Medical Policy

Infertility Services

Policy Number: OCA 3.725  
Version Number: 10  
Version Effective Date: 11/01/16

Product Applicability  

<table>
<thead>
<tr>
<th>All Plan* Products</th>
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<tbody>
<tr>
<td>Well Sense Health Plan</td>
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<tr>
<td>Boston Medical Center HealthNet Plan</td>
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</table>

- New Hampshire Medicaid
- NH Health Protection Program

- MassHealth
- Qualified Health Plans/ConnectorCare/Employer Choice Direct
- Senior Care Options

*Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

Infertility services are covered services only for Plan members who meet ALL of the following Plan criteria:

1. The member is a Massachusetts resident enrolled in a BMC HealthNet Plan product with coverage for infertility treatment (as specified in the member’s evidence of coverage or applicable benefit document available at www.bmchp.org); AND

2. The Plan’s medical criteria are met for coverage of infertility services, which are based on the member’s medical history, diagnostic testing, and medical evaluations (as specified in the Medical Policy Statement section and Limitations section of this policy); AND

3. The treating provider is a contracted network infertility services provider; AND

4. The member is in active infertility treatment.

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It will be determined during the Plan’s prior authorization process if the service is considered Medically Necessary for the requested indication. See the Definitions section of this policy for the definition of Medical Necessity or Medically Necessary Service.

**Plan Prior Authorization Requirements Table:** (See note below.*)

<table>
<thead>
<tr>
<th>Services NOT Requiring Prior Authorization when Member’s Condition Meets the Definition of Infertility ±</th>
<th>Services Requiring Prior Authorization by the Plan (See Medical Policy Statement Section and Limitations Section for Detailed Guidelines)</th>
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<tr>
<td>± Diagnostic tests and procedures provided in connection with an infertility evaluation and/or treatment will not require prior authorization UNLESS otherwise specified in the Medical Policy Statement, Limitations, and/or Applicable Coding sections of this policy.</td>
<td>1. Artificial insemination: Intracervical or intrauterine when done with donor sperm (i.e., the partner has a male factor infertility diagnosis; or donor sperm is being used as an alternative to preimplantation genetic diagnosis [PGD] when a couple meets the criteria for PGD).*</td>
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<td>2. Artificial insemination: Intracervical or intrauterine when done with non-donor (partner) sperm; and when there is at least one (1) patent fallopian tube; and spontaneous ovulation or normal ovarian reserve testing.</td>
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<td>3. Assisted hatching (AH).</td>
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<td>4. Retrieval, cryopreservation,‡ and storage of eggs/oocytes up to 12 calendar months for a member in active (and Plan authorized) fertility treatment (and enrolled in the Plan during the timeframe for cryopreservation and storage).</td>
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<td>5. Retrieval, cryopreservation,‡ and storage of eggs/oocytes up to 12 calendar months for a female member/member with female reproductive organs who is NOT in active fertility treatment before the member undergoes a medical treatment that is expected to cause permanent infertility (including but not limited to chemotherapy, radiotherapy, hormone therapy for the treatment of gender dysphoria, or risk-reducing bilateral salpingo-oophorectomy in a woman/individual with female reproductive organs with a BRCA1 and/or BRCA2 mutation), or the member has a diagnosed medical condition expected to cause permanent infertility (including but not limited to primary ovarian insufficiency, documented chromosomal abnormalities causing reproductive dysfunction such as fragile X syndrome or gonadal dysgenesis with or without Turner syndrome).</td>
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<td>The member must be enrolled in the Plan during the timeframe for cryopreservation and storage, have no prior history of sterilization, and the cryopreserved oocytes are intended to be used by the member.</td>
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<td>6. Retrieval, cryopreservation, and storage of embryos up to 12 calendar months for a member in active (Plan authorized) fertility treatment and enrolled in the Plan during the timeframe for cryopreservation and storage. See service limitations specified in Limitation section of this policy.</td>
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<td>7. Retrieval, cryopreservation, and storage of embryos up to 12 calendar months for a member NOT in active fertility treatment before the member undergoes medical treatment that is expected to cause permanent infertility, including but not limited to chemotherapy, radiotherapy, and hormone therapy for the treatment of gender dysphoria; the member must be enrolled in the Plan during the timeframe for cryopreservation and storage, have no prior history of sterilization, and are intended to be used by the member.</td>
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<td>8. Oocyte, embryo, or sperm retrieval, cryopreservation, and storage for up to 12 calendar months for transgender members undergoing Plan authorized genital sex reassignment surgery that is expected to result in a loss of reproductive functioning. The member must be enrolled in the Plan during the timeframe for cryopreservation and storage, have no prior history of sterilization, and are intended to be used by the member.</td>
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<tr>
<td>10. Electroejaculation.</td>
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<tr>
<td>11. Frozen embryo transfer (FET).</td>
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<td>12. Gamete intra-fallopian transfer (GIFT).</td>
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<td>15. In vitro fertilization (IVF): One cycle of IVF for a member who will undergo treatment that is expected to render the member infertile (excluding voluntary sterilization) or the member has an underlying medical disease that will render the member infertile.</td>
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<td>16. Intracytoplasmic sperm injection (ICSI) for the treatment of male factor infertility infertility related to male reproductive organs.</td>
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<td>17. Microsurgical epididymal sperm aspiration (MESA) for congenital absence or congenital obstruction of the vas deferens or for urologic surgery or inguinal surgery that is likely to result in an acquired obstructive disorder of the vas deferens (excluding voluntary sterilization).</td>
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<td>18. Sperm storage/banking up to 12 calendar months for a male member/member with male reproductive organs who is already in active (Plan authorized) infertility treatment who also has any one (1) of the following conditions listed in item a or item b below (and the member is enrolled in the Plan during the timeframe for cryopreservation and storage). See service limitations specified in Limitation section of this policy:</td>
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<td>a. Male member/member with male reproductive organs who has undergone MESA for congenital absence or congenital obstruction of the vas deferens; or</td>
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<tr>
<td>b. Male member/member with male reproductive organs who will undergo medical treatment that is expected to cause infertility, including chemotherapy, pelvic</td>
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### Services NOT Requiring Prior Authorization when Member’s Condition Meets the Definition of Infertility ±

- radiotherapy, or other gonadotoxic therapies.

19. Sperm storage/banking† up to 12 calendar months for a male member/member with male reproductive organs NOT in active fertility treatment before the member undergoes medical treatment that is expected to cause infertility, including but not limited to chemotherapy, pelvic radiotherapy, hormone therapy for the treatment of gender dysphoria causing irreversible infertility, or other gonadotoxic therapies. The member must be enrolled in the Plan during the timeframe for cryopreservation and storage, have no prior history of sterilization, and are intended to be used by the member.

20. Testicular tissue cryopreservation† in adult members with azoospermia in conjunction with the testicular biopsy only to identify sperm in preparation for an intracytoplasmic sperm injection procedure, if sperm are found.


### Services Requiring Prior Authorization by the Plan

(See Medical Policy Statement Section and Limitations Section for Detailed Guidelines)

Notes for Plan Prior Authorization Requirements Table:

* Refer to the Plan’s formulary for medication coverage and prior authorization requirements; review the Plan’s Infertility Medications pharmacy policy for clinical criteria for infertility drugs that require prior authorization. See the Preimplantation Genetic Testing (Preimplantation Genetic Diagnosis and Preimplantation Genetic Screening) medical policy (policy number OCA 3.726) for medical criteria for preimplantation genetic diagnosis.

† When Plan guidelines are met for cryopreservation of oocytes, embryos, or sperm (as specified in the Plan Prior Authorization Requirements Table), all applicable ART services to adequately utilize the cryopreserved oocytes, embryos, or sperm to improve fertility rates would be considered medically necessary when it is a covered service for the Plan member (according to applicable benefit documents available at [www.bmchp.org](http://www.bmchp.org)) and when service-specific criteria are met, as specified in item V of the Medical Policy Statement section of this policy.

± Diagnostic tests and procedures provided in connection with an infertility evaluation and/or treatment will not require prior authorization UNLESS otherwise specified in the Medical Policy Statement, Limitations, and/or Applicable Coding sections of this policy.

Infertility Services

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Description of Item or Service

Infertility Services: Service(s) provided to treat the condition where an individual in whom fertility would naturally be expected is unable to conceive or produce conception.

Medical Policy Statement

The Plan considers infertility services Medically Necessary for a member when Plan medical criteria are met and documented in the member’s medical record and the member is enrolled in a Boston Medical HealthNet Plan product with coverage for infertility treatment. Review the member’s applicable evidence of coverage or benefit document available at www.bmchp.org to determine benefit coverage of infertility services for the Plan member. The Plan Prior Authorization Requirements Table (included in the Policy Statement section of this policy) includes a list of infertility services the Plan considered medically necessary when the service is covered for the Plan member. The required Plan medical criteria include item I, item II, item III, and the service-specific criteria for each requested treatment in item IV, as specified below:

I. Mandated Services:

   A. Massachusetts State-Mandated Services:

      1. Definition of Infertility:

         According to Massachusetts law (G.L. c. 175, section 47H), infertility is defined as “the condition of an individual who is unable to conceive or produce conception during a period of:

         a. One (1) year if the female is age 35 or younger; OR
         b. Six (6) months if the female is over the age of 35.

