JOHNS HOPKINS HEALTHCARE

Medical Policy: Infertility Services  
Department: Health Services  
Lines of Business: ADVANTAGE MD

ACTION:
☒ New Policy: CMS23.02  
☐ Revising Policy Number  
☐ Superseding Policy Number  
☐ Archiving Policy Number  
☐ Retiring Policy Number

Effective Date: 03/04/2016

Johns Hopkins HealthCare LLC (JHHC) provides a full spectrum of health care products and services for Employer Health Programs, Priority Partners, Advantage MD, and US Family Health Plan. Each line of business possesses its own unique contract and guidelines which, for benefit and payment purposes, should be consulted to know what benefits are available for reimbursement. Specific contract benefits, guidelines or policies supersede the information outlined in this policy.

POLICY:

For US Family Health Plan see TRICARE Policy Manual 6010.57-M, February 1, 2008, Family Planning: Chapter 7, Section 2.3.

For Employee Health Plan (EHP) and Priority Partners, (PP), consult contract specific benefits.

Cross reference with Medical Policies:
- CMS07.03 Genetic Testing
- CMS09.02 InVitro Fertilization Attempts: A Definition of “Attempt”.

For Advantage MD:
Local Coverage Determinations (LCD’S) do not exist at this time (accessed February 27, 2017). Medicare does not have a National Coverage Determination (NCD) for infertility services.

For Advantage MD: infertility services are covered when Medicare criteria are met. Reasonable and necessary tests and treatments for infertility when fertility would be expected* are covered. See the Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services §20.1 - Physician Expense for Surgery, Childbirth, and Treatment for Infertility at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.

I. When benefits are provided under the member’s contract, JHHC considers covering infertility treatment when the following requirements are met:
   A. In all cases:
      1. Member must have one continuous year of coverage by the Advantage MD plan;
      2. Care Management Program must preauthorize treatment;
      3. Treatment must be provided at the Johns Hopkins Fertility Center. Infertility treatment received anywhere other than at the Johns Hopkins Fertility Center is not covered;
      4. The order of infertility treatment options must follow a logical succession of medically appropriate and cost-effective care;
5. There is a maximum of three in-vitro fertilization attempts (any implantation of oocyte). This maximum applies per birth mother’s lifetime. However, if a female member with individual coverage subsequently becomes covered under the coverage of another employee (husband and wife or family), any attempts during the employee’s individual coverage do not count against the three attempt limit under the subsequent coverage of the other employee;

6. All expenses connected with obtaining donor sperm or eggs are not covered, including expenses for acquisition, freezing, storing or thawing of sperm, eggs or embryos; coverage is provided for implantation only, AND;

7. Infertility must not be related to a previous sterilization by the member or spouse/partner.

B. For married opposite sex couples:
   1. Member and spouse must have a history of continuous infertility as a married couple for at least two consecutive years immediately before receiving infertility treatment, or have a specific medically documented infertility diagnosis, AND;
   2. The husband’s sperm and the wife’s egg must be used for in-vitro fertilization treatment, unless there is a documented medical condition unrelated to age whereby use of the husband’s sperm and/or the wife’s egg is not possible, AND;
   3. The mother must have one continuous year of coverage by the Johns Hopkins Advantage MD plan before treatment begins and must remain covered throughout the treatment.

C. For married female same sex couples:
   1. If spouse is to be the birth mother, she must be covered by the Plan for one continuous year, AND;
   2. The birth mother’s egg must be used, unless there is a documented medical condition unrelated to age whereby use of the birth mother’s egg is not possible.

D. For single females:
   1. Member’s egg must be used, unless there is a documented medical condition unrelated to age whereby use of member’s egg is not possible.

Note ~Unless specific benefits are provided under the member’s contract, infertility treatment benefits are not provided for married male same sex couples or male same sex domestic partnerships.

II. When benefits are provided under the member’s contract, JHHC considers infertility testing of family members who are not covered under the Advantage MD plan medically necessary when ALL of the following conditions are met:
   A. The information is needed to adequately assess risk in the Johns Hopkins Advantage MD plan member, AND;
   B. The information will directly impact the current specific medical treatment being delivered to the Advantage MD plan member, AND;
   C. The non-Johns Hopkins Advantage MD plan member's benefit plan, if any, will not cover the test (a copy of the denial letter from the non-Johns Hopkins Advantage MD plan must be provided).
III. The following tests and treatments are considered medically necessary:

A. Females: Examples include, but are not limited to:
   1. Pelvic exam
   2. Routine laboratory investigation for hormonal disturbances (e.g., FSH, LH, prolactin)
   3. Cultures for infectious agents
   4. Serum progesterone determination
   5. Hysterosalpingogram

