MEDICAL COVERAGE POLICY	
SERVICE: Infertility/Assisted Reproductive Technology	
Policy Number:	**141**
Effective Date:	**11/01/2020**
Last Review:	**09/24/2020**
Next Review Date:	**09/24/2021**

Important note
Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the following website: http://cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp

SERVICE: Infertility/Assisted Reproductive Technology

PRIOR AUTHORIZATION: Not required. Genetic/genomic testing requires prior authorization.

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for coverage details.

For Medicare plans, please refer to appropriate Medicare LCD (Local Coverage Determination). If there is no applicable LCD, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid TMPPM.

The following evaluations may be considered medically necessary in the diagnostic work up of a couple with infertility. All tests are not necessary for each individual; rather testing is performed in a stepwise fashion based upon history and prior results.

Definition of Infertility - the inability to conceive after one year of unprotected intercourse (six months if the woman is age 35 years or older) or the inability to carry a pregnancy to live birth. Evaluation for infertility may be initiated sooner in patients who have risk factors for infertility.

Evaluation of the male:

1. history and physical examination
2. semen analysis: semen volume, concentration, motility, pH, fructose, leukocyte count, microbiology, and morphology.
3. laboratory tests: endocrine evaluation (including FSH, total and free testosterone, prolactin, LH, TSH), antisperm antibodies, post-ejaculatory urinalysis
4. transrectal ultrasound, scrotal ultrasound
5. vasography and testicular biopsy for azoospermia
6. scrotal exploration

Evaluation of the female:

1. history and physical examination
2. laboratory tests: thyroid stimulating hormone (TSH), prolactin, follicle stimulating hormone (FSH), luteinizing hormone (LH), estradiol, progesterone
3. ultrasound of the pelvis

4. hysteroscopy
5. hysterosalpingography
6. sonohysterography
7. diagnostic laparoscopy with or without chromotubation

Infertility treatment is **NOT** a covered benefit for most SWHP/FirstCare plan. Where the benefit is present, the following services may be medically necessary:

Female infertility treatment in plans with a benefit:

1. FDA-approved ovulation induction medications
2. ovulation monitoring studies, i.e., ultrasound and endocrine evaluation
3. tubal recanalization, fluoroscopic/hysteroscopic selective tube cannulation, tuboplasty, salpingostomy, fimbrioplasty, tubal anastomosis, and salpingectomy
4. surgical laparoscopy, therapeutic hysteroscopy, cervical recanalization, lysis of adhesions, myomectomy, removal of tumors and cysts, septate uterus repair, ovarian wedge resection, ovarian drilling
5. ovarian reserve testing using anti-mullerian hormone (AMH) level, cycle day 3 FSH, ultrasonography for antral follicle assessment, or clomiphene challenge test when ANY of the following criteria is met:
    - women age 35 years or older
    - family history of early menopause
    - single ovary or history or previous ovarian surgery, chemotherapy, or pelvic radiation therapy
    - unexplained infertility
    - previous poor response to gonadotropin stimulation
    - planning treatment with assisted reproductive technologies (e.g., IVF)
6. in vitro fertilization with embryo transfer, in vitro with elective single embryo transfer, tubal embryo transfer, low tubal ovum transfer, pronuclear stage transfer, or natural cycle IVF, and associated services, including the following: ovulation induction, oocyte retrieval, sperm preparation and washing, associated laboratory tests and ultrasounds, mock embryo transfer/uterine sounding, embryo assessment and transfer, and embryologist services
7. assisted embryo hatching for women with ANY of the following criteria:
    - individuals 38 years of age or older
    - elevated day-3 FSH
    - increased zona thickness on microscopy
    - three or more IVF-attempt failures related to failed implantation
8. gamete intrafallopian transfer and associated services
9. zygote intrafallopian transfer and associated services
10. intracytoplasmic sperm injection and associated services, including sperm extraction and retrieval procedures

Male infertility treatment in plans with a benefit:

