oscar

Clinical Guideline

Guideline Number: CG016, Ver. 5

Diagnosis and Treatment of Infertility

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates, who may develop and adopt their own clinical criteria.

Clinical guidelines are applicable to certain plans. Clinical guidelines are applicable to members enrolled in Medicare Advantage plans only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of a prior authorization request. Services are subject to the terms, conditions, limitations of a member's policy and applicable state and federal law. Please reference the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

Summary

Oscar covers the diagnosis and treatment of infertility when the cause of infertility is a result of anatomical, acquired disease, inherited disease or other conditions resulting in an inability to conceive or establish pregnancy. Basic services to determine the cause of infertility may include semen analysis, serum hormone levels, hysterosalpingogram, and evaluation of ovulatory function. If basic infertility services do not result in a pregnancy, comprehensive services may include surgical and non-surgical treatments (e.g., ovulation induction, intrauterine insemination).

Note: Services for infertility may include diagnosis, treatment, or fertility preservation, and coverage is subject to the terms, conditions, limitations of a member's policy and applicable state and federal law.

Definitions

"Infertility" refers to the failure to establish a successful pregnancy after 12 months/cycles for women ages 21 - 35, or after 6 months/cycles for women ages 35 - 45, of unprotected heterosexual intercourse or therapeutic donor insemination. Infertility may be caused by disease, dysfunction, or malformation.

- Primary infertility refers to couples who have never established a successful pregnancy.

- Secondary infertility refers to couples who are experiencing infertility after having a history of establishing a successful pregnancy.

"**Iatrogenic Infertility**" refers to transient or permanent infertility caused by a necessary medical intervention such as chemotherapy, pelvic radiotherapy, gonadotoxic therapies, or the surgical removal of the reproductive organs for the treatment of disease.

"Recurrent Pregnancy Loss" refers to two or more failed pregnancies, or miscarriages, and is not considered infertility.

"Pregnancy" refers to clinical pregnancy documented by ultrasonography or histopathologic examination.

Clinical Indications and Coverage

General Coverage Criteria

Oscar will cover infertility services when the following criteria are met:

1. The requested service is covered per the member's benefit policy; ***and***
2. Infertility services are not being requested beyond 8 weeks of pregnancy; ***and***
3. Infertility is the result of disease, dysfunction, or malformation.
    a. Infertility is not defined to include the inability to conceive due to lack of a sex partner or having a same sex partner; ***and***
4. For ages 21 - 35, after trying to conceive after 12 months; ***and***
5. For ages 35 - 45, after trying to conceive after 6 months; ***and***
6. For comprehensive infertility services, clinical documentation indicates that basic fertility services did not result in a pregnancy; ***and***
7. For assisted reproductive technology, clinical documentation indicates that comprehensive fertility services did not result in a pregnancy and MCG A-0504 criteria is met; ***and***
8. For fertility preservation due to iatrogenic infertility, MCG A-0504 criteria is met.

Basic Infertility Services (Diagnosis)

Basic **female** infertility services may include:

- Initial Evaluation: History & Physical Exam
- Laboratory: Chlamydia Trachomatis screening, Rubella serology, viral status screening (HIV, Hepatitis B, Hepatitis C), TSH, Prolactin, FSH, Estradiol, Progesterone, Luteinizing Hormone, human chorionic gonadotropin, androgens (if there is evidence of hyperandrogenism), anti-mullerian hormone, Clomiphene citrate challenge test, Genetic karyotyping (Chromosome

analysis)

- Imaging: Sonohysterography (Saline Infusion Sonography), Pelvic or Transvaginal Ultrasonography, Hysterosalpingography, Hysteroscopy
- Diagnostic Procedures: Laparoscopy and chromotubation

Basic **male** infertility services may include:

- Initial Evaluation: History & Physical Exam
- Laboratory: Chlamydia Trachomatis screening, viral status screening (HIV, Hepatitis B, Hepatitis C), TSH, FSH, LH, PRL, Total and free Testosterone (T), estrogens, Genetic karyotyping
- (Chromosome analysis), Y-Chromosome Microdeletions
- Post-Ejaculatory Urinalysis
- Imaging: CT or MR imaging of sella turcica if prolactin is elevated, Transrectal or Scrotal Ultrasonography, Vasography or Venography
- Tissue Analysis or Testis Biopsy
- Scrotal exploration
- Semen & Sperm Analysis
    - Quantification of Leukocytes in Semen
    - Sperm concentration and motility
    - Seminal fructose
    - Cultures of prostatic secretion, semen, urine

Comprehensive Infertility Services (Treatment)

Comprehensive **female** infertility services may include:

