

Clinical Policy Title: Infertility — diagnosis

Clinical Policy Number: CCP.1388

Effective Date: July 1, 2018
Initial Review Date: May 1, 2018
Most Recent Review Date: July 17, 2019
Next Review Date: July 2020

Policy contains:

- Male infertility.
- Female infertility.
- Family planning.

Related policies:

CCP.1239 Infertility — treatment

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina's clinical policies are not guarantees of payment.

Coverage policy

There are no federal requirements for state Medicaid programs to cover services for infertility. Decisions to offer such services as a covered benefit are left to each state benefit plan (Center for Medicaid and Children's Health Insurance Program Services, 2016).

Select Health of South Carolina considers the use of any diagnostic service for evaluation of male or female infertility to be not medically necessary. For this policy, infertility is defined as a failure to establish a clinical pregnancy after 12 months of regular, unprotected sexual intercourse with the same partner or due to an impairment of a person's capacity to reproduce either as an individual or with their partner.

For Medicare members only:

Select Health of South Carolina considers the use of any medical procedures or pharmaceuticals related to treating infertility to be reasonable and necessary. Infertility is a condition sufficiently at variance with the usual state of health to make it appropriate for a person who normally is expected to be fertile

to seek medical consultation and treatment (Medicare Benefit Policy Manual, Chapter 15 — Covered Medical and Other Health Services. Table of Contents ([Rev. 228, 10-13-16]. Section 20.1).

Limitations:

Other services may be compensable except when related to infertility, including, but not limited to, hysterosalpingography, vasography, vesiculography, epididymography, and thyroid panel.

Alternative covered services:

None.

Background

The prevalence of infertility in the United States ranges widely (7 percent to 18 percent) depending on the definition of infertility and methods for data analysis (Thoma, 2013). The American Society of Reproductive Medicine (Zegers-Hochschild, 2017) defines infertility as a disease, which generates disability as an impairment of function. Infertility is characterized by the failure to establish a clinical pregnancy after 12 months of regular, unprotected sexual intercourse or due to an impairment of a person’s capacity to reproduce either as an individual or with their partner.

Causes of infertility may be potentially correctable; irreversible, but amenable to assisted reproductive techniques; irreversible and not amenable to assisted reproductive techniques; life- or health-threatening and may require medical attention; or genetic and may affect the health of offspring if assisted reproductive techniques are to be used (American Urological Association, 2011). A variety of testing modalities exist to determine the underlying cause and to inform management of infertility.

Searches

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
- The Cochrane Library.

We conducted searches on May 6, 2019. Search terms were: “infertility/diagnosis” (MeSH), “infertility, male/diagnosis” (MeSH), “infertility, female/diagnosis” (MeSH), and free text terms “male infertility” and “female infertility.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

Guidelines agree that evaluation of infertility is indicated for partners who fail to achieve a successful pregnancy after 12 months of regular, unprotected sexual intercourse (American College of Obstetricians and Gynecologists, 2018; American Society of Reproductive Medicine, 2015a, 2015b; American Urological Association, 2011). Infertility testing may be performed after six months of regular, unprotected sexual intercourse or earlier: when the female partner is older than 35 years; with a history of oligomenorrhea or amenorrhea; with known or suspected uterine or tubal disease or Stage III to IV endometriosis; or known or suspected male subfertility. The evaluation of both partners should begin at the same time, when possible.

A comprehensive medical and reproductive history and physical examination can reveal many anatomic and physiologic causes of infertility in men and women and should be carried out with emphasis on the least invasive and most cost-effective method(s) for detecting the most common causes of infertility.

In females, evaluation of ovarian function, structure, and patency of the female reproductive tract can detect most causes of infertility (American Society for Reproductive Medicine, 2015a; Armstrong, 2017). Endoscopy and imaging modalities assist in evaluation of cervical and uterine anatomy and function, tubal patency, and peritoneal pathology. Measures of ovarian reserve, which describes reproductive potential as a function of the number and quality of oocytes, do not establish a diagnosis of diminished ovarian reserve in women of reproductive age but may predict ovarian response to hormonal stimulation and the potential likelihood for achieving successful pregnancy with assisted reproductive technology (American Society for Reproductive Medicine, 2015c).

Semen analysis is the primary laboratory test used to assess male infertility (American Society for Reproductive Medicine, 2015b; American Urological Association, 2011; Barratt, 2017). Semen analysis provides information on semen volume and sperm concentration, motility, and morphology. Tests for endocrine function, post-ejaculatory urinalysis, ultrasonography, and specialized tests for sperm leukocytes, antisperm antibodies, sperm viability, deoxyribonucleic acid integrity, sperm fertilizing capacity, and genetic screening can further elucidate cause of infertility.

Regulatory considerations:

The Henry J. Kaiser Family Foundation (2016) published results of a survey of 50 states and the District of Columbia of Medicaid coverage for family planning benefits, including fertility diagnosis and treatment, as of July 2015. Family planning services are mandatory benefits under Medicaid and must be provided to individuals of childbearing age free of cost sharing. However, there is no formal federal definition of “family planning” or federal requirements for state Medicaid programs to cover fertility testing or treatment. States have considerable latitude in defining specific services covered under this benefit. Different Medicaid eligibility pathways (e.g., traditional Medicaid, Patient Protection and Affordable Care Act Medicaid expansion, or Medicaid Family Planning Expansion program) within each state add more variation in coverage standards.

