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Medicare Advantage Medical Coverage Policy

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Disclaimer

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/Transmittals.

There are no NCDs and/or LCDs for Infertility Evaluation and Treatment

Tura	Tal.	ID	Jurisdiction	Applicable
Туре	Title	Number	Medicare	States/Territories

			Administrative Contractors (MACs)	
Internet- Only Manuals (IOMs)	Chapter 15 Covered Medical and Other Health Services; Section 20.1	Medicare Benefit Policy Manual		

Description

Infertility is a condition defined by the failure to achieve conception. Primary infertility is a term applied when pregnancy has never been achieved; secondary infertility is the inability to conceive after already having a successful birth. Both types of infertility have similar causes and treatments.

For purposes of determining when evaluation and treatment for infertility is appropriate, pregnancy is defined as a clinical pregnancy documented by ultrasonography or histopathologic examination.

Evaluation

Diagnostic investigation of infertility includes physical examinations and several types of testing. Some issues are able to be corrected during the particular diagnostic intervention as well.

- **Specialized clinical testing** to rule out potential issues associated with infertility include, but may not be limited to:
 - o **Endometrial receptivity testing** (eg, Endometrial Receptivity Analysis [ERA], E-tegrity test)
 - o Laboratory studies collected by blood sample include, but may not be limited to:
 - Antimullerian hormone (AMH)
 - Clomiphene challenge test
 - Estradiol (E2)
 - FSH (may include a cycle day three FSH)
 - Luteinizing hormone (LH)
 - Progesterone
 - Prolactin
 - Testosterone levels
 - Thyroid stimulating hormone (TSH)
 - Postcoital testing (PCT), also known as Sims-Huhner test
 - Postejaculatory urinalysis
 - Tests that may be performed on semen/sperm include, but may not be limited to:

- Antisperm antibody testing
- Cap-Score Test
- Computer-aided semen analysis (CASA)
- Quantification of leukocytes (white blood cells) in semen
- Semen analysis
- Semen biochemistry (semen fructose)
- Semen culture
- Sperm function tests (eg, hypo-osmotic swelling [HOS] test, sperm viability testing or Zona free hamster oocyte penetration test)
- Sperm hyaluronan-binding assay (HBA)
- Y chromosome microdeletion analysis Laboratory procedure that aids in determining the source of infertility in males which is typically offered to men with azoospermia (absence of sperm in semen) or severe oligozoospermia (low sperm count). This is the second most commonly known genetic cause of male infertility.
- Imaging studies or other procedures for determining abnormalities that could impact fertility include, but may not be limited to:
 - Chromotubation of oviducts Procedure performed in combination with a laparoscopy that involves
 injecting dye into the uterine cavity and fallopian tubes to evaluate patency.
 - Endometrial (uterine lining) biopsy Procedure in which a small piece of tissue is removed for examination under a microscope. The endometrium can be prone to chronic low-grade infections, gland overgrowth resulting in polyps or even endometrial cancer which may impact fertility.
 - Fluoroscopic/hysteroscopic selective tubal cannulation Procedure used to confirm or exclude proximal fallopian tubal occlusion suggested by other tests (such as hysterosalpingogram [HSG]) and provides the means for possible treatment via recanalization using specialized catheter systems.
 - Hysterosalpingo-contrast sonography (HyCoSy) Procedure which involves a transvaginal ultrasound investigation of the fallopian tubes both before and after the injection of an echo-enhancing agent into the tubes via the uterine cavity.
 - Hysterosalpingography (HSG) Procedure involving insertion of a tube into the cervix in order to
 inject a dye which should pass into the uterus and the fallopian tubes if no blockages are present; the
 dye allows visualization via X-ray.

