Clinical Policy Title: Infertility — treatment

Clinical Policy Number: 12.01.03

Effective Date: October 1, 2016
Initial Review Date: June 15, 2016
Most Recent Review Date: June 5, 2018
Next Review Date: June 2019

Policy contains:
- Treatment for infertility.
- Assisted reproductive technology.

Related policies:

CP# 12.03.05 Cryopreservation of sperm and embryos
CP# 12.01.07 Infertility — diagnosis

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’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 Prestige Health Choice 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. Prestige Health Choice’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. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’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 CHIP Services, 2016).

Prestige Health Choice considers the use of any medical procedure or pharmaceutical related to treating infertility, including assisted reproductive technology, to be not medically necessary. For this policy, infertility is defined as 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 his/her partner (American Society of Reproductive Medicine, 2017).

Prestige Health Choice considers the use of cryopreservation fertility preservation for patients with cancer to be clinically proven and, therefore, medically necessary. See Clinical Policy #12.03.05 Cryopreservation of sperm and embryos.
For Medicare members only:

Prestige Health Choice 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:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

All other treatments for infertility services are not medically necessary.

- Family planning services do not include treatment of infertility.
- Services related to infertility treatment are not a covered benefit for KF/ACP/AHN members and not covered by Medical Assistance. KF/ACP/AHN members are notified of this restriction in the Member Handbook. KF/ACP/AHN Keystone First, Prestige Health Choice Pennsylvania and AmeriHealth Northeast.

Alternative covered services:

None.

Background

Infertility is defined as the failure to achieve pregnancy after 12 months of regular unprotected intercourse (Agency for Healthcare Research and Quality, 2008; American Society of Reproductive Medicine, 2017). Earlier evaluation and treatment may be warranted based on medical history and physical findings and is reasonable after six months for women over the age of 35 years (American Society of Reproductive Medicine, 2017). In addition, the inability of a woman to achieve conception after six trials of medically supervised artificial insemination over a one-year period may necessitate evaluation for infertility.

Infertility can affect one or both reproductive partners. Some underlying factors are reversible through medical intervention. The major underlying causes of infertility include: ovulatory, tubal, cervical, uterine/endometrial, and male partner factors.

Infertility services include but are not limited to:

- Diagnosis of infertility (male or female).
- Pharmacologic treatments of infertility (male or female).
Assisted reproductive technology procedures for the female such as:

- Artificial insemination.
- In vitro Fertilization.
- Embryo transfer and Gamete Intra-fallopian Transfer.
- Intra-Vaginal Insemination.
- Intra-Cervical Insemination.
- Intrauterine Insemination.
- Services associated with the reversal of voluntary sterilization.

Searches

Prestige Health Choice searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on April 16, 2018. Search terms were: “Infertility services” and “Reproductive Techniques, Assisted” (MeSH).

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

Policy updates:

As of May 12, 2017, there are no federal mandates for coverage of infertility treatments. The Patient Protection and Affordable Care Act does not require coverage for infertility treatments (42 U.S.C. § 18001). However, states may mandate infertility treatments as essential health benefits. Currently, 15 states have laws requiring insurance coverage for infertility treatment (RESOLVE.org, 2017).

In 2018, the number of states with mandated coverage for infertility services remains at 15 (RESOLVE.org). The Agency for Healthcare Research and Quality (2018) released a draft report for public comment on the comparative effectiveness of infertility treatments based on common etiologies. The strongest evidence
supports strategies for fertility treatment in women with polycystic ovary syndrome and unexplained infertility, whereas the evidence for treatment of other causes of infertility was less robust. The majority of randomized trials reported outcomes on pregnancy or ongoing pregnancy rather than live birth rate, or failed to document other important outcomes such as complications. The deadline for public comment is May 1, 2018, after which the final report will be available.

Summary of clinical evidence:

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<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| Agency for Healthcare Research and Quality (2018) Management of infertility (DRAFT report) | **Key points:**  
  - Comparative effectiveness review of studies of fertility treatments based on common etiologies: polycystic ovary syndrome (31 studies); endometriosis (eight studies); unexplained infertility (34 studies); tubal and peritoneal factor infertility (11 studies); male factor infertility (18 studies); donors in infertility (nine studies). Included only studies reported live birth rate or other long-term outcome.  
  - Evidence supports strategies for treatment of infertility in women with polycystic ovary syndrome and with unexplained infertility.  
  - Surgical treatment of endometriosis, including endometrioma, prior to assisted reproductive technology does not improve outcomes.  
  - For women with unexplained infertility, there is most likely shorter time to pregnancy with immediate in vitro fertilization. There may be no differences between immediate in vitro fertilization versus using other treatments prior to in vitro fertilization for the outcomes of live birth, multiple births, ectopic pregnancy, miscarriage, low birthweight, and ovarian hyperstimulation syndrome.  
  - Infertility treatments do not appear to increase overall cancer risk. |
| Chandra (2014) Infertility service use in the United States: data from the National Survey of Family Growth, 1982-2010. | **Key points:**  
  - Survey of 22,682 interviews with men and women aged 15-44 from June 2006 through June 2010. Response rates: females 78%, males 75%. Selected trends are shown based on prior data cycles.  
  - Twelve percent of women ages 15-44 (7.3 million women), or their husbands or partners, had ever used infertility services.  
  - Among women aged 25-44, ever use of any infertility service was 17% (6.9 million), a significant decrease from 20% in 1995.  
  - Ever use among men aged 25-44 was 9.4%, similar to levels seen in 2002.  
  - The most commonly used infertility services were advice, testing, medical help to prevent miscarriage, and ovulation drugs.  
  - Medical help to get pregnant was highest among older and nulliparous women, non-Hispanic white women, women with current fertility problems, and women with higher levels of education and household income. |
| Farr (2009) Predictors of pregnancy and discontinuation of infertility services among women who received medical help to become pregnant, National | **Key points:**  
  - A total of 530 women aged 18-44 years in the 2002 National Survey of Family Growth who had received infertility services.  
  - Fifty-nine percent of respondents became pregnant while receiving infertility services and 32% reported discontinuing infertility services before establishing a pregnancy. |
Citation | Content, Methods, Recommendations
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Survey of Family Growth | Women received infertility services for a median of eight months; among those who discontinued services, more than half did so within one month.
- Among women who received infertility services, those who were white, nonsmokers, nulliparous, had insurance coverage, and received more than advice had a higher likelihood of pregnancy. Non-whites, parous women, and smokers discontinued infertility services earlier than others.
- Patients should be adequately counseled regarding modifiable behaviors and the range of services available before making decisions regarding their infertility.

References

Professional society guidelines/other:


American College of Obstetricians and Gynecologists (ACOG):

American Urological Association (AUA):


**Peer-reviewed references:**


**CMS National Coverage Determinations (NCDs):**


No NCDs identified as of the writing of this policy.
Local Coverage Determinations (LCDs):

No LCDs 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.

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