- Non-Surgical Treatments
    - Endocrine management
    - Gonadotropins, Gonadotropin releasing hormone (GnRH), Gonadotropin releasing hormone (GnRH) antagonists, Corticosteroids, Estrogens, Progestins, Aromatase inhibitors, Lutropin alfa in combination with human FSH
    - Electroejaculation for diabetic neuropathy, prior retroperitoneal surgery or spinal cord injury
    - Hepatitis B vaccination of partners of people with hepatitis B
    - Rubella vaccination of women susceptible to rubella
    - Tamoxifen or oral clomiphene citrate for ovulation induction
    - Metformin for women with anovulatory disorders such as polycystic ovarian syndrome
    - Prolactin inhibitors for women with hyperprolactinemia
    - Artificial/intrauterine insemination [IUI] (including sperm washing)
    - Donor insemination for **ONE** of the following indications:

        - Obstructive or non-obstructive azoospermia; ***or***
        - Severe deficits in semen quality in couples who do not wish to undergo intracytoplasmic sperm injection (ICSI); ***or***
        - Severe rhesus isoimmunization; ***or***
        - High risk of transmitting a genetic disorder or infectious disease (such as HIV) in the male partner to the offspring.
- Surgery and Imaging, when MCG criteria is met:
    - Hysteroscopic adhesiolysis for women with amenorrhea and intrauterine adhesions
    - Hysteroscopic or fluoroscopic tubal cannulation (salpingostomy, fimbrioplasty), selective salpingography plus tubal catheterization, or transcervical balloon tuboplasty for women with proximal tubal obstruction
    - Laparoscopy for treatment of pelvic pathology
    - Open or laparoscopic resection, vaporization, or fulguration of endometriosis implants plus adhesiolysis in women with endometriosis
    - Ovarian wedge resection or ovarian drilling for women with polycystic ovarian syndrome who have not responded to clomiphene citrate and comparable estrogen modulators such as letrozole
    - Removal of myomas, uterine septa, cysts, ovarian tumors, and polyps
    - Surgical tubal reconstruction (unilateral or bilateral tubal microsurgery, laparoscopic tubal surgery, tuboplasty and tubal anastomosis), except in the case of prior tubal sterilization

Advanced Reproductive Technologies

Advanced reproductive technologies may include:

- In vitro fertilization (IVF)
- Gamete intrafallopian tube transfers (GIFT)
- Zygote intrafallopian tube transfers (ZIFT)
- Donor services (oocyte, ovum, sperm)

Fertility Preservation

Fertility preservation may include:

- Cryopreservation and storage of the following:
    - Ejaculated or testicular sperm
    - Embryo, with or without ovarian stimulation
    - Mature oocytes

    - Ovarian tissue for prepubertal patients or when there is not time for ovarian stimulation
- Gonadotropin releasing hormone (GnRH) agonists for patients with breast cancer and potentially other cancers for the purpose of protection from ovarian insufficiency
- Ovarian transposition (oophoropexy) for patients undergoing pelvic radiation
- Radiation (gonadal) shielding
- Cervicectomy/trachelectomy for patients with early stage (IA2 or small IB1) cervical adenocarcinoma
- Laparoscopic cystectomy for patients with ovarian endometriomas or early stage ovarian cancer

Coverage Exclusions

Services or procedures considered experimental, investigational, or unproven are not covered, including but not limited to:

- Acrosome reaction test
- Acupuncture
- Bariatric surgery
- Comet assay
- Computer-assisted sperm analysis (CASA)/computer-assisted sperm motion analysis
- Cryopreservation, storage, and thawing of immature oocytes
- Cryopreservation, storage, and thawing of testicular tissue
- Dehydroepiandrosterone (DHEA)
- Direct intra-peritoneal insemination, fallopian tube sperm transfusion, intra-follicular insemination, and the use of sperm precursors
- Double IUI (intrauterine insemination)
- Drainage of ovarian cyst, when billed for egg retrieval
- EmbryoGlue
- Endometrial receptivity testing, uterine receptivity testing
- Fine needle aspiration ("mapping") of testes
- FSH manipulation of women with elevated FSH levels
- Gonadotropin releasing hormone (GnRH) agonists or antagonists for males
- Growth hormone (GH) and growth hormone antagonists
- Hemizona assay
- Hyaluronan binding assay
- Hypoosmotic swelling test
- Intravenous immunoglobulins
- In-vitro maturation (IVM) of oocytes
- In-vitro testing of sperm penetration