         For purposes of meeting the criteria for infertility...if a person conceives but is unable to carry that pregnancy to live birth, the period of time she attempted to conceive prior to achieving that pregnancy, shall be included in the calculation of the one (1) year or six (6) month period, as applicable.”

         Note: The definition of infertility in G.L. c. 175, section 47H no longer contains a requirement that the person seeking treatment must be otherwise healthy.
2. Mandated Benefit Coverage (as Specified in 211 CMR 37.05):

The following procedures (as specified below in items a through i) must be covered if Medically Necessary:

a. Artificial insemination (AI) and intrauterine insemination (IUI)

b. Assisted hatching

c. Cryopreservation of eggs/oocytes

d. Gamete intrafallopian transfer (GIFT)

e. In vitro fertilization and embryo transfer (IVF-ET)

f. Intracytoplasmic sperm injection (ICSI) for the treatment of male factor infertility/infertility related to male reproductive organs

g. Sperm, egg, and/or inseminated egg procurement and processing, and banking of sperm or inseminated eggs, to the extent such costs are not covered by the donor’s insurer, if any

h. Zygote intrafallopian transfer (ZIFT)

i. All other non-experimental infertility procedures

3. External Review (as Specified in 958 CMR 128.020 and 211 CMR 52.03):

When the Plan denies coverage of infertility treatment based on Medical Necessity, a determination that a procedure is experimental or investigational, or other Plan criteria or guidelines, then these final adverse determinations will be eligible for external review. The review will be based upon Medical Necessity, as specified in the Definitions section of this policy.

B. Section 1557 of the Affordable Care Act (ACA) - Nondiscrimination Provision:

The federal law prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities. Transgender and gender non-conforming members have access to the same covered infertility services available to all Plan members when applicable Plan criteria are met according to reproductive capacity. The infertility criteria for a female member also apply to a transgender or gender non-conforming individual with female reproductive organs. Infertility criteria for a male member also apply to a transgender or gender non-conforming member with male reproductive organs. Transgender or gender non-
conforming members who no longer have reproductive capacity will be eligible for medically necessary infertility services consistent with all Plan members who have medical conditions or undergo medical treatments that have caused permanent infertility (according to benefit coverage specified in the member’s applicable benefit documents available at www.bmchp.org and included in the Plan Prior Authorization Requirements Table of the Policy Summary section, Medical Policy Statement section, and Limitations section of this policy).

II. General Eligibility Requirements for Coverage of Infertility Services:

The member must meet ALL of the following applicable eligibility requirements to be covered, as specified below in items A through K:

A. Massachusetts residency; AND

B. Diagnosis of infertility as per the infertility definition above or the member is permanently infertile due to hormone therapy used for the treatment of gender dysphoria or genital gender reassignment surgery that has resulted in the loss of reproductive functioning; AND

C. The member must be an individual in whom fertility would naturally be expected as specified in this Plan policy (but does not require that the member seeking treatment is otherwise healthy); AND

D. Coverage of infertility benefits for a female member/member with female reproductive organs without documented infertility and no exposure to sperm requires ONE (1) of the following, as specified below in item 1 or item 2:

1. A minimum of 12 or more IUI cycles for a female member/member with female reproductive organs under age 35, supervised by a physician or appropriate licensed practitioner, and do not result in a live birth; OR

2. A minimum of 6 or more IUI cycles for a female member/member with female reproductive organs over age 35 supervised by a physician, or appropriate licensed practitioner and do not result in a live birth; AND

E. Clinical factors to be considered in making the coverage decision regarding infertility may include, but are not limited to, age, hormone levels, medical history, smoking status, and a member’s body mass index (BMI); AND

F. Coverage for IUI in the absence of a male factor infertility/infertility related to male reproductive organs requires that the female member/member with female reproductive organs demonstrates the member’s own infertility by own inability to conceive through exposure to normal sperm through a period that meets ONE (1) of the following criteria, as specified below in item 1 or item 2:
1. 12 menstrual cycles for a female member/member with female reproductive organs ≤ age 35; OR

2. 6 menstrual cycles for a female member/member with female reproductive organs > age 35; AND

G. The infertile member must be the recipient of the intended infertility services; AND

H. Coverage for infertility treatment is based on the member’s individual medical history and should demonstrate > 5% chance of a live birth outcome; AND

I. For an infertile female member/member with female reproductive organs with a clear medical contraindication to pregnancy who is using the member’s own oocytes and self-paying for a gestational carrier, the Plan will cover the infertile member’s infertility evaluation, stimulation, retrieval, and fertilization; AND

J. ART procedures must be performed by one of the Plan’s contracting ART providers; AND

K. Coverage of medications: Injectable/non-injectable medications (not experimental) must be given in conjunction with covered infertility procedures in accordance with the Plan’s eligibility requirements, and the member must be entitled to prescription drug coverage under the terms of the member’s benefit plan. Refer to the following Plan documents at www.bmchp.org for medication coverage and prior authorization requirements, as specified below in items 1 through 3:

   1. Plan Drug Formulary


II. Evaluation Requirements for Coverage of Infertility Services by Reproductive Capacity:

A. Evaluation of a Female Member/Member with Female Reproductive Organs:

   To be considered for eligibility for infertility treatment approval and cycle initiation, the following evaluations must ALL be completed and documented in the member’s medical record, as specified below in items 1 through 8:

   1. Thyroid stimulating hormone (TSH); AND
2. Rubella immunity status (Rubella titer); all non-immune members must be vaccinated and wait 1 month thereafter before repeating Rubella testing and again seeking approval for ART; AND

3. Urine or serum cotinine levels for a member who quit smoking within the past 6 calendar months; AND

4. Tubal disease has been excluded using standard testing for the evaluation of tubal status including hysterosalpingogram (HSG), saline sonohysterogram, laparoscopic chromopertubation and/or selective hysteroscopic/fluoroscopic techniques; AND

5. BOTH of the following ovarian reserve criteria are met, as specified below in item a and item b:

   a. Estradiol (E2) test annually on cycle day 3 for a female member/member with female reproductive organs < age 40 on the date of service; AND

   b. Clomiphene citrate challenge test (CCCT):

       ONE (1) of the following sets of applicable criteria is met, as specified below in item (1) or item (2):

       (1) Testing meets BOTH of the following guidelines, as specified below in item (a) and item (b):

           (a) Tested annually for a female member/member with female reproductive organs ≥ age 40 on the date of service; AND

           (b) Day 3 FSH test repeated every 6 calendar months for any female member/member with female reproductive organs ≥ 40 years of age and repeated annually for a female member/member with female reproductive organs < age 40; OR

       (2) CCCT test does NOT need to be repeated after the initial result if BOTH of the following criteria are met, as specified below in items (a) and (b):

           (a) Female member/member with female reproductive organs has a history of an abnormal CCCT; AND

           (b) Is eligible for donor egg services; AND

6. Normal uterine cavity evaluation must occur within 1 year prior to any ART cycle; AND
7. A female member/member with female reproductive organs with BMI ≥ 35 must submit documentation of an anesthesiology consult within 6 calendar months prior to the initial approval of coverage of an IVF cycle; AND

8. A female member/member with female reproductive organs with BMI ≥ 40 or BMI < 18 must submit BOTH of the following documentation prior to the initial approval of assisted reproductive treatment including IUI and IVF, as specified below in item a and item b:

   a. Nutrition consult within the previous 6 calendar months; AND

   b. Maternal fetal medicine/high risk obstetrics consult within the previous 6 calendar months.

B. Evaluation of a Male Member/Member with Male Reproductive Organs:

To be considered for eligibility for infertility treatment approval, ALL of the following evaluations must be completed and documented in the member’s medical record, as specified below in items 1 through 4:

1. Semen analysis must be submitted within 1 year of treatment; AND

2. Urine or serum cotinine levels for a member who quit smoking within the past 6 calendar months; AND

3. Evaluation by an urologist or reproductive endocrinologist; AND

4. ALL of the following criteria are required for a male member/member with male reproductive organs found to have abnormal semen analysis with severe male factor infertility/infertility related to male reproductive organs (total motile sperm [TMS] count < 10 million) requesting coverage for donor sperm or ART/ICSI, as specified below in items a through d:

   a. Evaluation by an infertility specialist/urologist; AND

   b. Two (2) semen analyses including pH, volume, FSH and testosterone levels; AND

   c. Karyotyping and Y chromosome microdeletion (YCMD) for non-obstructive azospermia and for all S/A < 5 million sperm/mL; AND

   d. Cystic fibrosis screening for male member/member with male reproductive organs with obstructive azospermia with congenital absence of the vas deferens (CAVD) and karyotyping; AND
V. Service-Specific Criteria:

A. Gonadotropin Stimulation with Intrauterine Insemination (IUI) - ART Coverage Criteria:

Note: There is a cycle limit of 3 per member’s lifetime, as it is typically more appropriate after this point to move on to IVF-based ART. This limit shall INCLUDE cycles completed before Plan membership.

