Clinical Policy Title: Treatment for infertility

Clinical Policy Number: 12.01.03

Effective Date: October 1, 2016
Initial Review Date: June 15, 2016
Most Recent Review Date: June 15, 2016
Next Review Date: June 2017

Related policies:

CP# 12.03.05 Cryopreservation of sperm and embryos

ABOUT THIS POLICY: Arbor Health Plan has developed clinical policies to assist with making coverage determinations. Arbor Health Plan’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 Arbor Health Plan 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. Arbor Health Plan’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. Arbor Health Plan’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Arbor Health Plan will update its clinical policies as necessary. Arbor Health Plan’s clinical policies are not guarantees of payment.

Coverage policy

Arbor Health Plan considers the use of any medical procedures or pharmaceuticals related to treating infertility not to be medically necessary.

Arbor Health Plan considers the use of cryopreservation fertility preservation for patients with cancer to be clinically proven and, therefore, medically necessary. (See policy 12.03.05 Cryopreservation of sperm and embryos for criteria).

Medicare coverage

Reasonable and necessary services associated with treatment for infertility are covered under Medicare. 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.157, 060812) Available at:

Limitations:
All other treatment 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, Arbor Health Plan 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 [AHRQ], 2008; American Society of Reproductive Medicine [ASRM], 2013). 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 (ASRM, 2013). 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.
- Pharmacologic treatments of female infertility.
- Evaluation of male infertility.
- Diagnostic procedures for the female.
- Evaluation of female infertility
- Pharmacologic treatments for male infertility
- Assisted reproductive technology (ART) procedures for the female such as:
  - Artificial Insemination (AI).
  - In vitro Fertilization (IVF).
  - Embryo transfer and Gamete Intra-fallopian Transfer (GIFT).
  - Intra-Vaginal Insemination (IVI).
  - Intra-Cervical Insemination (ICI).
  - Intrauterine Insemination (IUI).
  - Services associated with the reversal of voluntary sterilization.

**Searches**

Arbor Health Plan 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 May 5, 2016. Search terms were: “Infertility services” and “female and male,” [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.

Policy updates:

None

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tr>
<td>Farr SL et al (2009)</td>
<td>Key points:</td>
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| Predictors of pregnancy and discontinuation of infertility services among women who received medical help to become pregnant, National Survey of Family Growth, (NSFG) 2002. | - To determine demographic characteristics associated with pregnancy and, separately, discontinuation of infertility services when unsuccessful at achieving pregnancy, among a national sample of women who received infertility services.  
- Using a log-linear regression model, we examined associations with becoming pregnant among women who had received infertility services, and using a Cox proportional hazards model, we examined associations with earlier infertility service discontinuation. 2002 NSFG, Cycle 6.  
- A total of 530 women aged 18-44 years in the 2002 NSFG who had received infertility services.  
- Relative risks for predictors of pregnancy after receiving infertility services; median time to discontinuation of infertility services; hazard ratios for predictors of earlier discontinuation of services.  
- Fifty-nine percent of respondents became pregnant while receiving infertility services and 32% reported discontinuing infertility services before establishing a pregnancy. Women received infertility services for a median of 8 months; among those who discontinued services, more than half did so within 1 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 |
| Infertility service use in the United States: data from the National Survey of Family Growth, 1982-2010. | - The 2006-2010 NSFG, consisting of 22,682 interviews with men and women aged 15-44, was conducted from June 2006 through June 2010. The response rate for females in the 2006-2010 NSFG was 78%, and for males was 75%. Selected trends are shown based on prior NSFG cycles.  
- Twelve percent of women aged 15-44 in 2006-2010 (7.3 million women), or their husbands or partners, had ever used infertility services.  
- Among women aged 25-44, 17% (6.9 million) had ever used any infertility service, a
<table>
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<tr>
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| **Bates GW (1996)**<br>Infertility services in a managed care environment. | Significant decrease from 20% in 1995. Thirty-eight percent of nulliparous women with current fertility problems in 2006-2010 had ever used infertility services, significantly less than 56% of such women in 1982.  
- 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.  
- The most commonly used infertility services among women aged 25-44 in 2006-2010 were advice, testing, medical help to prevent miscarriage, and ovulation drugs.  
- Ever-use of infertility services was reported by 9.4% of men aged 25-44 in 2006-2010, similar to levels seen in 2002. |
| **Griffin M et al (1998)**<br>The economic cost of infertility-related services: An examination of the Massachusetts infertility insurance mandate. | **Key points:**  
- Reimbursement for infertility services has been excluded from many managed care plans as infertility is viewed as a social condition, not a medical condition, and coverage for infertility diagnosis and treatment is viewed as unnecessary in the bundle of services offered by insurers and other managed care organizations.  
- Some states mandate infertility coverage and some managed care organizations realize that provision of care for infertile couples makes their product more attractive.  
- Large managed care organizations such as Blue Cross/Blue Shield of Illinois and some entrepreneurial organizations are developing managed care plans that incorporate infertility services. Comprehensive services—including in-vitro fertilization—can be offered at a lower cost than traditional fee-for-service care.  
- Newer technologies such as in-vitro fertilization are replacing fallopian tube surgery and surgical treatment for male infertility. These can be implemented at a lower cost and with better outcome for infertile couples than traditional services. |

### Glossary

**Artificial insemination (AI)** — The deliberate introduction of sperm into a female's uterus or cervix for the purpose of achieving a pregnancy through in vivo fertilization by means other than sexual intercourse.

**Embryo cryopreservation** — A process in which the embryos are frozen in liquid nitrogen and may be thawed for future use.
**In vitro fertilization (IVF)** — A complex series of procedures used to treat fertility or genetic problems and assist with the conception of a child. During IVF, mature eggs are collected (retrieved) from your ovaries and fertilized by sperm in a lab.

**Intrauterine insemination (IUI)** — A type of artificial insemination procedure for treating infertility. Sperm that have been washed and concentrated are placed directly in your uterus around the time your ovary releases one or more eggs to be fertilized. Older types of artificial insemination placed the sperm in the vagina.

**Medically Necessary** - A service or benefit is Medically Necessary if it is compensable under the Medical Assistance Program and if it meets any one of the following standards:
- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

**References**

**Professional society guidelines/other:**


American College of Obstetricians and Gynecologists (ACOG), ACOG Committee on Obstetric Practice; ACOG Committee on Gynecologic Practice; ACOG Committee on Genetics. ACOG Committee Opinion #324: Perinatal risks associated with assisted reproductive technology. Obstet Gynecol. 2005 Nov;106(5 Pt 1):1143-6.


**Peer-reviewed references:**


**Clinical trials:**

Searched clinicaltrials.gov on May 3, 2016 using term “infertility services” | Open Studies. 139 studies found, none relevant.

https://clinicaltrials.gov/ct2/results?term=infertility+services&recr=Open&no_unk=Y.

**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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<th>CPT Code</th>
<th>Description</th>
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<table>
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