B. Males: Examples include, but are not limited to:
   1. Medical history
   2. General physical examination
   3. Semen analysis up to 3 times following 5 days of abstinence
   4. Laboratory studies
   5. Anti-sperm antibodies (e.g., immunobead or mixed antiglobulin method)
   6. Cultures
      a. Prostatic secretion
      b. Semen
      c. Urine
   7. Serum hormone levels
      a. 17-hydroxyprogesterone
      b. Adrenal cortical stimulating hormone (ACTH)
      c. Androgens (testosterone, free testosterone)
      d. Estrogens (e.g., estradiol, estrone)
      e. Gonadotropins (FSH, LH)
      f. Growth hormone (GH)
      g. Prolactin for men with reduced sperm counts, galactorrhea, or pituitary tumors
      h. Sex hormone binding globulin (SHGB) for men with signs and symptoms of hypogonadism and low normal testosterone levels. (SHGB is not indicated in the routine evaluation of male infertility)
      i. Thyroid stimulating hormone (TSH) for men with symptoms of thyroid disease.
   8. Semen analysis (volume, pH, liquefaction time, sperm concentration, total sperm number, motility (forward progression), motile sperm per ejaculate, vitality, round cell differentiation (white cells versus germinal), morphology, viscosity, agglutination) is considered medically necessary for the evaluation of infertility in men. Because of the marked inherent variability of semen analyses, an abnormal result should be confirmed by at least one additional sample collected one or more weeks after the first sample.
   9. Vasography
   10. Semen leukocyte analysis (e.g., Endtz test, immunohistochemical staining)
   11. Seminal fructose

Note ~ Unless specific benefits are provided under the member’s contract, JHHC considers seminal alpha-glucosidase, zinc, citric acid, and acid phosphatase experimental and investigational for all other indications, as they do not meet Technology Evaluation Criteria (TEC) #2-5.
12. Blood test for cytogenetic analysis (karyotype and FISH) in men with severe deficits of semen quality or azoospermia (for consideration of ICSI)

13. Cystic fibrosis mutation testing in men with congenital absence of vas deferens

14. Y chromosome microdeletion analysis in men with severe deficits of semen quality or azoospermia (for consideration of ICSI). Note: Y chromosome microdeletion analysis is not routinely indicated before ICSI, and is subject to medical necessity review

15. Post-coital test (PCT) (Simms-Huhner test) of cervical mucus

16. Sperm function tests:
   a. Sperm penetration assay (zona-free hamster egg penetration test)

Note ~ For men with abnormal semen analysis exposed to gonadotoxins, up to 4 semen analyses may be allowed.

Note ~ For men with a normal initial semen analysis, a repeat semen analysis is considered medically necessary if there is no pregnancy 4 months after the initial normal semen analysis. If the result of the first semen analysis is abnormal and the man has not been exposed to gonadotoxins, up to 2 repeat confirmatory tests may be considered medically necessary.

Note ~ SHGB, (Sex hormone-binding globulin) is not indicated in the routine evaluation of male infertility.

IV. Unless specific benefits are provided under the member’s contract, JHHC considers the following sperm function test experimental and investigational for all other indications, as they do not meet Technology Evaluation Criteria (TEC) # 2-5:
   A. Acrosome reaction test
   B. Comet assay
   C. Computer-assisted sperm analysis (CASA)/computer-assisted sperm motion analysis
   D. Hemizona assay
   E. Hyaluronan binding assay
   F. Hypoosmotic swelling test
   G. In vitro testing of sperm penetration
   H. Reactive oxygen species (ROS) test
   I. Sperm chromatin assay
   J. Sperm DNA condensation test
   K. Sperm DNA fragmentation assay
   L. Sperm nucleus maturation
   M. TUNEL assay

V. Unless specific benefits are provided under the member’s contract, JHHC considers general laboratory studies, treatments and technologies experimental and investigational for all other indications, as they do not meet Technology Evaluation Criteria (TEC) # 2-5. Examples include, but not limited to:
   A. Antiphospholipid antibodies
   B. Antiprothrombin antibodies
C. Embryotoxicity assay
D. Endometrial receptivity testing (e.g., endometrial receptivity array (ERA), integrin testing, beta-3 integrin test)
E. Uterine and endometrial receptivity testing (Endometrial function test (EFT) (cyclin E and p27) and E-tegrity)
F. Measurement of natural killer cell activity
G. Reproductive immunophenotyping
H. Serum inhibit B measurement (value in assessing ovarian reserve is uncertain).
I. Th1 (T Helper 1) and Th2 (T Helper 2) intracellular cytokine assay (Th1/Th2 ratio)
J. Growth hormone for infertility treatment
K. Intravenous immunoglobulins for treatment of infertility
L. Drainage of ovarian cyst for infertility treatment
M. In-vitro maturation (IVM) of oocytes for infertility treatment
N. Intra-prostatic antibiotic injection
O. Urinary FSH testing is considered experimental and investigational, as serum, not urinary FSH is the standard of care for determination of menopausal status (AACE, 1999; NAMS, 2000; SOGC, 2002)
P. Sonohysterosalpingography or saline hysterosalpingography (e.g., Femvue) are considered experimental and investigational to screen for tubal occlusion
Q. Leukocyte immunization (immunizing the female partner with the male partner's leukocytes)
R. Dehydroepiandrosterone (DHEA)
S. FSH manipulation of women with elevated FSH levels is considered experimental and investigational
T. Parenteral administration of lipids
U. Bariatric surgery as a treatment for infertility
V. Uterine transplant as a treatment for infertility
W. Human chorionic gonadotropin (hCG) is considered experimental and investigational for in vitro fertilization with frozen-thawed embryos.
X. Co-culture of oocyte(s)/embryo(s)
Y. Cryopreservation of ovarian tissue
Z. Cryopreservation of oocytes not related to fertility preservation secondary to cancer treatment, is considered experimental and investigational
AA. Seminal plasma immunotherapy
BB. Trophoblast membrane immunotherapy
CC. Paternal leukocyte immunotherapy
DD. Intravenous immunoglobulin infusion (IVIG)

