KAISER PERMANENTE®
Mid-Atlantic States

Infertility - Diagnosis and Treatment

Medical Coverage Policy

Utilization *ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- This policy applies only to members whose benefit plans cover infertility services. The member benefits (EOC or brochure or Medicaid handbook) are the primary source of benefit coverage, and all coverage is subject to the terms and conditions of the member's benefit plan;
- Coverage varies widely for diagnosis and treatment of infertility, and in exclusions and limitations of procedures.
- Many members have a high-cost share (up to 50%) for services related to evaluating and treating infertility physicians and medical center staff should provide resources for cost estimates to assist members in their treatment decisions.

I. Procedure: **Infertility diagnosis and treatment**
Related Medical Coverage Policies: Preimplantation Genetic Testing (PGT), Fertility preservation for Iatrogenic Infertility

II. Diagnoses: **Female and Male Infertility**

III. Specialties/Services: OB/GYN, Urology, Reproductive Endocrinology, Laboratory and Radiology

IV. Definition of Infertility

Kaiser Permanente Mid-Atlantic States (KPMAS) defines infertility as one of the following:

A. He or she (female is younger than 35) is unable to conceive or produce conception after one year of frequent, unprotected heterosexual sexual intercourse OR
B. For a female 35years of age or older, she is unable to conceive or produce conception after six months of frequent, unprotected heterosexual sexual intercourse OR
C. Women with known tubal or other infertility disease (e.g., Polycystic ovary syndrome) OR
D. Women planning to use donor sperm for artificial insemination OR
E. Same sex couples, where mandated per jurisdiction or line of business, OR
F. Opposite sex couples with known male-factor infertility OR
G. Female patients who have undergone early menopause. Per ASRM Premature Ovarian Failure is the cessation of menstrual periods due to failure of the ovaries before age 40.
H. Women who are post-menopausal (Postmenopausal: After menopause, the period of time after a woman has experienced 12 consecutive months without menstruation) are NOT considered infertile unless they are less than age 40 as per ASRM
I. Single women or couples who have a genetic condition that meets the KP-MAS Preimplantation Genetic Testing MCP criteria for PGT-M or PGT-SR

V. Patient Workup

Prior to referral to infertility provider or a Reproductive Endocrinologist Infertility specialist (REI), the primary care Obstetrician/Gynecologist must perform or confirm the following diagnostic studies for both the male and female, as applicable. Female members must have the testing/documentation performed by their primary care gynecologist. Except for the Pap smear (A1), all services are subject to infertility cost share as determined by member's benefit contract.

A. Female Factor Workup - Initial referrals

1. Pap smear up to date as per ACOG (American College of Obstetricians and Gynecologists) guidelines and GC/Chlamydia cultures (mycoplasma if necessary) as indicated.
2. HIV, Syphilis IgG, HBsAg, Hep C core Ab
3. Complete Blood Count (CBC), hemoglobin electrophoresis as indicated
4. ABO blood type (unless documented)
5. Rubella, VZV (Varicella Zoster Virus) IgG (if not documented immune)
6. Hormonal Studies within 13 months
    a. AM Day 3 Follicle Stimulating Hormone (FSH);
    b. Luteinizing Hormone (LH);
    c. Estradiol (aka E2-Estrogen);
    d. Thyroid Stimulating Hormone (TSH);
    e. Fasting AM Prolactin (if a patient does not have normal menstrual cycles); *and*
    f. Anti-Mullerian Hormone (AMH)
7. Hysterosalpingogram (HSG) or diagnostic laparoscopy within the past 2 years unless there is a previous HSG which shows bilateral tubal occlusion at any time in the past, and there has been no tubal surgery subsequent to the HSG. This requirement is waived if this member meets the criteria for infertility consultation due to a genetic condition supported by our Preimplantation Genetic Testing MCP as IVF will be required.