ALL of the following criteria are met for gonadotropin stimulation with IUI, as specified below in items 1 through 3:

1. Age-specific guidelines:

   ONE (1) of the following criteria is met, as specified below in item or item b:

   a. Gonadotropin (FSH) treatment and intrauterine insemination (IUI) are covered for members who have a diagnosis of infertility, meet the Plan infertility definition, and ONE (1) of the following applicable age-specific criteria are met, as specified below in item (1), item (2), or item (3):

   (1) Female members/members with female reproductive organs < age 40:

   Within the past 12 calendar month, BOTH of the following tests are obtained and documented, as specified below in item (a) and item (b):

   (a) E2 level on cycle day 3 with E2 level < 100 pg/mL; AND
   (b) Day 3 FSH test; OR

   (2) Female members/members with female reproductive organs aged 40 to 41:

   ALL of the following criteria are met, as specified below in items (a) through (c):

   (a) CCCT is required annually; AND
   (b) FSH level is < 15 mIU/ml on cycle day 3 and cycle day 10 (tested within the past 6 calendar months); AND
   (c) E2 level < 100 pg/mL on cycle day 3 (tested within the past 6 calendar months); OR

   (3) Female members/members with female reproductive organs age 42 to 44:

   ...
ALL of the following criteria are met, as specified below in items (a) through (c):

(a) CCCT is required annually; AND

(b) FSH level is < 12 mIU/ml on cycle day 3 and cycle day 10 (tested within the past 6 calendar months); AND

(c) E2 level < 100 pg/mL on cycle day 3 (tested within the past 6 calendar months); OR

2. Female members/members with female reproductive organs who have been denied IVF services are generally not appropriate candidates for FSH/IUI cycles. Exceptions based upon an individual’s medical history will be considered; AND

3. IUI treatments are not covered after a female member/member with female reproductive organs has done and failed to deliver with IVF (since there is no study proving these IUI cycles have a > 5% live birth rate in women/individuals with ovaries and uteri who have failed prior IVF treatment), except when switching to unmedicated IUIs with donor sperm due to male factor infertility (infertility related to male reproductive organs) in the member’s present male partner/partner with male reproductive organs.

B. In Vitro Fertilization (IVF) - ART Coverage Criteria:

The following criteria must be met for IVF, including general guidelines (item 1), embryo transfer guidelines (item 2), age-specific guidelines (item 3), guidelines for oocytes use (item 4), cycle limits (item 5), and additional services related to IVF (in item 6, when applicable):

1. General Guidelines for IVF:

   IVF is a covered benefit for female members/members with female reproductive organs who meet infertility criteria as defined in this medical policy when fertility is otherwise expected as a natural state (e.g., female members/members with female reproductive organs < age 40 with an abnormal FSH level or CCCT); AND
Note: A clomiphene citrate challenge test (CCCT) needs to be completed annually with the day 3 FSH and E2 levels repeated every 6 calendar months for any female member/member with female reproductive organs ≥ 40 years of age.

2. Embryo Transfer Guidelines:

The American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART) recommend the use of elective single embryo transfer (eSET) to reduce multiple gestations when clinically appropriate. Elective eSET should be considered for the member according to ASRM and SART guidelines in effect of the prior authorization request for services and include appropriate patient education and meet at least ONE (1) of the following criteria, as specified below in item a or item b:

a. Female member/member with female reproductive organs will utilize eSET according to current ASRM and SART guidelines; OR

(Note: ASRM and SART guidelines dated April 2012 state eSET is most appropriate for members with a good prognosis; i.e., women/individuals with female reproductive organs age < 35 years, more than 1 top-quality embryo available for transfer, first or second treatment cycle, previous successful IVF, and recipients of embryos from donated eggs. Women/individuals with female reproductive organs aged 35-40 years may be considered for eSET if they have top-quality blastocyst-stage embryos available for transfer. Decisions regarding eSET of cryopreserved embryos should take into consideration prognosis, embryo quality, and success rates of the individual cryopreservation program.)

b. The treating infertility provider has determined that the female member/member with female reproductive organs does not meet current ASRM and SART guidelines for eSET; AND

3. Age-Specific Guidelines for IVF:

Age-related infertility is not a covered benefit, and is demonstrated by an abnormal CCCT in a female member/member with female reproductive organs > age 40. This is defined below in item a (for a woman/individual with female reproductive organs age 40 or 41) or item b (for a woman/individual with female reproductive organs ≥ age 42):

a. For a woman/individual with female reproductive organs age 40 and 41, at least ONE (1) of the following criteria is met, as specified below in item (1) or item (2):

(1) Cycle day 3 and/or cycle day 10 FSH levels ≥ 15 mIU/ml; OR
(2) Cycle day 3 E2 level ≥ 100pg/mL; OR

b. For a female member/member with female reproductive organs age ≥ 42, at least ONE (1) of the following criteria is met, as specified below in item (1) or item (2):

(1) Cycle day 3 and/or cycle day 10 FSH levels ≥ 12 mIU/ml; OR

(2) Cycle day 3 E2 level ≥ 100pg/mL; AND

4. Guidelines for Oocyte Use with IVF:

BOTH of the following criteria must be met, as specified below in item a and item b:

a. IVF using a member’s own eggs continues to be the treatment of choice for a female member/member with female reproductive organs ≤ age 44 when the following outcome is achieved for each previous IVF cycle initiated, as specified below in BOTH item (1) and item (2):

(1) Embryo transfer when ONE (1) of the following criteria is met, as specified below in item (a) or item (b):

(a) For Day 3 transfer 3-4 embryos, each of which are at least 6-8 cells; OR

(b) For Day 2 transfer, 4 embryos, each of which are at least 2-4 cells; AND

(2) Reasonable quality (grade B or its equivalent) are available for transfer per cycle (including up to fair fragmentation < 25%-50%); AND

b. For female members/members with female reproductive organs from age 40 up to age 44, the decision for coverage will be based upon a 5% expected chance of a live birth outcome and a current history of infertility as a disease state verses an expected state associated with the menopausal transition. Female members/member with female reproductive organs > age 44 requesting to use their own eggs will not be covered for infertility treatment and/or related services regardless of FSH levels or previous cycle response unless there is significant evidence that the chance of a live birth outcome is ≥ 5% or using own previously cryopreserved oocytes before the age of 44 according to Plan guidelines; AND

5. Cycle Limits with IVF:

Coverage is limited to a maximum of 6 cycles, whether the member’s egg or a donor egg is used, and whether or not previous cycles were covered by the Plan and includes ALL of the following guidelines specified below in items a through e. (Also review the cycle limits

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outlined in the Plan Authorization Requirements Table in the Summary section of this Plan policy.)

a. A cycle begins when a member fills her prescription for medications; AND

b. Guidelines regarding cycle coverage limits are subject to individual consideration based on the member’s particular clinical situation and unique medical circumstances; AND

c. Fewer than 6 cycles may be covered when medically appropriate, including situations where additional cycles are unlikely (<5% probability) to result in a live birth; AND

d. Previous ART cycles resulting in a live birth, thaw cycles in the absence of gonadotropin therapy, and IUI cycles do not count towards the 6 cycle coverage limit; AND

e. Cancelled cycles count towards the 6 cycle limit; AND

6. Additional Services Related to IVF:

Additional IVF services may include the following when applicable Plan criteria are met, as specified below as items a, b, and/or c (and criteria must be met for each requested service):

a. Assisted Hatching Coverage Criteria:

While not generally recommended for female members/members with female reproductive organs < age 40, the service may be covered when at least ONE (1) of the following criteria is met, as specified below in item (1) or item (2):

(1) 2 to 3 (or more) failed IVF cycles that produced >3 good quality embryos with failure to implant after embryo transfer; OR

(2) Documented prior pregnancy following IVF that required assisted hatching.

b. Donor Egg/Donor Embryo Coverage and Criteria:

BOTH of the following criteria must be met, as specified below in item (1) for donor coverage and item (2) for donor criteria:

(1) Donor Egg/Embryo Coverage:

Donor egg/donor embryo/ART treatment may be covered for female members/members with female reproductive organs who meet infertility criteria...
when the member’s fertility would be expected as a natural state when ONE (1) of the following criteria are met, as specified below in item (a), item (b), or item (c):

(a) Medical illness or medical treatment which causes an unnatural egg/oocyte quantity, including hormonal therapy, premature menopause or premature ovarian failure/diminished ovarian reserve (with onset prior to age 40 with an FSH ≥ 15 mIU/ml on cycle days 3 or 10); OR

Note: A female member/member with female reproductive organs with abnormal FSH levels after age 40 is not eligible for donor egg coverage regardless of evidence of abnormal FSH levels prior to age 40.