- Leukocyte immunization (immunizing the female partner with the male partner's leukocytes)
- Microdissection of the zona
- Natural killer (NK) cell measurement
- Partial zonal dissection (PZD)
- Reactive oxygen species (ROS) test
- Sonohysterosalpingography or saline hysterosalpingography for tubal occlusion
- Sperm chromatin assay
- Sperm DNA condensation test
- Sperm DNA fragmentation assay
- Sperm function tests
- Sperm nucleus maturation
- Subzonal sperm insertion (SUZI)
- TUNEL assay
- Uterine Transplant

Applicable Billing Codes

Codes covered if clinical criteria are met:

Infertility Services	
Code	*Description*
49203	Excision or destruction, open, intra-abdominal tumors, cysts or endometriomas, 1 or more peritoneal, mesenteric, or retroperitoneal primary or secondary tumors; largest tumor 5 cm diameter or less
49204	Excision or destruction, open, intra-abdominal tumors, cysts or endometriomas, 1 or more peritoneal, mesenteric, or retroperitoneal primary or secondary tumors; largest tumor 5.1-10.0 cm diameter
49205	Excision or destruction, open, intra-abdominal tumors, cysts or endometriomas, 1 or more peritoneal, mesenteric, or retroperitoneal primary or secondary tumors; largest tumor greater than 10.0 cm diameter
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)
54500, 54505	Biopsy, Testis
55110	Scrotal exploration

55870	Electroejaculation
57530	Trachelectomy (cervicectomy), amputation of cervix (separate procedure)
58925	Ovarian cystectomy, unilateral or bilateral
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
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)
58558-58563	Hysteroscopy
58575	Laparoscopy, surgical, total hysterectomy for resection of malignancy (tumor debulking), with omentectomy including salpingo-oophorectomy, unilateral or bilateral, when performed
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)
58720	Salpingo-oophorectomy, 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)
58800	Drainage of ovarian cyst(s), unilateral or bilateral (separate procedure); vaginal approach
58805	Drainage of ovarian cyst(s), unilateral or bilateral (separate procedure); abdominal approach
58900	Biopsy of ovary, unilateral or bilateral (separate procedure)
58920	Wedge resection or bisection of ovary, unilateral or bilateral
58974	Embryo Transfer, Intrauterine
58976	Gamete, zygote, or embryo intrafallopian transfer, any method
70480 - 70482	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear (CT scan of sella turcica)
70551 - 70553	Magnetic resonance (eg, proton) imaging, brain (including brain stem) [MR of sella turcica]
74440	Vasography, vesiculography, or epididymography, radiological supervision and interpretation
74740	Hysterosalpingography, 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
76870	Ultrasound, scrotum and contents
76872	Ultrasound, transrectal
80400-80426	Serum Hormone Levels (TSH, FSH, LH, PRL, Total Testosterone (T) Concentrations, Inhibin B, Progesterone, Estrogen, Estradiol)
80426	Gonadotropin releasing hormone stimulation panel This panel must include the following: Follicle stimulating hormone (FSH) (83001 x 4) Luteinizing hormone (LH) (83002 x 4)
82670-82679	Non-injectable medication; Estrogen
86631	Antibody; Chlamydia
86632	Antibody; Chlamydia, IgM
86689	Antibody; HTLV or HIV antibody, confirmatory test (eg, Western Blot)
86701	Antibody; HIV-1
86702	Antibody; HIV-2
86703	Antibody; HIV-1 and HIV-2, single result
86704	Hepatitis B core antibody (HBcAb); total
86705	Hepatitis B core antibody (HBcAb); IgM antibody
86706	Hepatitis B surface antibody (HBsAb)
86762	Antibody; rubella
86803	Hepatitis C antibody
86804	Hepatitis C antibody; confirmatory test (eg, immunoblot)
87110	Culture, chlamydia, any source
87270	Infectious agent antigen detection by immunofluorescent technique; Chlamydia trachomatis