Note ~ Separate benefits are not provided for trial (mock) IUI transfer, as it is considered an integral part of the intrauterine insemination (IUI) procedure.

Note ~ Reimbursement will not be made for maintaining frozen embryos.

Note ~ Infertility services for non-members (e.g., surrogate mothers who are not Johns Hopkins Advantage MD plan members) are not covered.
VI. Infertility services that are not reasonable and necessary, and therefore not covered: Examples include, but are not limited to:
   A. Infertility from a previous elective vasectomy or tubal ligation
   B. Inoculation of women with husband’s white cells
   C. Microdissection of the zona or sperm microinjection
   D. For post-menopausal women
   E. Reversal of a previous elective vasectomy or tubal ligation
   F. Treatment of female sterility in which a donor ovum would be necessary (e.g., post-menopausal syndrome)
   G. Other infertility treatment when continued treatment has no reasonable chance to produce a pregnancy

BACKGROUND:

According to The American Society of Reproductive Medicine (ASRM), 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. A condition sufficiently at variance with the usual state of health is defined as the inability to conceive following 1 year of unprotected intercourse or therapeutic donor insemination in cases where the female is ≤ 35 years of age or following 6 months of unprotected intercourse or therapeutic donor insemination for females > 35 years of age.

Attempt: any implantation of the fertilized oocyte into the uterus and not the act of stimulating the ovaries to extrude oocytes. Each attempt is considered a cycle.

CODING INFORMATION:

   CPT Copyright 2016 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage and referral requirements. All inpatient admissions require pre-authorization.
## CPT® Codes

<table>
<thead>
<tr>
<th>CPT® CODES</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>83001</td>
<td>Gonadotropin; follicle stimulating hormone (FSH)</td>
</tr>
<tr>
<td>83002</td>
<td>Gonadotropin; luteinizing hormone (LH)</td>
</tr>
<tr>
<td>84146</td>
<td>Prolactin</td>
</tr>
<tr>
<td>80426</td>
<td>Gonadotropin releasing hormone stimulation panel</td>
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<tr>
<td>87015</td>
<td>Concentration (any type), for infectious agents</td>
</tr>
<tr>
<td>84144</td>
<td>Progesterone</td>
</tr>
<tr>
<td>74740</td>
<td>Hysterosalpingography, radiological supervision and interpretation</td>
</tr>
<tr>
<td>89300</td>
<td>Semen analysis; presence and/or motility of sperm including Huhner test (post coital)</td>
</tr>
<tr>
<td>89310</td>
<td>Semen analysis; motility and count (not including Huhner test)</td>
</tr>
<tr>
<td>89320</td>
<td>Semen analysis; volume, count, motility, and differential</td>
</tr>
<tr>
<td>89321</td>
<td>Semen analysis; sperm presence and motility of sperm, if performed</td>
</tr>
<tr>
<td>89322</td>
<td>Semen analysis; volume, count, motility, and differential using strict morphologic criteria (eg, Kruger)</td>
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## HCPCS Codes

<table>
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<th>HCPCS CODES</th>
<th>DESCRIPTION</th>
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<tr>
<td>G0027</td>
<td>Semen analysis; presence and/or motility of sperm excluding Huhner</td>
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## ICD10 Codes are for Informational Purposes Only
ICD10 CODES | DESCRIPTION
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N46.01-N46.9 | Male infertility
N97.0-N97.9 | Female infertility

REVENUE CODES | DESCRIPTION
--- | ---
0300 | Laboratory-General, Hospital outpatient
0310 | Laboratory-Pathology-General Hospital outpatient
0320 | Radiology-Diagnostic-General; Hospital outpatient
0329 | Other Radiology-Diagnostic

REFERENCE STATEMENT:
Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins HealthCare LLC (JHHC) Medical Policy Team during the development and implementation of this medical policy. Per NCQA standards, the Medical Policy Team will continue to monitor and review any newly published clinical evidence and adjust the references below accordingly if deemed necessary.

REFERENCES:

Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services; [https://www.cms.gov](https://www.cms.gov)

Optum, Clinical Performance Guideline Infertility, [https://www.myoptumhealthcomplexmedical.com](https://www.myoptumhealthcomplexmedical.com)

The American Society of Reproductive Medicine (ASRM) [http://www.reproductivefacts.org](http://www.reproductivefacts.org)

UnitedHealthcare, Coverage Summary, Policy Number: I-002; [https://www.unitedhealthcareonline.com](https://www.unitedhealthcareonline.com)