(b) Previously (before the age of 40) failed IVF in a female member/member with female reproductive organs with normal ovarian reserve for a member between ages 40 and 42 are defined below. One of the following applicable criteria is met, as specified in items i through iii:

i. Female member/member with female reproductive organs age 40 to 41:

BOTH of the following criteria are met, as specified below in item (i) and item (ii):

(i) FSH levels which are < 15 mIU/ml on cycle day 3 and cycle day 10; AND

(ii) E2 level is < 100 pg/mL on cycle day 3; OR

ii. Female members/members with female reproductive organs from 42 up to the 44rd birthday:

BOTH of the following criteria are met, as specified below in item (i) and item (ii):

(i) FSH levels which are < 12 mIU/ml on cycle day 3 and cycle day 10; AND

(ii) E2 level is < 100 pg/mL on cycle day 3; OR

iii. Female members/members with female reproductive organs age 44 or older, who are unable to achieve a viable birth outcome using their own eggs/embryos, are NOT covered for infertility services, including donor egg. They are experiencing normal and expected age-related decline in

Infertility Services

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fertility. These changes are no longer consistent with a disease process; OR

(c) Absent ovaries from chemotherapy, radiation therapy, or surgical removal (which may include genital gender reassignment surgery) or female members/members with female reproductive organs who are born without ovaries; AND

(2) Donor Criteria:

ONE (1) of the following criteria must be met, as specified below in item (a) or item (b):

(a) Anonymous or designated donors must be meet ONE (1) of the following criteria, as specified below in item i or item ii:

i. < 35 years of age; OR

ii. Between ages 36 and 39 with normal ovarian reserve as demonstrated by a normal CCCT (i.e., cycle day 3 and cycle day 10 FSH levels are < 12 mIU/ml and a day 3 E2 level < 80 pg/mL); OR

(b) Women/individuals with female reproductive organs age 40 or older are not generally appropriate candidates to donate oocytes/embryos and donor egg is not covered from this source.

c. Frozen Embryo Transfers (FET) Coverage Criteria:**

BOTH of the following criteria must be met for FET, as specified below in items (1) and (2):

(1) Cryopreserved embryos must be used prior to authorization for additional fresh ART cycles under the following circumstances, as specified below in either item (a) or item (b):

(a) Maternal age < 35 years old and 3 cryopreserved embryos of a similar developmental stage are available for transfer; OR

(b) Maternal age > 35, and 4 cryopreserved embryos of a similar developmental stage are available for transfer; AND

(2) Members seeking coverage for FET must meet the definition of infertility and when fertility would be expected as a natural state.

Infertility Services

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**Note:** It is recognized that some female members/members with female reproductive organs may elect to undergo an FET cycle regardless of the number of available embryos before proceeding to another fresh cycle. Such requests will be approved as long as the member continues to be eligible for coverage of infertility treatment.

C. Moderate Male Factor Infertility/Infertility Related to Male Reproductive Organs with IVF Only - ART Coverage Criteria:

Moderate male factor infertility/infertility related to male reproductive organs may impact a male member or a member with male reproductive organs. IVF (alone) is approved for coverage if criteria are met for moderate male factor infertility/infertility related to male reproductive organs for semen analyses performed on 2 or more occasions at least 2 weeks apart containing either ONE (1) of the following, as specified below in item 1 or item 2:

1. A total motile sperm count between > 3 and < 10 million on a post-wash specimen; OR
2. < 4 % normal forms (Kruger Strict Morphology) on a pre-wash specimen

D. Severe Male Factor Infertility/Infertility Related to Male Reproductive Organs with IVF Plus Intra-Cytoplasmic Sperm Injection (ICSI) - ART Coverage Criteria:

Severe male factor infertility/infertility related to male reproductive organs may impact a male member or a member with male reproductive organs. IVF plus ICSI is approved for coverage if criteria are met for severe male factor infertility/infertility related to male reproductive organs as defined by EITHER of the following criteria, as specified below as item 1 or item 2:

1. Semen analysis on 2 separate specimens, performed at least 2 weeks apart, with either of the following results, as specified below in item a or item b:
   a. < 10 million total motile sperm/ejaculate (pre-wash specimen); OR
   b. < 3 million total motile sperm (post-wash specimen); OR
2. The rate of standard fertilization in the previous cycle is poor (< 50%)

E. Donor Sperm or Therapeutic Donor Insemination (TDI) Services – Coverage Criteria:

The Plan provides coverage for donor sperm or TDI/IUI services that are provided to ONE (1) of the following, as specified below in item 1 or item 2:
1. Plan members who have partners diagnosed with severe male factor infertility/infertility related to male reproductive organs; OR

2. In addition, coverage decisions regarding donor sperm services will be based upon the following information, as specified below in item a, item b, and item c:

   a. Member’s past medical/infertility history, including, but not limited to past infertility interventions; AND

   b. If approved by an Authorized Reviewer, the Plan may initially authorize up to 3 donor sperm /IUI cycles; AND

   c. After the authorization end date, or completion of the authorized cycles, the member must go through a new prospective review approval process for coverage of additional cycles; AND

F. In Vitro Fertilization Due to Inadvertent Ovarian Hyperstimulation During Preparation for a Stimulated Intrauterine Insemination Cycle - Coverage Criteria:

Coverage for IVF services due to inadvertent ovarian hyperstimulation during stimulation in preparation for a stimulated intrauterine insemination cycle may be approved when ALL of the following are met, as specified below in items 1, 2 and 3:

1. Member has a diagnosis of infertility; AND

2. Member is eligible for coverage of Medically Necessary infertility treatment as defined by the Plan and ALL of the following criteria are met, as specified below in items a through c; AND

   a. Member is < age 40 with an infertility diagnosis; AND

   b. The estradiol (E2) level is greater than 800 pg/mL; AND

   c. At least ONE (1) of the following criteria are met, as specified below in items (1) through (3):

      (1) There are at least 3 or more follicles > 16mm; OR

      (2) There are 4-8 follicles that are greater than or equal to 14mm; OR

      (3) There are a large number of smaller follicles on day the decision is made to convert; AND
3. If the member is > age 40, it is not Medically Necessary to convert an IUI cycle to IVF due to ovarian hyperstimulation unless E2 is > 2000 and therefore coverage will be based on prior cycle response and individual history.

**Note:** Members must receive IVF services with a Plan contracted ART provider.

**Limitations**

The Plan either does not cover or limits the following services, as specified below in items 1 through 25:

1. Any assisted reproductive technology (ART) procedure or related treatments that are deemed experimental or investigative based on the scientific body of evidence with input from the American Society of Reproductive Medicine, the American College of Obstetrics and Gynecology, or another infertility expert recognized by the Massachusetts Division of Insurance.

2. The Plan considers ANY of the following procedures and products to be experimental and investigational as a treatment for infertility or as an effective artificial reproductive technology because there are insufficient data to verify the safety, clinical validity, and/or clinical utility of each of these procedures or products:
   a. Co-culture of embryos; OR
   b. EmbryoGlue® (a medium developed for embryo transfer by Vitrolife); OR
   c. In vitro maturation (IVM) of oocytes; OR
   d. Uterine transplant.

3. The Plan considers ANY of the following tests to be experimental and investigational when used as reproductive biomarkers, to reliably predict a predict treatment response, determine etiology of infertility, or assist with infertility treatment because there are insufficient data to verify the clinical validity and/or clinical utility of each of these tests:
   a. Computer-aided semen analysis/CASA (since the data do not suggest that the predictive value of CASA is superior compared with conventional semen analysis); OR
   b. Inhibin B levels; OR
   c. Postcoital cervical mucus penetration test; OR
   d. Reactive oxygen species (ROS) test; OR
e. Sperm acrosome reaction test.

4. Infertility treatment, when infertility is the result of prior voluntary sterilization unless BOTH of the following criteria are met, as specified below in item a and item b:

   a. The diagnosis of infertility is unrelated to a previous sterilization procedure; AND

   b. ONE (1) of the following criteria is met, as specified below in item (1) or item (2):

      (1) For a female member/member with female reproductive organs, diagnostic testing confirms at least one (1) patent fallopian tube; OR

      (2) For a male member/member with male reproductive organs, diagnostic testing confirms return of sperm to the ejaculate; AND.

5. Infertility services for individuals who have not met the definition of infertility, or the likelihood of a ‘success’ (defined as a live birth rate) is less than 5%.

6. There is a limit for coverage of gonadotropin/intrauterine insemination of three (3) cycles per member lifetime.

7. Coverage for in vitro fertilization (IVF) services is limited to a maximum of six (6) cycles, whether the member’s egg or donor egg is used, and whether or not previous cycles were covered by the Plan.

8. Fewer than 6 cycles of IVF may be covered when medically appropriate, including situations where additional cycles are unlikely (< 5% probability) to result in a live birth.

9. Previous IVF cycles resulting in a live birth, cancelled cycles, thaw cycles in the absence of gonadotropin therapy, and IUI cycles do not count toward the 6 cycle coverage limit.

10. Infertility treatment is not covered for female members/members with female reproductive organs with age-related infertility (> 40 age) based upon hormonal testing or who do not demonstrate infertility as a disease state. Any single elevation in FSH level for these members > age 40 (which was not elevated prior to age 40) is considered infertility as a natural state and therefore infertility services are not covered.

