Clinical Policy Title: Infertility — treatment

Clinical Policy Number: CCP.1239

Effective Date: October 1, 2016
Initial Review Date: June 15, 2016
Most Recent Review Date: July 17, 2019
Next Review Date: July 2020

Related policies:

- CCP.1173 Cryopreservation of sperm and embryos
- CCP.1388 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 CCP.1173 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 (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. 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.
- The Centers for Medicare & Medicaid Services.
- The Cochrane Library.

We conducted searches on May 14, 2019. 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.

In 2019, the Agency for Healthcare Research and Quality published its final report on management of infertility (Meyers, 2019). The systematic review of 151 studies compared the effectiveness and safety of fertility treatment strategies for: 1) women of reproductive age (18–44) who are infertile due to polycystic ovary syndrome, endometriosis, unknown reasons, or tubal or peritoneal factors; and 2) couples with male factor infertility. It also evaluated short- and long-term health outcomes of gamete donors in infertility. The authors concluded there is evidence supporting some strategies for treatment of infertility for specific diagnoses and for couples with any diagnosis, but there is a lack of consensus on which outcomes to collect and report and which areas of uncertainty are most important to resolve. The policy ID was changed from CP# 12.01.03 to CCP.1239.

References

Professional society guidelines/other:


Peer-reviewed references:


Centers for Medicare & Medicaid Services National Coverage Determinations:

No National Coverage Determinations identified as of the writing of this policy. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services. Table of Contents (Rev. 228, 10-13-16)). Section 20.1.


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.

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