1. semen analysis
2. Kruger strict criteria for sperm morphology

3. pharmacologic treatment of endocrinopathies including hypogonadotropic hypogonadism with FDA-approved drugs such as human chorionic gonadotropins, human menopausal gonadotropin or pulsatile gonadotropin-releasing hormone, corticosteroids, and androgens
4. surgical/microsurgical reconstruction or repair of the vas and/or epididymis or other epididymis surgery, such as vasovasostomy, epididymovasostomy, and epididymectomy
5. transurethral resection of the ejaculatory ducts for the treatment of ejaculatory duct obstruction
6. repair of varicocele, excision of tumors (e.g., epididymal), testicular biopsy, orchiopexy, spermatic vein ligation, and excision of spermatocele
7. seminal tract washout
8. sperm extraction and retrieval procedures such as: electroejaculation, microsurgical epididymal sperm aspiration, testicular sperm aspiration, testicular fine needle aspiration, testicular sperm extraction (TESE), microscopic-TESE, percutaneous epididymal sperm aspiration, vasal sperm aspiration, and seminal vesicle sperm aspiration

The following services or tests are considered experimental, investigational, or unproven:

1. acupuncture
2. hyperbaric oxygen therapy for IVF and/ or treatment of male factor infertility
3. intravaginal culture of oocytes (e.g., INVOcell)
4. immunological testing (e.g., antiprothrombin antibodies, embryotoxicity assay, circulating natural killer cell measurement, antiphopholipid antibodies, reproductive immunophenotype [RIP], T1 and T2 Helper ratios)
5. immune treatments (e.g., peri-implantation glucocorticoids, anti-tumor necrosis factor agents, leukocyte immunization, IV immunoglobulins)
6. computer-assisted sperm motion analysis
7. cryopreservation, storage, thawing, and re-transplantation of ovarian and testicular reproductive tissue
8. culture of oocyte(s), embryo(s), less than 4 days with co-culture (i.e., co-culturing of embryos/oocytes)
9. direct intraperitoneal insemination, intrafollicular insemination, fallopian tube sperm transfusion
10. endometrial receptivity testing (e.g., Endometrial Function Test™, integrin testing, Beta-3 integrin test, E-tegrity®, endometrial receptivity array
11. fine needle aspiration mapping
12. hemizona test
13. hyaluronan binding assay
14. serum inhibin B
15. sperm viability test (e.g., hypo-osmotic swelling test), when performed as a diagnostic test
16. the use of sperm precursors (i.e., round or elongated spermatid nuclei, immature sperm) in the treatment of infertility
17. manual soft tissue therapy for the treatment of pelvic adhesions (WURN Technique®, Clear Passage Therapy)
18. laser-assisted necrotic blastomere removal from cryopreserved embryos
19. reactive oxygen species testing

20. time-lapse monitoring/imaging of embryos (e.g., EmbryoScope, Eeva™ Test)
21. uterine transplantation
22. vaginal microbiome testing (e.g., SmartJane™ screening test)
23. saline-air infused sono-hysterosalpingogram (e.g., femVue®)

OVERVIEW: Infertility is defined as the failure to achieve pregnancy after twelve months of unprotected intercourse in women < 35, and after six months in women age 35 and over. U.S. prevalence is estimated at seven to eight percent. The term primary infertility is applied to a couple who has never achieved a pregnancy, while secondary infertility indicates that at least one previous conception has taken place. Infertility may be due to a male factor(s), female factor(s), or a combination of both. An infertility evaluation involves an investigation of potential problems in both partners with the intent of identifying modifiable factors. Diagnoses and treatments range from the very simple to the highly complex. The causes are generally distributed as follows;

- Male factor 26%
- Ovulation problems 21%
- Tubal damage 14%
- Endometriosis 6%
- Coital problems 6%
- Cervical factor 3%
- Unexplained 28%

Most SWHP/FirstCare EOCs or SPDs provide a benefit for the diagnosis of the cause(s) of infertility, but NOT for infertility treatment expect as a rider to the contract.

MANDATES: TIC 1366.003-1366.004; 28 TAC 11.510(1) – Unless rejected in writing by the group contract holder, any evidence of coverage (EOC) providing coverage for pregnancy related procedures must offer and make available coverage for outpatient expenses that may arise from in vitro fertilization procedures.

SENIOR CARE (CMS): There are no Medicare NCDs or LCDs issued.