11. For female members/members with female reproductive organs at age > 44, coverage for infertility treatment and/or related services will not be covered, regardless of FSH levels or previous cycle response as the live birth outcome is < 5%.
12. Use of donor egg and gestational carrier together is not covered, as the female member/member with female reproductive organs is not physically treated in this situation and is effectively a surrogate service.

13. An ART - IVF cycle when it is known at the initiation of a cycle that none of the resulting embryos will be transferred during the same cycle, and/or the intent is to cryopreserve all of the embryos for future use (unless necessary for the transfer of a specimen for accurate and timely preimplantation genetic testing when Plan criteria are met in the Preimplantation Genetic Testing policy, policy number OCA 3.726).

14. Infertility treatment when the infertile member is not the recipient of said services (e.g., donor egg in conjunction with gestational carrier) and drugs that are directly related to a stimulated ART cycle for anonymous or designated donors unless the ART service is prior authorized, and the member is the sole recipient of the donor's eggs.

15 Surrogacy/gestational carrier-related costs: This means all procedures and costs incurred by a fertile woman/individual with female reproductive organs to achieve a pregnancy as a surrogate or gestational carrier for an infertile member.

16. ART/infertility services for members who consume any medications or substances that are against medical advice, and are known to negatively affect fertility potential and/or outcome.

17. Gonadotropin usage greater than 600 IU/day (8 amps/day) as there is no proven medical necessity or efficacy to support utilization beyond this amount.

18. Intrauterine insemination (IUI) or IVF-based forms of assisted reproductive technology (ART) in the absence of male factor infertility/infertility related to male reproductive organs or the absence of a male partner/partner with male reproductive organs, until the female member/member with female reproductive organs meets the definition of infertility (if ever) and coverage criteria for said services.

19. The cost of donor sperm, IUI, IVF with or without ICSI, and related services, if the male partner/partner with male reproductive organs has a history of prior vasectomy.

20. The cost of donor sperm, if the infertile member does not have a male partner/partner with male reproductive organs with a diagnosis of male factor infertility.

21. Services or drugs directly related to non-covered services. (Specifically, there is no coverage of ART procedures or drugs when related to, or in conjunction with a non-covered benefit, or when the procedure is outside the scope of this medical policy.)

22. Infertility services for women who are not Rubella immune or who actively smoke.
23. Cryopreservation and storage limitations include ALL of the following, as specified below in item a (for oocytes), item b (for embryos), item c (for ovarian tissue), item d (for testicular tissue), and item e (for sperm):

a. Cryopreservation and storage of oocytes/eggs:

(1) Cryopreservation of donor eggs is not covered.

(2) Cryopreservation and/or storage of eggs from a female member/member with female reproductive organs are not covered for ANY of the following conditions, as specified below in items (a) through (c):

(a) Female member/member with female reproductive organs has not maintained eligibility for Plan coverage during the timeframe for cryopreservation and/or storage; OR

(b) Cryopreservation and storage of eggs from a female member/member with female reproductive organs for greater than 12 calendar months in duration when the member is NOT in active infertility treatment; OR

(Note: See the Plan Prior Authorization Table in the Summary section of this policy for the Plan medical criteria for coverage of cryopreservation and storage of eggs for female members/members with female reproductive organs who are NOT in active infertility treatment. Cryopreservation and/or storage of oocytes for a member requesting this service for convenience is not covered unless applicable Plan criteria are met in the Plan Authorization Table.)

(c) Cryopreservation and storage of eggs from a female member/member with female reproductive organs for greater than 12 calendar months in duration when the member is in active infertility treatment.

(Note: See the Plan Prior Authorization Table in the Summary section of this policy for the Plan medical criteria for coverage of cryopreservation and storage of eggs for female members/members with female reproductive organs who are in active infertility treatment. Cryopreservation and/or storage of oocytes for a member requesting this service for convenience is not covered unless applicable Plan criteria are met in the Plan Authorization Table.)

(3) Oocyte retrieval, freezing, and storage greater than 12 calendar months in duration for transgender member undergoing Plan authorized genital sex reassignment surgery.
Note: See the Plan Prior Authorization Table in the Summary section of this policy for the Plan medical criteria for coverage of oocyte retrieval, freezing, and storage for a transgender member undergoing Plan authorized genital sex reassignment surgery. Oocyte retrieval, freezing, and storage for a member requesting this service for convenience is not covered unless applicable Plan criteria are met in the Plan Authorization Table.

b. Cryopreservation and/or storage of embryos are not covered for ANY of the following conditions, as specified below in items (1) through (5):

(1) Member has not maintained eligibility for Plan coverage during the timeframe for cryopreservation and/or storage; OR

(2) Cryopreservation and storage of member’s embryo’s greater than 12 calendar months in duration when the member is NOT in active infertility treatment; OR

Note: See the Plan Prior Authorization Table in the Summary section of this policy for the Plan medical criteria for coverage of cryopreservation and storage of embryos for members NOT in active infertility treatment. Cryopreservation and/or storage of embryos for a member requesting this service for convenience is not covered unless applicable Plan criteria are met in the Plan Authorization Table.

(3) Cryopreservation and storage of embryos greater than 12 calendar months in duration when the member is in active infertility treatment; OR

Note: See the Plan Prior Authorization Table in the Summary section of this policy for the Plan medical criteria for coverage of cryopreservation and storage of member’s embryos when the member is in active infertility treatment. Cryopreservation and/or storage of embryos for a member requesting this service for convenience is not covered unless applicable Plan criteria are met in the Plan Authorization Table.

(4) Embryo retrieval, freezing, and storage greater than 12 calendar months in duration for transgender member undergoing Plan authorized genital sex reassignment surgery; OR

Note: See the Plan Prior Authorization Table in the Summary section of this policy for the Plan medical criteria for coverage of embryo retrieval, freezing, and storage for a transgender member undergoing Plan authorized genital sex reassignment surgery. Embryo retrieval, freezing, and storage for a member requesting this service for convenience is not covered unless applicable Plan criteria are met in the Plan Authorization Table.

(5) The embryo(s) is intended for implantation in a person other than the member.
c. Cryopreservation, storage, thawing, and/or reimplantation of ovarian tissue or an entire ovary are considered experimental and investigational infertility services and therefore are not covered by the Plan. Cryopreservation of ovarian tissue or an entire ovary with subsequent auto- or heterotopic transplant has been investigated as a technique to sustain the reproductive function of a female member/member with female reproductive organs who will undergo medical treatment that is expected to cause permanent infertility or requires a sterilizing procedure, including but not limited to chemotherapy, radiotherapy, or surgery due to a malignant disease; these techniques have not been sufficiently studied to determine the clinical utility and clinical validity for fertility treatment.

d. Testicular tissue cryopreservation, storage, thawing, and/or reimplantation or grafting of human testicular tissue are not Plan covered infertility services. The clinical utility and clinical validity of these techniques to preserve fertility have not been established and therefore are considered experimental and investigational.

Note: As specified in the Prior Authorization Table, testicular tissue cryopreservation is considered medically necessary in adults with azoospermia in conjunction with the testicular biopsy only to identify sperm in preparation for an intracytoplasmic sperm injection procedure, if sperm are found.

e. Sperm storage/banking is not covered for ANY of the following conditions, as specified below in items (1) through (4):

(1) Member has not maintained eligibility for Plan coverage during the timeframe for sperm storage/banking; OR

(2) Sperm storage/banking greater than 12 calendar months for male members/members with male reproductive organs who are NOT in active infertility treatment; OR

Note: See the Plan Prior Authorization Table in the Summary section of this policy for the Plan medical criteria for coverage of sperm banking for male members/members with male reproductive organs who are NOT in active infertility treatment. Sperm storage/banking for a member requesting this service for convenience or as an alternate specimen is not covered unless applicable Plan criteria are met in the Plan Authorization Table.

(3) Sperm storage/banking for male members/members with male reproductive organs already in active infertility treatment greater than 12 calendar months; OR

Note: See the Plan Prior Authorization Table in the Summary section of this policy for the Plan medical criteria for coverage of sperm banking for male members/members with male reproductive organs who are in active infertility treatment.
storage/banking for a member requesting this service for convenience or as an alternate specimen is not covered unless applicable Plan criteria are met in the Plan Authorization Table.

(4) Sperm retrieval, freezing, and storage greater than 12 calendar months in duration for a transgender member undergoing Plan authorized genital sex reassignment surgery.

Note: See the Plan Prior Authorization Table in the Summary section of this policy for the Plan medical criteria for coverage of sperm banking for a transgender member undergoing Plan authorized genital sex reassignment surgery. Sperm storage/banking for a member requesting this service for convenience or as an alternate specimen is not covered unless applicable Plan criteria are met in the Plan Authorization Table.

24. Turner syndrome is a contraindication for pregnancy. Cardiology and paternal-fetal medicine consultation and careful screening are recommended before considering pregnancy by oocyte donation and other types of assisted reproductive technology (ART). When a cardiac assessment for the female member/member with female reproductive organs identifies a significant cardiac abnormality, Turner syndrome is an absolute contraindication for pregnancy. Female members/members with female reproductive organs with Turner syndrome having normal results from the cardiac assessment are still at a higher risk for associated morbidity and mortality and require careful clinical observation and reevaluation throughout gestation and postpartum.