B. Male Factor Workup – Initial referrals

1. Semen analysis (SA) within 1 year.
2. HBs Ag, HCV core Ab, Syphilis IgG,and HIV within one year. Neisseria gonorrhea and chlamydia testing, if indicated.
3. Referral to Urology (within the member's service delivery option, (MAPMG for HMO Sig) as indicated for abnormal parameters.
4. If a previous semen analysis and urology workup indicates any of the following, an additional SA and/or a repeat urology work up is not required:
    a. Absence of sperm; or
    b. An uncorrectable and permanent condition; or
    c. A thorough urology work up with no subsequent surgical recommendations

VI. Initial Specialist Consultation Referral - Female

After completing the above evaluations, the Obstetrician/Gynecologist may determine that the member requires further evaluation and/or treatment by a participating Reproductive Endocrinology and Infertility (REI) specialist.

A. The initial referral to an REI specialist should be limited to two consultation visits. The purpose of these visits is to obtain recommendations from the infertility specialist regarding the member's options for infertility

B. The initial referral for two visits should be accompanied by appropriate medical records, radiology, and lab results. These may be forwarded to the specialist through release of medical records or be hand-carried by the member. (All labs and tests should be completed before referral);

C. REI consult includes endo-vaginal ultrasound with antral follicle count to assess ovarian functional status, as appropriate.

D. Referrals for second opinions are not customarily approved.

E. Referrals for additional consultation visits will be reviewed on a case-by-case basis and will not be covered if there is documentation that the member's evaluation and required testing are complete.

VII. Female Fertility Treatment Referrals

A. Upon receipt of a satisfactory fertility treatment plan from the REI specialist, the REI specialist should enter a referral with a request for the specific treatment and the appropriate number of visits required.
B. All referral requests include individual consideration of the patient's age, history, comorbid conditions, and outcome prognosis for each treatment, including the level of care required.
C. Any questions regarding appropriateness of treatment plans must be reviewed by the Utilization Management Operations Center (UMOC) UM Referral Management physician, and/or the Regional Ob/Gyn Consultant for Infertility Referral Management.
D. Stages of treatment are sequential and progressive; all referrals for infertility treatment expire in 180 days.

VIII. Female Treatments

A. Basic Infertility Treatment

Up to 6 cycles of Basic Infertility Treatment (IUI (Intrauterine insemination)) are generally authorized for Natural cycle/IUI and any combination of six cycles of drug+ IUI per live birth:

1. Natural cycle/ovulation kit/intrauterine insemination (IUI) -- 12 visits per referral up to 4-6 cycles
2. Clomid, Femara (Letrozole) or other drug up to 3 cycles, 12 visits per referral
3. Clomid/FSH/IUI (injectable gonadotropins) -- up to 3 cycles, 18 visits per referral. Once gonadotropins are in use, management will be with the Reproductive Endocrinologist.
4. FSH/IUI – up to 3 cycles, 24 visits per referral.

5. For cycles using FSH, all lab work required during the cycle and ultrasound follicular monitoring will be done through the Reproductive Endocrinology and Infertility (REI) office.
6. For HMO members, the referring provider should order preliminary labs to be done at KPMAS medical centers.

B. Advanced Reproductive (infertility) Treatments

1. IVF – up to 15 visits per referral. One cycle of IVF will be authorized at a time. A cycle of IVF is counted once oocyte retrieval is completed. A completed IVF cycle includes IVF with fresh embryo transfer or IVF with frozen embryo transfer. Another egg retrieval to create more embryos will not be authorized if a patient is less than 35 years old and has 3 cryopreserved embryos or 35 years and older and has 4 embryos of similar development stage and reasonable quality for transfer.
2. Frozen embryo transfer (FET) – each FET counting as an IVF attempt, 7 visits per referral.
3. For cycles using FSH, the Reproductive Endocrinologist's office orders all lab work required during the cycle and ultrasound follicular monitoring. (For HMO Signature members, preliminary labs should be done by the referring provider at the medical centers).
4. ICSI, when IVF is covered, for either the male or the female partner, unless specifically excluded by EOC/brochure, for the following indications:
    a. Where there is azoospermia (obstructive or non-obstructive) or severe deficits in semen quality or quantity (asthenospermia, teratospermia or oligospermia) demonstrated on two separate occasions at least 2 weeks apart. See Section XI for definitions.
    b. When the male patient has had cancer and has cryopreserved sperm /frozen sperm collected prior to cancer treatment, which may be limited in number and quality.
    c. When there has been a previous IVF cycle with less than 50% fertilization of the eggs.
    d. When a patient is approved for preimplantation genetic diagnosis (PGT-M or PGT-SR) as per the Preimplantation Genetic Diagnosis (Preimplantation Genetic Testing) medical coverage policy.
    e. ICSI is NOT covered when using donor sperm
5. Assisted Hatching when the member has the IVF benefit.
    a. Assisted embryo hatching is covered for all Frozen Embryo Transfer (FET) cycles.
    b. Assisted hatching is covered for IVF cycles for women with ANY of the following:
        i. 38 years of age or older at time of embryo transfer (ET);
        ii. An elevated day-3 FSH;
        iii. Who have previously failed 2 cycles or more of IVF
    c. Assisted hatching is also covered as an adjunct procedure to Preimplantation Genetic Testing (PGT-M, PGT-SR) when IVF is covered.