- Hysteroscopy Procedure that examines the uterus via a thin telescope-like device (hysteroscope)
 which is placed through the cervix.
- Intrauterine foam A novel contrast agent for use with transvaginal ultrasound as an adaptation of the HyCoSy. This new procedure using the foam will be referred to as the hysterosalpingo-foam sonography (HyFoSy).
- Laparoscopy Surgical procedure which utilizes a lighted viewing instrument and 1 or more small cuts (incisions) in the abdomen that can be utilized for further evaluation or treatment for an individual with infertility.
- Magnetic resonance imaging (MRI) Noninvasive imaging procedure that uses strong magnetic fields and radiofrequency energy and may be done with or without contrast (dye).
- o **Sonohysterography (SHG)** Ultrasound procedure used to evaluate the uterine cavity. It involves filling the uterine cavity with saline solution using a catheter prior to an ultrasound examination.
- Testicular biopsy Procedure in which a small portion of testicle is removed for examination. It is conducted when a semen analysis suggests that there is abnormal sperm and other tests have not found the cause.
- Ultrasound Noninvasive diagnostic exam that uses sound waves to produce images to assess organs and structures (eg, pelvic [cervix, fallopian tubes, ovaries, uterus], scrotal, testicular, transrectal, transvaginal).
- Vasography X-ray study that is performed to determine patency (degree of openness) of the vas deferens (duct that conveys sperm).

Treatment

Infertility treatment may involve a series of procedures and other interventions in an attempt to address the cause(s) of infertility. Some of these procedures and interventions include, but may not be limited to:

- Artificial insemination (AI), donor insemination or intrauterine insemination (IUI) Method used to deliver sperm directly to the cervix or uterus. Sometimes sperm are prepared or washed to increase the likelihood of conception.
- **Donor embryo(s), oocyte(s) or sperm/semen** For some assistive reproductive techniques such as Al/IUI or in vitro fertilization, embryos, oocytes or sperm/semen may be obtained from one individual for use in another.
- Embryo transfer (ET) Procedure which involves the placement of an embryo into the uterus. This is typically performed for a subsequent round of in vitro fertilization (using a thawed embryo) or when a donor embryo is utilized.

- **Gamete intrafallopian transfer (GIFT)** Technique that may be used instead of in vitro fertilization for an individual with open fallopian tubes. After an egg retrieval, the eggs are inseminated (mixed with sperm) then immediately injected into the fallopian tubes for fertilization.
- In vitro fertilization (IVF) Essentially, this is fertilization of an egg in a laboratory dish or test tube. The embryo is then instilled into the uterus via a tiny catheter. The general components of an IVF cycle are pharmacologic ovarian stimulation (eg, ovulation induction or superovulation), oocyte aspiration, fertilization and embryo transfer. There are other potential interventions that may also be necessary which include, but may not be limited to: assisted embryo hatching, intracytoplasmic sperm injection (ICSI), sperm retrieval, uterine embryo lavage, etc.
- In vitro maturation (IVM) Eggs are retrieved before they are considered mature. In this process they are allowed to mature outside the body in a petri dish whereas in IVF the maturation is induced inside the uterus and involves injectable hormones.
- **INVOcell intravaginal IVF technology** Small device holding an egg and sperm is placed in the vagina for 3–5 days, allowing the individual to become an incubator for gametes during fertilization and for embryos during preimplantation development. Embryos are then transferred into the uterus.
- Leukocyte immunization therapy (LIT) Treatment whereby white blood cells from the potential father that are injected into the skin of the prospective mother to purportedly promote fertility by developing the immune system's tolerance to genetically foreign pregnancy tissues, especially in those with a history of failed IVF cycles and suspected immunologic reasons for failed implantation.
- Low tubal ovum transfer Procedure in which oocytes are transferred past a blocked or damaged section of the fallopian tube to an area closer to the uterus.
- Platelet rich plasma (PRP) PRP (liquid fraction of peripheral blood that has been prepared to include a higher than baseline concentration of platelets) is under investigation as an adjunctive treatment in assisted reproductive technology (ART) to purportedly improve reproductive outcomes through stimulating endometrial tissue growth or increasing the availability of viable eggs.
- **Prescription drug therapy** Medication administration to correct hormone levels or to be used in conjunction with other assistive reproductive procedures may be appropriate.
- **Reversal of elective sterilization** Individual has previously chosen to have an elective sterilization procedure (eg, tubal ligation, vasectomy) and later desires to have the procedure reversed.
- Sperm retrieval procedures include, but may not be limited to:
 - Electro-ejaculation An electric probe is inserted into the rectum, adjacent to the prostate gland.
 This probe creates a stimulus voltage which excites nearby nerves, resulting in contraction of the pelvic muscles and ejaculation.
 - Microsurgical epididymal sperm aspiration (MESA) Technique for collecting sperm that involves using a surgical microscope to open the small tubes within the epididymis to look for sperm.