CODES:

Important note:
CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	These codes may be part of infertility care: 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 (e.g., ovarian cyst) (single or multiple) 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 vasogram, seminal vesiculograms, or epididymograms, unilateral or bilateral 55400 Vasovasostomy, vasovasorrhaphy 55550 Laparoscopy, surgical, with ligation of spermatic veins for varicocele 55870 Electroejaculation 55870 Electroejaculation 58100 Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method (separate procedure) 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 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 58555 Hysteroscopy, diagnostic (separate procedure) 58558 Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D & C 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 58740 Lysis of adhesions (salpingolysis, ovariolysis) 58750 Tubotubal anastomosis 58752 Tubouterine implantation 58760 Fimbrioplasty 58770 Salpingostomy (salpingoneostomy) 58900 Biopsy of ovary, unilateral or bilateral (separate procedure) 58970 Follicle puncture for oocyte retrieval, any method 58974 Embryo transfer, intrauterine 58976 Gamete, zygote, or embryo intrafallopian transfer, any method 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 76830 Ultrasound, transvaginal 76831 Saline infusion sonohysterosonography (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 76948 Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation 81025 Urine pregnancy test, by visual color comparison methods 82670 Estradiol 82670 Estradiol 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-p 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 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)/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) 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 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) 89343 Storage, (per year); sperm/semen 89353 Thawing of cryopreserved; sperm/semen, each aliquot
HCPCS codes:	These codes may be part of infertility care: G0027 Semen analysis; presence and/or motility of sperm excluding huhner Q0115 Post-coital direct, qualitative examinations of vaginal or cervical mucous S3655 Antisperm antibodies test (immunobead) 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 S4027 Storage of previously frozen embryos S4028 Microsurgical epididymal sperm aspiration (mesa) S4030 Sperm procurement and cryopreservation services 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 (interpretation of diagnostic tests and studies, non-face-to-face medical management of the patient), per cycle
ICD10 Codes:	

POLICY HISTORY:

Status	Date	Action
New	01/01/2011	New policy
Reviewed	12/12/2011	Reviewed.

Reviewed	10/4/2012	Reviewed. References updated.
Reviewed	7/11/2013	No changes
Reviewed	5/22/2014	No changes
Reviewed	5/28/2015	No changes
Reviewed	6/09/2016	No changes
Reviewed	5/16/2017	Limited corrections to criteria
Reviewed	4/17/2018	Updated code list. Medically necessary services outlined, exclusion list updated.
Reviewed	7/25/2109	Minor updates and corrections
Reviewed	9/24/2020	Re-formatted for SWHP/FirstCare

REFERENCES: The following scientific references were utilized in the formulation of this medical policy. SWHP/FirstCare will continue to review clinical evidence surrounding immune globulin and may modify this policy at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP/FirstCare so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Agency for Healthcare Research and Quality (AHRQ) Website. Effectiveness of assisted reproductive technology, May 2008. www.ahrq.gov. Accessed June 18, 2013
2. American Society for Reproductive Medicine (ASRM) Website. Correct coding for laboratory procedures during assisted reproductive technology cycles, Fertil Steril 2012; 98: 808-811. www.asrm.org. Accessed June 18, 2013.
3. American Society for Reproductive Medicine (ASRM) Website. Diagnostic evaluation of the infertile female: a committee opinion. Fertil Steril 2012; 98: 302-307., www.asrm.org. Accessed June 18, 2013.
4. American Society for Reproductive Medicine (ASRM) Website. Diagnostic evaluation of the infertile male, Fertil Steril 98: 294-301. www.asrm.org. Accessed June 18, 2013.
5. Up to Date Online, Overview of Infertility 11/22/2017; www.uptodate.com. Accessed 4/16/2018
6. Up to Date Online, Evaluation of Male Infertility 10/31/2017; www.uptodate.com. Accessed 4/16/2018
7. Up to Date Online, Evaluation of Female Infertility 10/27/2017; www.uptodate.com. Accessed 4/16/2018
8. Up to Date Online, Treatment of Female Infertility 2/28/2018, www.uptodate.com. Accessed 4/16/2018
9. Up to Date Online, Treatment of Male Infertility 2/28/2018, www.uptodate.com. Accessed 4/16/2018