortality. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have male factor infertility who receive ICSI, the evidence includes observational studies and a systematic review. Relevant outcomes are health status measures, resource utilization, and treatment-related morbidity. No RCTs are available. Observational studies, which are subject to limitations e.g. selection bias have found similar rates of clinical pregnancy and live birth after ICSI and standard IVF, and a meta-analysis of observational studies found a higher rate of genitourinary malformations in children born after ICSI but only when lower-quality studies were included in the analysis. RCTs comparing health outcomes after ICSI for male factor infertility and standard IVF are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have azoospermia who receive cryopreservation of testicular tissue as part of ICSI, the evidence includes no clinical trials. Relevant outcomes are health status measures, resource utilization and treatment-related morbidity. Cryopreservation of testicular tissue in adult men with azoospermia is a well-established component of the ICSI procedure. However, there is a lack of clinical trials. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have cancer who are prepubertal boys who receive cryopreservation of testicular tissue, the evidence includes no clinical trials. Relevant outcomes are health status measures, resource utilization and treatment-related morbidity. No clinical trials were identified evaluating the safety and efficacy of cryopreservation of testicular tissue in prepubertal boys undergoing cancer therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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ARTIFICIAL INSEMINATION (AI) is the introduction of semen into the vagina or uterus by mechanical or instrumental means rather than by sexual intercourse. The procedure is planned to coincide with the expected time of ovulation so that fertilization can occur.

ASSISTED HATCHING- a procedure involving thinning or making a small hole in the zona pellucida that surrounds the embryo. There is some evidence that assisted hatching may improve implantation rate.

CO-CULTURE OF EMBRYOS – refers to techniques, which involve tissue culture of human embryos in the presence of oviductal, uterine, granulosa or other cells. This purpose of co-culture is to produce a more viable embryo at the blastocyst stage of development for subsequent transfer to the uterus.

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CRYOPRESERVATION- Preservation of biological materials, such as tissue, sperm, fluids, blood, or plasma at very low temperatures. This enables the tissue to be used at a later time, as it remains viable after thawing.

INFERTILITY -The medically documented diminished ability to conceive, or to conceive and carry to live birth. A couple is considered infertile if conception does not occur after a one-year period of unprotected coital activity without contraceptives, or there is the inability on more than one occasion to carry to live birth.

INTRACYTOPLASMIC SPERM INJECTION (ICSI) is a laboratory procedure developed to help infertile couples undergoing in vitro fertilization (IVF) due to male factor infertility. ICSI is a form of micromanipulation, involving the injection of a single sperm directly into the cytoplasm of a mature egg (oocyte) using a glass needle (pipette). This process increases the likelihood of fertilization when there are abnormalities in the number, quality, or function of the sperm.

IN VITRO FERTILIZATION (IVF) is a method of fertilizing human ova outside the body by collecting the mature ova and placing them in a dish with a sample of sperm. After an incubation period of forty-eight to seventy-two hours, the fertilized ova are injected into the uterus through the cervix.

GAMETE INTRAFALLOPIAN TRANSFER (GIFT) is a human fertilization technique in which ova and sperm are injected through a laparoscope into the fimbriated ends of the fallopian tube.

ZYGOTE INTRAFALLOPIAN TRANSFER (ZIFT) is the retrieval of oocytes (eggs) from the ovary, followed by their fertilization and culture in the laboratory and placement of the resulting zygotes in the fallopian tubes by laparoscopy twenty-four (24) hours after oocyte retrieval.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy

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between this medical policy and a member’s benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational and therefore not covered:

CPT Codes®								
0357T	0058T	89251	89253	89258	89259	89337	89342	89343
89344	89346	89352	89353	89354	89356			

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Covered when medically necessary:

CPT Codes ®							
54500	54505	54800	55400	55870	58321	58322	58323
58970	58974	58976	58999	76948	84830	89240	89250
89254	89255	89257	89260	89261	89264	89268	89272
89280	89280	89281	89310	89321	89330	89335	

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HCPCS Code	Description
S4011	In vitro fertilization;
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 cancelled prior to stimulation, case rate
S4018	Frozen embryo transfer procedure cancelled before transfer, case rate
S4020	In vitro fertilization procedure cancelled before aspiration, case rate
S4021	In vitro fertilization procedure cancelled 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
S4027	Storage of previously frozen embryos

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HCPCS Code	Description
S4028	Microsurgical epididymal sperm aspiration (mesa)
S4030	Sperm procurement and cryopreservation services; initial visit
S4031	Sperm procurement and cryopreservation services; subsequent visit
S4035	Stimulated intrauterine insemination (iui), case rate
S4037	Cryopreserved embryo transfer, case rate
S4040	Monitoring and storage of cryopreserved embryos, per 30 days
S4042	Management of ovulation induction per cycle

ICD-10-CM Diagnosis Codes	Description
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
N73.6	Female pelvic peritoneal adhesions (postinfective)
N80.3	Endometriosis of pelvic peritoneum
N97.0	Female infertility associated with anovulation
Z31.41	Encounter for fertility testing
Z31.7	Encounter for procreative management and counseling for gestational carrier
Z31.81	Encounter for male factor infertility in female patient
Z31.82	Encounter for rh incompatibility status
Z31.83	Encounter for assisted reproductive fertility procedure cycle
Z31.84	Encounter for fertility preservation procedure
Z31.89	Encounter for other procreative management

IX. REFERENCES

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	CAC 8/31/04
	CAC 8/30/05
	CAC 11/29/05
	CAC 11/28/06
	CAC 11/27/07
	CAC 11/25/08
	CAC 1/26/10 Consensus review
	CAC 4/26/11 Consensus review
	CAC 6/26/12 Adopting BCBSA. Changed title. Previously Assisted Fertilization and Infertility Treatment. Policy statement changed to include blastocyst transfer as medically necessary. See policy for other new specific criteria
	7/25/13 Admin coding review complete
	CAC 9/24/13 Consensus review. Minor wording change in the medically necessary policy statement, ‘intracytoplasmic sperm injection’ changed to ‘intracytoplasmic sperm injection for male factor infertility.’ Rationale section added. References updated.
	CAC 9/30/14 Consensus review. Rationale and references updated. No changes to the policy statements.
	01/2015- New 2015 CPT code added. 2/18/15 - Admin Coding Correction
	CAC 9/29/15 Minor revision. Intacytoplasmic sperm injection in the absence of male factor infertility added to the investigational statement. Reference and rationale update. Coding Reviewed
	CAC 9/27/16 Consensus. No change to policy statements. References and rationale updated. Variation reformatted. Coding updated. New diagnosis codes added effective 10/1/16
	8/24/18 Retired policy. Rationale condensed to the summary of evidence only. Please refer to the member’s certificate of coverage for any applicable benefits related to these services. Effective 1/1/19.

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