25. Bariatric surgery of a female member/member with female reproductive organs within the last 12 calendar months is a contraindication for assisted reproductive technology (ART). The American Society for Reproductive Medicine (ASRM) recommends that individuals who have bariatric surgery should wait one (1) year postoperatively before becoming pregnant.

An infertility service that is deemed to be not Medical Necessary (as specified in the Definitions section of this policy), is considered experimental and investigational, and/or does not meet Plan criteria will be eligible for external review of those denials before a final determination is made.

Definitions

Anovulation: Failure to ovulate.

Assisted Hatching (AH): A microscopic manipulation procedure involving puncture of the embryo’s zona pellucida layer just prior to embryo transfer, felt by some to facilitate hatching of the embryo. According to the American Society of Reproductive Medicine, AH has not been demonstrated definitively to improve the live birth rates.

Assisted Reproductive Technology (ART): A general term referring to methods used to achieve pregnancy by artificial or partially artificial means. The Centers for Disease Control (CDC) defines ART
as fertility treatments in which both the eggs and sperm are handled. Not included in ART is assisted insemination (artificial insemination) using sperm from either a woman’s partner/partner of an individual with female reproductive organs or a sperm donor. The most common methods include intracytoplasmic sperm injection (ICSI), intrauterine insemination (IUI), and in vitro fertilization (IVF). These procedures usually take place through office visits and may include: diagnostic evaluation and testing, ovarian stimulation, egg retrieval, procurement and processing of sperm and eggs or inseminated/fertilized eggs, transfer of embryos, and banking of extra embryos when associated with active infertility treatment. (Banking is covered only when associated with active infertility treatment.) Examples of ART include but are not limited to gamete intrafallopian transfer (GIFT), transuterine fallopian transfer (TUFT), natural oocyte retrieval with intravaginal fertilization (NORIF), pronuclear state tubal transfer (PROST), tubal embryo transfer (TET), zygote intrafallopian transfer (ZIFT), gamete and embryo cryopreservation, oocyte and embryo donation, and gestational surrogacy.

**Body Mass Index (BMI):** Body mass index describes relative weight for height and correlates with total fat content. BMI is calculated as weight (kg)/height squared (m²). The classification of BMI is specified in the table below. To estimate BMI using pounds and inches, use the following formula: Weight (pounds)/height (inches) x 703.

<table>
<thead>
<tr>
<th>Description</th>
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<tr>
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**Clomiphene Citrate Challenge Test (CCCT):** Ovarian function test used to assess the ability of the ovaries to respond to hormone signals. First, serum estradiol (E2) and follicle stimulating hormone (FSH) levels are measured on day 3 of the female’s cycle (or cycle of individual with female reproductive organs). Clomiphene citrate (100 mg) is then administered orally (usually day 5 though cycle day 9). Serum FSH and E2 levels are measured again on cycle day 10. Serum estradiol (E2) levels are almost always tested simultaneously with the serum FSH levels to prevent an inappropriate interpretation of the test results; basal serum E2 alone (without FSH levels) should not be used to screen for diminished ovarian reserve. An elevated FSH level measured on day 3 or (after clomiphene citrate stimulation) on day 10 indicates diminished ovarian reserve with the expectation of poor ovarian response to gonadotropin stimulation and associated low live birth rate with stimulated cycles using either intrauterine insemination (IUI) or in vitro fertilization (IVF).
Co-culture of Embryos: A process by which embryos develop on culture containing cells grown from the mother’s uterine lining, or endometrium, before being transferred to the mother’s uterus during an IVF cycle.

Cryopreservation: Cooling of cells and tissue to sub-zero temperatures in order to stop all biological activity and preserve them for future use.

Donor Egg (Donor Oocyte) In Vitro Fertilization (IVF): Procedure by which the eggs of a healthy donor are obtained surgically and implanted after fertilization, using some form of IVF, in the infertile female member/member with female reproductive organs.

Gamete Intrafallopian Transfer (GIFT): Similar to IVF in that the sperm are allowed to fertilize eggs by placing both close together, but different in that the gametes (egg and sperm) are transferred using a laparoscopic surgical procedure into the fallopian tubes where fertilization takes place rather than in the laboratory container.

Hyaluronan Binding Assay (HBA): Qualitative assay for the maturity of sperm in a fresh semen sample. The assay is based on the ability of mature, but not immature, sperm to bind hyaluronan, the main mucopolysaccharide of the cumulus oophorus matrix and a component of human follicular fluid. Hyaluronan-binding capacity is acquired late in the sperm maturation process. A low level of sperm binding to hyaluronan suggests that there is a low proportion of mature sperm in the sample. Similar to the sperm penetration assay, it has been suggested that the HBA assay may be used to determine the need for an intracytoplasmic sperm injection (ICSI) for ART. The HBA is a laboratory test that has received U.S. Food and Drug Administration (FDA) clearance through the 510(k) approval process as a component of the standard analysis of semen in the diagnosis of suspected male infertility (or suspected infertility related to male reproductive organs) or as a component of analyses for determining the proper course of in vitro fertilization treatment of infertility.

In Vitro Fertilization (IVF): The process of fertilization by manually combining an egg and sperm in a laboratory container.

In Vitro Maturation (IVM) of Oocytes: Oocytes are removed from ovaries when they are still immature and then matured in the laboratory before being fertilized and implanted (as would occur with conventional IVF treatment). With IVF, oocytes are mature when they are collected. The ovaries are minimally stimulated with IVM, requiring less fertility medications than IVF to stimulate the ovaries to produce oocytes.

Intra-Cytoplasmic Sperm Injection (ICSI): An in vitro fertilization procedure in which a single sperm is injected directly into an egg using a small tube called a micropipette.

Intrauterine Insemination (IUI): A fertility treatment that uses a catheter to place a number of washed sperm directly into the uterine cavity of a woman/individual with female reproductive organs in an Infertility Services

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effort to achieve successful fertilization. The goal of IUI is to increase the number of high-quality sperm that reach the fallopian tubes and subsequently increase the chance of fertilization. Washing of sperm results in a reduction in seminal fluid volume which also has the secondary benefit of decreased uterine cramping for some women who are sensitive to the fluid itself. Preparation for this procedure can include pre-treatment with various pharmacologic agents (including, but not limited to gonadotropins, clomiphene citrate, GnRH agonists and antagonists) to produce controlled ovarian hyperstimulation.

**Male Infertility/Infertility Related to Male Reproductive Organs:** The inability to produce conception with documented abnormal semen analysis as defined by the findings of 2 abnormal semen analyses (by Krüger Strict classification) at least 14 days apart, with a minimum of 2 days abstinence, within 1 year of a request for infertility services. Whether male infertility (infertility related to the individual’s male reproductive organs) is moderate or severe may depend on specific findings (i.e., total motile sperm count and % normal forms) in the semen analysis. In addition, the diagnosis of severe male infertility may also be discovered if a poor fertilization rate occurs during a failed trial of IVF. The exact definitions are as follows:

1. **Moderate Male Infertility (Moderate Infertility Related to the Individual’s Male Reproductive Organs):**

   When semen analysis shows results of either:
   
   a. A total motile sperm count between > 3 and < 10 million on a post-wash specimen; OR
   
   b. < 4 % normal forms (Kruger Strict Morphology) on a pre-wash specimen

2. **Severe Male Infertility (Severe Infertility Related to the Individual’s Male Reproductive Organs):**

   a. When semen analysis shows results of either:

      (1) < 10 million total motile sperm/ejaculate (pre-wash specimen); OR

      (2) < 3 million total motile sperm (post-wash specimen); OR

   b. Poor (< 50%) rate of standard fertilization in the previous cycle

**Medical Necessity or Medically Necessary:** As defined by Massachusetts law or regulations (211 CMR 52.03), health care services that are consistent with generally accepted principles of professional medical practice as determined by whether:

1. The service is the most appropriate available supply or level of service for the insured in question considering potential benefits and harms to the individual;
2. The service is known to be effective, based on scientific evidence, professional standards and expert opinion, in improving health outcomes; OR

3. For services and interventions not in widespread use, is based on scientific evidence.

**Microsurgical Epididymal Sperm Aspiration (MESA):** The retrieval of sperm from the epididymis by using microsurgical techniques usually performed in men with obstructive azoospermia (blocked epididymal tubes).

**Oligoovulation:** Infrequent or irregular ovulation seen in women with irregular or very long menstrual cycles (with cycle length greater than 50 days).

**Primary Ovarian Insufficiency:** Primary ovarian insufficiency is the depletion or dysfunction of ovarian follicles with cessation of menses before age 40 years. The condition has previously been referred to as premature menopause or primary ovarian failure. “Primary ovarian insufficiency” is the preferred term advocated by the National Institutes of Health because ovarian function is intermittent or unpredictable in many cases. Fertility may persist even when few functional follicles are present. Because of occasional spontaneous resumption of ovarian function, there is a 5–10% chance of spontaneous pregnancy despite a diagnosis of primary ovarian insufficiency. (Source: The American College of Obstetricians and Gynecologists.)