- Testicular sperm aspiration (TESA) Procedure where a needle is inserted in the testicle and sperm are aspirated.
- **Surgical procedures to correct issues** that may hinder fertility or assisted reproduction technology efforts include, but may not be limited to:
 - Metroplasty (hysteroplasty) Reconstructive surgery used to repair congenital anomalies of the uterus.
 - o **Myomectomy** Removal of submucosal or intramural fibroids that distort the uterine cavity.
 - Salpingectomy Performed to treat fallopian tube occlusion or prior to ART to prevent ectopic pregnancy; 1 or both of the fallopian tubes may be removed.
 - o **Salpingostomy** Creation of an opening into the fallopian tube, but the tube itself is not removed.
 - Varicocelectomy Removes swollen veins inside the scrotum (varicocele) which may be restricting blood flow that could be impacting sperm or testosterone production.
- **Surrogacy** Arrangement in which an individual (the surrogate) agrees to carry and give birth to a child on behalf of another person or couple.
- **Uterine transplant** Major surgical procedure currently in clinical trials where a healthy uterus from one individual is placed into another individual's body in order to replace an absent or diseased uterus and allow that individual to possibly become pregnant.
- **Zygote intrafallopian transfer (ZIFT)** Used when a blockage in the fallopian tubes prevents the normal binding of sperm to the egg. Eggs are removed from ovaries and fertilized. The resulting zygote is placed into the fallopian tube by laparoscopy.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

Infertility Evaluation and Treatment

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically

necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

<u>US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage</u>

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
49320	Laparoscopy, abdomen, peritoneum, and omentum, diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)	
49321	Laparoscopy, surgical; with biopsy (single or multiple)	
49322	Laparoscopy, surgical; with aspiration of cavity or cyst (eg, ovarian cyst) (single or multiple)	
52402	Cystourethroscopy with transurethral resection or incision of ejaculatory ducts	
53899	Unlisted procedure, urinary system	
54500	Biopsy of testis, needle (separate procedure)	
54505	Biopsy of testis, incisional (separate procedure)	
54800	Biopsy of epididymis, needle	
54840	Excision of spermatocele, with or without epididymectomy	
54900	Epididymovasostomy, anastomosis of epididymis to vas deferens; unilateral	
54901	Epididymovasostomy, anastomosis of epididymis to vas deferens; bilateral	
55110	Scrotal exploration	
55200	Vasotomy, cannulization with or without incision of vas, unilateral or bilateral (separate procedure)	
55300	Vasotomy for vasograms, seminal vesiculograms, or epididymograms, unilateral or bilateral	
55400	Vasovasostomy, vasovasorrhaphy	