6. Endometrial receptivity testing (e.g., endometrial receptivity array (ERA), integrin testing, beta-3 integrin test) are considered investigational and experimental and are not covered.

C. General Instructions

1. Instruct members under treatment by a REI specialist to call the treating physician's answering

service for questions related to the care she is receiving, or medical problems related to infertility.
2. If she is unable to reach the specialist or his or her covering physician, instruct the member to call the Kaiser Permanente Member Services call center, which will forward the call to the covering MAPMG Ob/Gyn in her service area.
3. After providing documentation of a positive pregnancy test, the REI specialist cares for the patient and then releases the member to the home center MAPMG Ob/Gyn Department for prenatal care, usually at 6 – 8 weeks. Once the care is transferred to the MAPMG Ob/Gyn provider, the care is expected to remain there.

IX. Male factor workup, Infertility Specialist Referrals and Treatments

A. Male Factor Workup

1. Semen analysis;
2. Infectious Disease Blood Work: Hep C core antibody, HBsAg, syphilis IgG, HIV, Neisseria gonorrhea and chlamydia (if indicated)

B. Infertility Specialist Referrals

1. Initial urology consults must occur within the Members service delivery option (MAPMG for HMO Sig) before referrals can be authorized to a urologist specializing in male infertility.
2. Additionally, referral to male infertility specialists is indicated if:
   a. IVF and Intra-cytoplasmic sperm injection (ICSI) is a covered benefit of the male partner (not excluded per EOC) AND
   b. The male will require a sperm extraction procedure OR
   c. ICSI will be required, and the female partner does not have the ICSI benefit

X. Male infertility Treatments

A. Sperm extraction for male factor infertility meets criteria for coverage only when the male partner has IVF as a covered benefit and a confirmed diagnosis of azoospermia (a complete absence of sperm in the ejaculate) or documented irreversible inability to ejaculate.

B. The following sperm functions tests are considered **experimental and investigational** so are not covered benefits.
1. Acrosome reaction test;
2. Comet assay;
3. Computer-assisted sperm analysis (CASA)/computer-assisted sperm motion analysis;
4. Hemizona assay;
5. Hyaluronan binding assay;
6. Hypoosmotic swelling test;
7. In vitro testing of sperm penetration;
8. Reactive oxygen species (ROS) test;
9. Sperm chromatin assay;
10. Sperm DNA condensation test;
11. Sperm DNA fragmentation assay;

12. Sperm nucleus maturation; and
13. TUNEL assay

XI. Definitions

A. Normal semen parameters
1. Semen volume: 1.4 ml or more
2. Sperm concentration: 15 million spermatozoa per ml or more
3. Total sperm number: 39 million spermatozoa per ejaculate or more
4. Total motility (percentage of progressive motility and non-progressive motility): 42% or more motile or 30% or more with progressive motility
5. Vitality: 54% or more live spermatozoa

B. Azoospermia: a complete absence of sperm in the ejaculate. Can be obstructive or non-obstructive

C. Oligospermia: less than 15 million spermatozoa per ml

D. Asthenospermia: less than 42 % motile sperm or 30% with progressive motility

E. Teratospermia: less than 4% normal sperm morphology

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*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.