**Recurrent Pregnancy Loss (RPL):** Disease, as defined by the American Society of Reproductive Medicine, distinct from infertility, when two or more pregnancy losses occur. Both infertility and RPL may occur concurrently as determined by an infertility specialist.

**Semen Analysis (S/A):** Normal semen analysis includes total sperm count greater than 20 million/mL, motility greater than 50% (total motile count of 10 million) and normal morphology (greater than 14% normal forms by Krüger Strict classification) and total motile sperm count (if available) is greater than 15 million.

**Single Embryo Transfer (SET):** The transfer of a single embryo at either the cleavage stage (day 2 or 3 after an egg retrieval) or blastocyst stage (day 5 or 6 after an egg retrieval). Elective single-embryo transfer (eSET) is when a woman/individual with female reproductive organs undergoing IVF chooses to have a single embryo transferred when multiple embryos are available to reduce multiple gestations (and associated health risks).

**Total Motile Sperm Count (TMSC):** Test that involves counting the total number of sperm, degree of motility (scale of 0-4), percent of adequate motility (score of 2.5 or better), and total volume of sample.

**Zygote Intrafallopian Transfer (ZIFT):** Following IVF (fertilization which takes place when eggs and sperm are placed in a laboratory container), the fertilized egg is then transferred into the fallopian
tubes using a laparoscopic surgical procedure, similar to GIFT. ZIFT differs from GIFT in that the fertilization process takes place in the laboratory versus the fallopian tubes.

**Applicable Coding**

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United States by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy for infertility treatment, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

See plan policy, *Preimplantation Genetic Testing (Preimplantation Genetic Diagnosis and Preimplantation Genetic Screening)* policy number OCA 3.726, for applicable coding, medical criteria, and prior authorization requirements for preimplantation genetic testing. Review Plan reimbursement policy, *Reimbursement Guidelines: Infertility Services* (policy number 4.34), for infertility coverage and billing guidelines.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Services Covered When Medically Necessary for Infertility Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>55870</td>
<td>Electroejaculation</td>
</tr>
<tr>
<td>58321</td>
<td>Artificial insemination, intra-cervical</td>
</tr>
<tr>
<td>58322</td>
<td>Artificial insemination, intra-uterine</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>58323</td>
<td>Sperm washing for artificial insemination</td>
</tr>
<tr>
<td>58970</td>
<td>Follicle puncture for oocyte retrieval, any method</td>
</tr>
<tr>
<td>58974</td>
<td>Embryo transfer, intrauterine</td>
</tr>
<tr>
<td>58976</td>
<td>Gamete, zygote, or embryo intrafallopian transfer, any method</td>
</tr>
<tr>
<td>59866</td>
<td>Multifetal pregnancy reduction(s) (MPR)</td>
</tr>
<tr>
<td>74742</td>
<td>Transcervical catheterization of fallopian tube, radiological supervision</td>
</tr>
<tr>
<td></td>
<td>and interpretation</td>
</tr>
<tr>
<td>76948</td>
<td>Ultrasonic guidance for aspiration of ova, imaging supervision and</td>
</tr>
<tr>
<td></td>
<td>interpretation</td>
</tr>
<tr>
<td>89250</td>
<td>Culture of oocyte(s)/embryo(s), less than 4 days</td>
</tr>
<tr>
<td></td>
<td>Plan note: Code used to report in vitro maturation of oocytes, including</td>
</tr>
<tr>
<td></td>
<td>cryopreservation, storage, and thawing of immature oocytes. The Plan</td>
</tr>
<tr>
<td></td>
<td>considers in vitro maturation of oocytes to be experimental and investiga-</td>
</tr>
<tr>
<td></td>
<td>tional.</td>
</tr>
<tr>
<td>89253</td>
<td>Assisted embryo hatching, microtechniques (any method)</td>
</tr>
<tr>
<td>89254</td>
<td>Oocyte identification from follicular fluid</td>
</tr>
<tr>
<td>89255</td>
<td>Preparation of embryo for transfer (any method)</td>
</tr>
<tr>
<td>89257</td>
<td>Sperm identification from aspiration (other than seminal fluid)</td>
</tr>
<tr>
<td>89258</td>
<td>Cryopreservation; embryo(s)</td>
</tr>
<tr>
<td>89259</td>
<td>Cryopreservation; sperm</td>
</tr>
<tr>
<td>89260</td>
<td>Sperm isolation; simple prep (e.g., sperm wash and swim-up) for insemination</td>
</tr>
<tr>
<td></td>
<td>or diagnosis with semen analysis</td>
</tr>
<tr>
<td>89261</td>
<td>Sperm isolation; complex prep (e.g., Percoll gradient, albumin gradient)</td>
</tr>
<tr>
<td></td>
<td>for insemination or diagnosis with semen analysis</td>
</tr>
<tr>
<td>89264</td>
<td>Sperm identification from testis tissue, fresh or cryopreserved</td>
</tr>
<tr>
<td>89268</td>
<td>Insemination of oocytes</td>
</tr>
<tr>
<td>89272</td>
<td>Extended culture of oocyte(s)/embryo(s), 4-7 days</td>
</tr>
<tr>
<td>89280</td>
<td>Assisted oocyte fertilization, microtechnique; less than or equal to 10</td>
</tr>
<tr>
<td></td>
<td>oocytes</td>
</tr>
<tr>
<td>89281</td>
<td>Assisted oocyte fertilization, microtechnique; greater than 10 oocytes</td>
</tr>
<tr>
<td>89325</td>
<td>Sperm antibodies</td>
</tr>
<tr>
<td>89329</td>
<td>Sperm evaluation; hamster penetration test</td>
</tr>
<tr>
<td></td>
<td>Plan note: The Plan considers the postcoital cervical mucus penetration</td>
</tr>
<tr>
<td></td>
<td>test and sperm acrosome reaction assay to be experimental and investiga-</td>
</tr>
<tr>
<td></td>
<td>tional.</td>
</tr>
<tr>
<td>89330</td>
<td>Sperm evaluation; cervical mucus penetration test, with or without spin-</td>
</tr>
<tr>
<td></td>
<td>nbarkeit test</td>
</tr>
<tr>
<td></td>
<td>Plan note: The Plan considers the postcoital cervical mucus penetration</td>
</tr>
<tr>
<td></td>
<td>test and sperm acrosome reaction assay to be experimental and investiga-</td>
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<tr>
<td></td>
<td>tional.</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>89335</td>
<td>Cryopreservation, reproductive tissue, testicular</td>
</tr>
<tr>
<td>89337</td>
<td>Cryopreservation, mature oocyte(s)</td>
</tr>
<tr>
<td>89342</td>
<td>Storage (per year); embryo(s)</td>
</tr>
<tr>
<td>89343</td>
<td>Storage (per year); sperm/semen</td>
</tr>
<tr>
<td>89344</td>
<td>Storage (per year); reproductive tissue, testicular/ovarian</td>
</tr>
<tr>
<td>89346</td>
<td>Storage (per year); oocyte(s)</td>
</tr>
<tr>
<td>89352</td>
<td>Thawing of cryopreserved; embryo(s)</td>
</tr>
<tr>
<td>89353</td>
<td>Thawing of cryopreserved; sperm/semen, each aliquot</td>
</tr>
<tr>
<td>89354</td>
<td>Thawing of cryopreserved; reproductive tissue, testicular/ovarian</td>
</tr>
<tr>
<td>89356</td>
<td>Thawing of cryopreserved; oocytes, each aliquot</td>
</tr>
<tr>
<td>89398</td>
<td>Unlisted reproductive medicine laboratory procedures</td>
</tr>
</tbody>
</table>
HCPCS Codes | Description: Services Covered When Medically Necessary for Infertility Treatment  
--- | ---  
S4011 | In vitro fertilization; including but not limited to identification and incubation of mature oocytes, fertilization with sperm, incubation of embryo(s), and subsequent visualization for determination of development  
S4013 | Complete cycle, gamete intrafallopian transfer (GIFT), case rate  
S4014 | Complete cycle, zygote intrafallopian transfer (ZIFT), case rate  
S4015 | Complete in vitro fertilization cycle, not otherwise specified, case rate  
S4016 | Frozen in vitro fertilization cycle, case rate  
S4017 | Incomplete cycle, treatment cancelled prior to stimulation, case rate  
S4018 | Frozen embryo transfer procedure cancelled before transfer, case rate  
S4020 | In vitro fertilization procedure cancelled before aspiration, case rate  
S4021 | In vitro fertilization procedure cancelled after aspiration, case rate  
S4022 | Assisted oocyte fertilization, case rate  
S4023 | Donor egg cycle, incomplete, case rate  
S4025 | Donor services for in vitro fertilization (sperm or embryo), case rate  
S4026 | Procurement of donor sperm from sperm bank  
S4028 | Microsurgical epididymal sperm aspiration (MESA)  
S4030 | Sperm procurement and cryopreservation services; initial visit  
S4031 | Sperm procurement and cryopreservation services; subsequent visit  
S4035 | Stimulated intrauterine insemination (IUI), case rate  
S4037 | Cryopreserved embryo transfer, case rate  

CPT Codes | Description: Services Considered Experimental and Investigational for Infertility Treatment  
--- | ---  
82397 | Chemiluminescent assay  

Plan note: Code used to bill for the reactive oxygen species testing. Prior authorization is required when this code is used for infertility treatment.