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55530	Excision of varicocele or ligation of spermatic veins for varicocele; (separate procedure)	
55535	Excision of varicocele or ligation of spermatic veins for varicocele; abdominal approach	
55540	Excision of varicocele or ligation of spermatic veins for varicocele; with hernia repair	
55550	Laparoscopy, surgical, with ligation of spermatic veins for varicocele	
55870	Electroejaculation	
58100	Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method (separate procedure)	
58140	Myomectomy, excision of fibroid tumor(s) of uterus, 1 to 4 intramural myoma(s) with total weight of 250 g or less and/or removal of surface myomas; abdominal approach	
58145	Myomectomy, excision of fibroid tumor(s) of uterus, 1 to 4 intramural myoma(s) with total weight of 250 g or less and/or removal of surface myomas; vaginal approach	
58146	Myomectomy, excision of fibroid tumor(s) of uterus, 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g, abdominal approach	
58321	Artificial insemination; intra-cervical	
58322	Artificial insemination; intra-uterine	
58323	Sperm washing for artificial insemination	
58340	Catheterization and introduction of saline or contrast material for saline infusion sonohysterography (SIS) or hysterosalpingography	
58345	Transcervical introduction of fallopian tube catheter for diagnosis and/or re-establishing patency (any method), with or without hysterosalpingography	
58350	Chromotubation of oviduct, including materials	
58540	Hysteroplasty, repair of uterine anomaly (Strassman type)	
58545	Laparoscopy, surgical, myomectomy, excision; 1 to 4 intramural myomas with total weight of 250 g or less and/or removal of surface myomas	
58546	Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g	
58555	Hysteroscopy, diagnostic (separate procedure)	
58558	Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D & C	

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58559	Hysteroscopy, surgical; with lysis of intrauterine adhesions (any method)	
58560	Hysteroscopy, surgical; with division or resection of intrauterine septum (any method)	
58660	Laparoscopy, surgical; with lysis of adhesions (salpingolysis, ovariolysis) (separate procedure)	
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)	
58662	Laparoscopy, surgical; with fulguration or excision of lesions of the ovary, pelvic viscera, or peritoneal surface by any method	
58672	Laparoscopy, surgical; with fimbrioplasty	
58673	Laparoscopy, surgical; with salpingostomy (salpingoneostomy)	
58700	Salpingectomy, complete or partial, unilateral or bilateral (separate procedure)	
58740	Lysis of adhesions (salpingolysis, ovariolysis)	
58750	Tubotubal anastomosis	
58752	Tubouterine implantation	
58760	Fimbrioplasty	
58770	Salpingostomy (salpingoneostomy)	
58970	Follicle puncture for oocyte retrieval, any method	
58974	Embryo transfer, intrauterine	
58976	Gamete, zygote, or embryo intrafallopian transfer, any method	
58999	Unlisted procedure, female genital system (nonobstetrical)	
74440	Vasography, vesiculography, or epididymography, radiological supervision and interpretation	
74740	Hysterosalpingography, radiological supervision and interpretation	
74742	Transcervical catheterization of fallopian tube, radiological supervision and interpretation	
76830	Ultrasound, transvaginal	
76831	Saline infusion sonohysterography (SIS), including color flow Doppler, when performed	
76856	Ultrasound, pelvic (nonobstetric), real time with image documentation; complete	
76857	Ultrasound, pelvic (nonobstetric), real time with image documentation; limited or follow-up (eg, for follicles)	
76870	Ultrasound, scrotum and contents	
76872	Ultrasound, transrectal;	

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76948	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation	
80414	Chorionic gonadotropin stimulation panel; testosterone response This panel must include the following: Testosterone (84403 x 2 on 3 pooled blood samples)	
80415	Chorionic gonadotropin stimulation panel; estradiol response This panel must include the following: Estradiol, total (82670 x 2 on 3 pooled blood samples)	
80426	Gonadotropin releasing hormone stimulation panel This panel must include the following: Follicle stimulating hormone (FSH) (83001 \times 4) Luteinizing hormone (LH) (83002 \times 4)	
80438	Thyrotropin releasing hormone (TRH) stimulation panel; 1 hour This panel must include the following: Thyroid stimulating hormone (TSH) (84443 x 3)	
81015	Urinalysis; microscopic only	
81403	MOLECULAR PATHOLOGY PROCEDURE LEVEL 4	
82397	Chemiluminescent assay	
82626	Dehydroepiandrosterone (DHEA)	
82627	Dehydroepiandrosterone-sulfate (DHEA-S)	
82670	Estradiol; total	
82671	Estrogens; fractionated	
82672	Estrogens; total	
82679	Estrone	
82757	Fructose, semen	
83001	Gonadotropin; follicle stimulating hormone (FSH)	
83002	Gonadotropin; luteinizing hormone (LH)	
83498	Hydroxyprogesterone, 17-d	
83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified	
84144	Progesterone	
84146	Prolactin	
84402	Testosterone; free	
84403	Testosterone; total	
84443	Thyroid stimulating hormone (TSH)	
84830	Ovulation tests, by visual color comparison methods for human luteinizing hormone	
86950	Leukocyte transfusion	
89240	Unlisted miscellaneous pathology test	
89250	Culture of oocyte(s)/embryo(s), less than 4 days;	