87340	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; hepatitis B surface antigen (HBsAg)
87341	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; hepatitis B surface antigen (HBsAg) neutralization
88261	Chromosome analysis; count 5 cells, 1 karyotype, with banding
88262	Chromosome analysis; count 15-20 cells, 2 karyotypes, with banding
88263	Chromosome analysis; count 45 cells for mosaicism, 2 karyotypes, with banding
88264	Chromosome analysis; analyze 20-25 cells
88280	Chromosome analysis; additional karyotypes, each study
88283	Chromosome analysis; additional specialized banding technique (eg, NOR, C-banding)
88285	Chromosome analysis; additional cells counted, each study
88289	Chromosome analysis; additional high resolution study
88364-88366	Fluorescent In-Situ Hybridization, Sperm Chromosome Aneuploidy
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
89280	Assisted oocyte fertilization, microtechnique; less than or equal to 10 oocytes
89281	Assisted oocyte fertilization, microtechnique; greater than 10 oocytes
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
89331	Sperm evaluation, for retrograde ejaculation, urine (sperm concentration, motility, and morphology, as indicated)
G0010	Administration of hepatitis B vaccine
G0027	Semen analysis; presence and/or motility of sperm excluding Huhner
G0472	Hepatitis C antibody screening for individual at high risk and other covered indication(s)
J0725	Injection, chorionic gonadotropin, per 1,000 USP units
J1000	Injection, depo-estradiol cypionate, up to 5 mg
J1094	Injection, dexamethasone acetate, 1 mg
J1100	Injection, dexamethasone sodium phosphate, 1 mg
J1380	Injection, estradiol valerate, up to 10 mg
J1410	Injection, estrogen conjugated, per 25 mg
J1620	Injection, gonadorelin HCI, per 100 mcg
J2675	Injection, progesterone, per 50 mg
J3355	Injection, urofollitropin, 75 IU
J7512	Prednisone, immediate release or delayed release, oral, 1 mg
J9218	Leuprolide acetate, per 1 mg
S0122	Injection, menotropins, 75 IU
S0126	Injection, follitropin alfa, 75 IU
S0128	Injection, follitropin beta, 75 IU

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 of development
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
S4028	Microsurgical epididymal sperm aspiration (MESA)
S4035	Stimulated intrauterine insemination (IUI), case rate
S4037	Cryopreserved embryo transfer, case rate
ICD-10 codes covered:	
Code	*Description*
N97.1 - N97.9	Female infertility
N46.01- N46.9	Male Infertility
Z31.7	Encounter for procreative management and counseling for gestational carrier
Z31.83	Encounter for assisted reproductive fertility procedure cycle
Z31.89	Encounter for other procreative management
ICD-10 codes not covered for the above procedures:	

N92.4, N95.0 - N95.9	Menopausal and other perimenopausal disorders
Q50.02	Congenital absence of ovary, bilateral
Q55.0	Absence and aplasia of testis
Z31.0	Encounter for reversal of previous sterilization
Z78.0	Asymptomatic menopausal state
Z79.890	Hormone replacement therapy (postmenopausal)
Z98.51-Z98.52	Sterilization status

Codes covered if clinical criteria are met:

Fertility Preservation	
Code	*Description*
0058T	Cryopreservation; reproductive tissue, ovarian
89258	Cryopreservation; embryo(s)
89259	Cryopreservation; sperm
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
S4027	Storage of previously frozen embryos
S4030	Sperm procurement and cryopreservation services; initial visit
S4031	Sperm procurement and cryopreservation services; subsequent visit

S4040	Monitoring and storage of cryopreserved embryos, per 30 days
ICD-10 codes covered:	
C.00.0 - D49	Neoplasms
D27.0 - D27.1, D39.10 - D39.12	Neoplasm of ovary
D40.10 - D40.12	Neoplasm of testis
N70.01 - N70.03	Acute salpingitis and oophoritis
N70.11 - N70.13	Chronic salpingitis and oophoritis
N83.511 - N83.519	Torsion of ovary and ovarian pedicle
Z31.84	Encounter for fertility preservation procedure

CPT/HCPCS codes considered experimental or investigational for infertility:	
Code	*Description*
10004	Fine needle aspiration of additional lesion
10005	Fine needle aspiration of first lesion using ultrasound guidance
10006	Fine needle aspiration of additional lesion using ultrasound guidance
10007	Fine needle aspiration of first lesion using fluoroscopic guidance
10008	Fine needle aspiration of additional lesion using fluoroscopic guidance
10009	Fine needle aspiration of first lesion using CT guidance
10010	Fine needle aspiration of additional lesion using CT guidance
10011	Fine needle aspiration of first lesion using MR guidance
10012	Fine needle aspiration of additional lesion using MR guidance
10021	Fine needle aspiration; without imaging guidance [Fine needle aspiration ("mapping") of testes]
43631 - 43635 43644 - 43645	Bariatric Surgery

43770 - 43775 43842 - 43848 43886 - 43888	
82626	Dehydroepiandrosterone (DHEA)
86357	Natural killer (NK) cells, total count
89240	Unlisted miscellaneous pathology test [Sperm DNA Fragmentation Testing]
89335	Cryopreservation, reproductive tissue, testicular
89398	Unlisted reproductive medicine laboratory procedure **[when billed for Cryopreservation of immature oocytes]**
97810 - 97814	Acupuncture
S9558	Home injectable therapy; growth hormone, including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

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Clinical Guideline Revision / History Information

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