Infertility Services

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**Clinical Background Information**

Lifestyle choices can have adverse effects on human reproduction. According to the American Society for Reproductive Medicine (ASRM) committee opinion on obesity and reproduction (November 2015), obesity in women and men appears to be associated with impaired reproductive function (including but not limited to ovulation and endometrial dysfunction in women and decreased sperm count and motility in men). In addition, obese women are at an increased risk of developing maternal and fetal complications during pregnancy. For obese individuals, reproductive function and pregnancy rates often improve with weight loss. The health benefits of postponing pregnancy for weight loss must be weighed against the risk of declining fertility with advancing age. ASRM recommends that women who have bariatric surgery should wait one (1) year postoperatively before becoming pregnant.

ASMR reports that some infertility may be attributable to cigarette smoke by accelerating the loss of reproductive function in women. There is evidence that smoking increases the risk of a spontaneous abortion and ectopic pregnancy in women. Although smoking has not been demonstrated as conclusively reducing male fertility (infertility related to the individual’s male reproductive organs), there is evidence of decreased results in sperm function tests with smokers (when compared to male nonsmokers/nonsmokers with male reproductive organs). According to the ASMR committee opinion on smoking and infertility (December 2012: “There is good evidence that smokers require nearly twice the number of IVF attempts to conceive as nonsmokers.”) Nonsmokers with excessive exposure to tobacco smoke (passive smoking or second-hand smoke) may experience the same adverse reproductive effects as smokers. ASMR recommends that individuals who smoke or are exposed to smoke/nicotine products stop exposure for at least two (2) months before beginning infertility treatment.

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<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Plan Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>83520</td>
<td>Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified</td>
<td>Code used to report serum inhibin B testing. Prior authorization is required when this code is used for infertility treatment.</td>
</tr>
<tr>
<td>89240</td>
<td>Unlisted miscellaneous pathology test</td>
<td>Code used to report media preparation for storage of oocytes, sperm or embryos (e.g., EmbryoGlue®). Prior authorization is required when this code is used for infertility treatment.</td>
</tr>
<tr>
<td>89251</td>
<td>Culture of oocyte(s)/embryo(s), less than 4 days; with co-culture of oocyte(s)/embryos</td>
<td>Code used to report co-culture of embryos. The Plan considers the co-culture of embryos to be experimental and investigational.</td>
</tr>
<tr>
<td>89331</td>
<td>Sperm evaluation, for retrograde ejaculation, urine (sperm concentration, motility, and morphology, as indicated)</td>
<td></td>
</tr>
</tbody>
</table>
References

Aboulghar M et al. Controlled ovarian hyperstimulation and intrauterine insemination for treatment of unexplained infertility should be limited to a maximum of three trials. Fertility and Sterility 2001; (1):88-91.


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American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART). The Practice Committees of ASRM and SART. Elective single embryo transfer.
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<table>
<thead>
<tr>
<th>Original Approval Date and Version Number</th>
<th>Original Effective Date and Version Number</th>
<th>Policy Owner</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Approval: N/A</td>
<td>01/01/12 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)</td>
<td>MPCTAC and QIC</td>
</tr>
<tr>
<td>Internal Approval: 06/29/11: MPCTAC 07/27/11: QIC</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Policy Revisions History**

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/01/12</td>
<td>Updated references, revised applicable code list, and revised the introductory paragraph in Applicable Coding section. Added eligibility requirement that a female member seeking infertility services with a BMI &lt; 18 (as well as BMI ≥ 40) must submit to Plan nutrition consult and maternal fetal medicine/high risk obstetrics consult.</td>
<td>11/01/12 Version 2</td>
<td>06/20/12: MPCTAC 07/18/12: MPCTAC 08/22/12: QIC</td>
</tr>
<tr>
<td>06/01/13, 07/01/13, and 08/01/13</td>
<td>Review for effective date 12/01/13. Reformatted Summary section. Revised Description of Item or Service section. Updated and added references. Deleted CPT codes 89290 and 89291 for preimplantation genetic testing; these codes are included in the Plan’s Preimplantation Genetic Testing (Preimplantation Genetic Diagnosis and Pregenetic Screening) policy. Applicable Plan policies referenced. Deleted duplicate text. Revised definition of infertility (which no longer contains a requirement that the member seeking treatment must be otherwise healthy), revised list of covered infertility services, and referenced external review process for final adverse determinations to comply with the Commonwealth of Massachusetts mandated benefits. Added criteria for male infertility without ICSI, revised criteria for male infertility with ICSI, revised definition of male infertility, and added guidelines for coverage for a</td>
<td>12/01/13 Version 3</td>
<td>06/19/13: MPCTAC 07/17/13: MPCTAC 08/21/13: MPCTAC 09/19/13: QIC</td>
</tr>
</tbody>
</table>

Infertility Services

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Policy Revisions History

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision Description</th>
<th>Effective Date</th>
<th>Version</th>
<th>Reviewer(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/01/14</td>
<td>Review for effective date 05/01/14. Updated table in Summary section. Revised criteria for ovarian reserve in the Medical Policy Statement section. Added introductory sentence and reformatted Medical Policy Statement section. Reformatted and revised Limitations section and the prior authorization table in the Summary section. Added 24 month timeline for cryopreservation of embryos when member in active infertility treatment, added 24 month timeline for cryopreservation of eggs for female member in active infertility treatment, and added 12 month timeframe for sperm banking for male member in active infertility treatment.</td>
<td>05/01/14</td>
<td>01/15/14</td>
<td>MPCTAC 02/18/14: QIC</td>
</tr>
<tr>
<td>06/01/14</td>
<td>Review for effective date 10/01/14. Reformatted Medical Policy Statement section and Limitations section without changing criteria. Revised Summary section. Deleted CPT codes 59866 and 74742 since these services may be utilized for indications unrelated to infertility service. Added CPT code 89353 as an applicable code.</td>
<td>10/01/14</td>
<td>06/18/14</td>
<td>MPCTAC 07/09/14: QIC</td>
</tr>
<tr>
<td>12/01/14</td>
<td>Review for 2015 code revisions effective 03/01/15. Added CPT code 89337.</td>
<td>03/01/15</td>
<td>12/02/14</td>
<td>MPCTAC (electronic vote) 12/10/14: QIC</td>
</tr>
<tr>
<td>06/01/15</td>
<td>Review for effective date 10/01/15. Updated template. Updated criteria in the Plan Prior Authorization Requirements Table in the Summary section, the Medical Policy Statement section, and the Limitations section. Defined active infertility treatment as Plan authorized active infertility treatment in the Summary section. Updated Definitions and References sections.</td>
<td>10/01/15</td>
<td>06/17/15</td>
<td>MPCTAC 07/08/15: QIC</td>
</tr>
<tr>
<td>11/01/15</td>
<td>Review for effective date 01/01/16. Updated template with list of applicable products. Revised language in the Applicable Coding section.</td>
<td>01/01/16</td>
<td>11/18/15</td>
<td>MPCTAC (electronic vote) 12/09/15: QIC</td>
</tr>
<tr>
<td>06/01/16</td>
<td>Review for effective 10/01/16. Added language in the Clinical Background Information section for increased risk of impaired reproductive function with obesity and/or exposure to cigarette smoke. Revised criteria in the Plan Prior Authorization Requirements Table (in the Policy Statement section), Medical Policy Statement section, and Limitations section. Revised applicable code list and added Plan notes in the Applicable Coding section. Updated Definitions, References, Reference to Applicable</td>
<td>10/01/16</td>
<td>06/15/16</td>
<td>MPCTAC 07/13/16: QIC</td>
</tr>
</tbody>
</table>

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<th>Version</th>
<th>Date</th>
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<tbody>
<tr>
<td>09/28/16</td>
<td>Review for effective date 11/01/16. Administrative changes made to clarify language related to gender.</td>
<td>11/01/16</td>
<td>Version 10</td>
<td>09/30/16: MPCTAC (electronic vote)</td>
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<td>Version 10</td>
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<td>10/12/16: QIC</td>
</tr>
</tbody>
</table>

Last Review Date

09/28/16

Next Review Date

06/01/17

Authorizing Entity

QIC

Other Applicable Policies

Clinical Coverage Guidelines - GnRH Agents, policy number 9.136
Clinical Coverage Guidelines - Infertility Medications, policy number 9.175
Medical Policy - Preimplantation Genetic Testing (Preimplantation Genetic Diagnosis and Preimplantation Genetic Screening), policy number OCA 3.726
Reimbursement Policy - Infertility Services, policy number 4.34

Reference to Applicable Laws and Regulations


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**Disclaimer Information:**

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.