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89251	Culture of oocyte(s)/embryo(s), less than 4 days; with co-culture of oocyte(s)/embryos	
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, microtechnique; 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	
89300	Semen analysis; presence and/or motility of sperm including Huhner test (post coital)	
89310	Semen analysis; motility and count (not including Huhner test)	
89320	Semen analysis; volume, count, motility, and differential	
89321	Semen analysis; sperm presence and motility of sperm, if performed	
89322	Semen analysis; volume, count, motility, and differential using strict morphologic criteria (eg, Kruger)	
89325	Sperm antibodies	
89329	Sperm evaluation; hamster penetration test	
89330	Sperm evaluation; cervical mucus penetration test, with or without spinnbarkeit test	

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89331	Sperm evaluation, for retrograde ejaculation, urine (sperm concentration, motility, and morphology, as indicated)	
89335	Cryopreservation, reproductive tissue, testicular	
89337	Cryopreservation, mature oocyte(s)	
89342	Storage (per year); embryo(s)	
89343	Storage (per year); sperm/semen	
89344	Storage (per year); reproductive tissue, testicular/ovarian	
89346	Storage (per year); oocyte(s)	
89352	Thawing of cryopreserved; embryo(s)	
89353	Thawing of cryopreserved; sperm/semen, each aliquot	
89354	Thawing of cryopreserved; reproductive tissue, testicular/ovarian	
89356	Thawing of cryopreserved; oocytes, each aliquot	
89398	Unlisted reproductive medicine laboratory procedure	
96040	Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family	
0253U	Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (eg, pre-receptive, receptive, post-receptive)	
CPT®		
Category III Code(s)	Description	Comments
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed	
0664T	Donor hysterectomy (including cold preservation); open, from cadaver donor	
0665T	Donor hysterectomy (including cold preservation); open, from living donor	
0666T	Donor hysterectomy (including cold preservation); laparoscopic or robotic, from living donor	
0667T	Donor hysterectomy (including cold preservation); recipient uterus allograft transplantation from cadaver or living donor	

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0668T	Backbench standard preparation of cadaver or living donor uterine allograft prior to transplantation, including dissection and removal of surrounding soft tissues and preparation of uterine vein(s) and uterine artery(ies), as necessary	
0669T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; venous anastomosis, each	
0670T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; arterial anastomosis, each	
0255U	Andrology (infertility), sperm-capacitation assessment of ganglioside GM1 distribution patterns, fluorescence microscopy, fresh or frozen specimen, reported as percentage of capacitated sperm and probability of generating a pregnancy score	
HCPCS Code(s)	Description	Comments
G0027	Semen analysis; presence and/or motility of sperm excluding Huhner	
P9020	Platelet rich plasma, each unit	
Q0115	Postcoital direct, qualitative examinations of vaginal or cervical mucous	

References

1. Centers for Medicare & Medicaid Services (CMS). Medicare Benefit Policy Manual. Covered medical and other health services. https://www.cms.gov. Updated August 3, 2003. Accessed November 7, 2023.

Change Summary

- 01/01/2024 New Policy.

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