Forty states and the District of Columbia responded to the survey. Nine of 41 respondents (22 percent) cover infertility testing in their traditional Medicaid program, six of 25 respondents (24 percent) under Patient Protection and Affordable Care Act expansion, and three of 23 (13 percent) under a family planning waiver. States may cover diagnostic services to detect the underlying medical reasons for infertility. One state Medicaid program — Michigan — is a member of the AmeriHealth Family of Companies and offers fertility testing for men and women for members under both traditional Medicaid and Patient Protection and Affordable Care Act Medicaid expansion.

Policy updates:

In 2019, we identified no relevant, newly published information to add to the policy.

References

Professional society guidelines/other:

American College of Obstetricians and Gynecologists. Female age-related fertility decline. Committee opinion number 589. <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Female-Age-Related-Fertility-Decline>. Published March 2014. Last reviewed 2018. Accessed May 6, 2019.

American Society for Reproductive Medicine, Practice Committee. Diagnostic evaluation of the infertile female: a committee opinion. *Fertil Steril*. 2015;103(6):e44-50. Doi: 10.1016/j.fertnstert.2015.03.019.(a)

American Society for Reproductive Medicine, Practice Committee. Diagnostic evaluation of the infertile male: a committee opinion. *Fertil Steril*. 2015;103(3):e18-25. Doi: 10.1016/j.fertnstert.2014.12.103.(b)

American Society for Reproductive Medicine, Practice Committee. Testing and interpreting measures of ovarian reserve: a committee opinion. *Fertil Steril*. 2015;103(3):e9-e17. Doi: 10.1016/j.fertnstert.2014.12.093.(c)

American Urological Association. Optimal evaluation of the infertile male. Best practice statement. [www.auanet.org/guidelines/male-infertility-optimal-evaluation-\(reviewed-and-validity-confirmed-2011\)](http://www.auanet.org/guidelines/male-infertility-optimal-evaluation-(reviewed-and-validity-confirmed-2011)). Published April 2001. Last reviewed 2011. Accessed May 6, 2019.

Barratt CLR, Bjorndahl L, De Jonge CJ, et al. The diagnosis of male infertility: an analysis of the evidence to support the development of global WHO guidance-challenges and future research opportunities. *Hum Reprod Update*. 2017;23(6):660-680. Doi: 10.1093/humupd/dmx021.

Henry J. Kaiser Family Foundation. Medicaid coverage of family planning benefits: Results from a state survey. <https://www.kff.org/womens-health-policy/report/medicaid-coverage-of-family-planning-benefits-results-from-a-state-survey/>. Published September 2016. Accessed May 6, 2019.

Peer-reviewed references:

Armstrong SC, Showell M, Stewart EA, et al. Baseline anatomical assessment of the uterus and ovaries in infertile women: A systematic review of the evidence on which assessment methods are the safest and most effective in terms of improving fertility outcomes. *Hum Reprod Update*. 2017;23(5):533-547. Doi: 10.1093/humupd/dmx019.

Thoma ME, McLain AC, Louis JF, et al. The prevalence of infertility in the United States as estimated by the current duration approach and a traditional constructed approach. *Fertil Steril*. 2013;99(5):1324-1331.e1321. Doi: 10.1016/j.fertnstert.2012.11.037.

Zegers-Hochschild F, Adamson GD, Dyer S, et al. The international glossary on infertility and fertility care, 2017. *Fertil Steril*. 2017;108(3):393-406. http://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/international_glossary_on_infertility_and_fertility_care-2017-noprint.pdf. Accessed May 6, 2019.

Centers for Medicare & Medicaid National Coverage Determinations:

Medicare Benefit Policy Manual, Chapter 15-Covered medical and other health services. Table of contents (Rev. 228, 10-13-16)). Section 20.1. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed May 6, 2019.

Center for Medicaid and CHIP Services. Letter to state health officials and state Medicaid directors. SHO # 16-008. Re: Medicaid family planning services and supplies. <https://www.medicaid.gov/federal-policy-guidance/downloads/sho16008.pdf>. Published June 14, 2016. Accessed May 6, 2019.

Local Coverage Determinations:

No Local Coverage Determinations identified as of the writing of this policy.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

CPT code	Description	Comments
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)	
83001	Gonadotropin; follicle stimulating hormone (FSH)	
83002	Gonadotropin; luteinizing hormone (LH)	
83498	Hydroxyprogesterone, 17-d	

ICD-10 code	Description	Comments
N46.8-N46.9	Male infertility	
N46.11- N46.12	Oligospermia	
N46.01- N46.02	Azoospermia	
N97.0-N97-9	Female infertility	
Z31.8	Encounter for other procreative management	

HCPCS Level II code	Description	Comments
G0027	Semen analysis; presence and/or motility of sperm excluding Huhner	