In Vitro Fertilization

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<tr>
<th>Policy Number:</th>
<th>Current Effective Date:</th>
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<tr>
<td>MM.03.002</td>
<td>January 01, 2020</td>
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<tr>
<th>Lines of Business:</th>
<th>Original Effective Date:</th>
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<tr>
<td>HMO; PPO</td>
<td>May 21, 1999</td>
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<tr>
<th>Place of Service:</th>
<th>Precertification:</th>
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<tr>
<td>Outpatient</td>
<td>Required, see Section IV</td>
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I. Description

In vitro fertilization is a method used to treat infertility in an individual who is not expected to be infertile. It involves the administration of medications to stimulate the development, growth and maturation of eggs that are within the ovaries. The eggs are retrieved from the follicles when they reach optimum maturation and are combined with sperm in the laboratory before being placed in an incubator to promote fertilization and embryo development. The embryos are then transplanted back into the woman’s uterus.

The chances that fertility treatment will successfully lead to a live birth vary with the couple, individual, treatment, and other conditions. Some treatments have such a low chance of success that they may be considered futile, while others, though not futile, may have a very poor prognosis. American Society of Reproductive Medicine (ASRM) considers treatment as having a very poor prognosis when the odds of achieving a live birth are very low but not nonexistent (>1% to ≤5% per cycle). ASRM defines futility as when the odds of achieving a live birth is ≤1%.

Maternal age and ovarian reserve is a major determinant for IVF success.

II. Policy Criteria

A. In vitro fertilization for women ages 18 years or older with a male partner is covered (subject to Limitations and Administrative Guidelines) when all of the following criteria are met:
   1. If the woman ages 18 years or older and her male partner have a five-year history of infertility, or infertility associated with one or more of the following conditions:
      a. Endometriosis
      b. Exposure in utero to diethylstilbestrol (DES)
      c. Blockage or surgical removal of one or both fallopian tubes
      d. Abnormal male factors contributing to the infertility
   2. The woman ages 18 years or older and her male partner have been unable to attain a successful pregnancy through other infertility treatments for which coverage is available.

B. In vitro fertilization for women ages 18 years or older without a male partner is covered (subject to Limitations and Administrative Guidelines) when the woman, who is not known to be otherwise infertile, has failed to achieve pregnancy following 3 cycles of physician directed, appropriately timed intrauterine insemination (IUI). This applies whether or not the IUI is a covered service.

C. The in vitro procedure must be performed at a medical facility that conforms to the American College of Obstetricians and Gynecologists (ACOG) guidelines for in vitro fertilization clinics or the American Society for Reproductive Medicine’s (ASRM) minimal standards for programs of in vitro fertilization.
III. Limitations

A. Coverage is limited to a one-time only benefit for one outpatient in vitro fertilization procedure ("IVF Benefit") per HMO (e.g., Health Plan Hawaii plan) or PPO product (e.g., Preferred Provider Plan/Comprehensive Medical Plan) in which the patient is enrolled or has been enrolled with HMSA (in either a group or individual plan). Once the patient has exhausted such benefits under prior coverage with HMSA, she will be entitled to a one-time additional single IVF Benefit, if she subsequently enrolls with a new group plan, but only if she has not previously received an IVF Benefit under an HMSA plan with that group.

1. Federal Plan 87 has a separate limit of one complete procedure. A complete in vitro attempt or cycle is defined as a complete effort to fertilize eggs and transfer the resulting embryo(s) into the patient.

2. International Longshore and Warehouse Union (ILWU) Hotels: Health & Welfare Trust Workers members have separate benefits. Section II.A and II.C are the only policy criteria applicable for ILWU members. Section II.B is not a covered benefit according to ILWU’s GTB.

B. It is the stance of HMSA, in accordance with ARSM guidelines, that IVF treatments will not be covered when the chance for success is considered to be very poor or futile.

C. In vitro fertilization services are not covered when a surrogate is used. A surrogate is defined as a woman who carries a child for a couple or single person with the intention of giving up that child once it is born.

D. While most of HMSA’s plans cover in vitro fertilization using donor oocytes and sperm, there are a few that do not. Providers should check the patient’s plan benefits before considering the procedure. While the patient may be precertified for the IVF procedure, HMSA will not cover the cost of donor oocytes and donor sperm, and any donor-related services, including, but not limited to collection, storage and processing of donor oocytes and donor sperm.

E. Cryopreservation of oocytes, ovarian tissue, embryos or sperm is not covered.

F. Infertility services for women ages 40 years or older with natural menopause are not covered as such services are not considered treatment of disease. Women with ovarian failure who are less than 40 years of age are considered to have premature ovarian failure (also known as premature ovarian insufficiency, primary ovarian insufficiency, or hypergonadotropic hypogonadism).

G. Infertility services are not covered for women who have undergone a hysterectomy.

H. Infertility services are not covered for individuals who have undergone genital gender reassignment surgery (female to male or male to female).

I. Assisted reproductive technology (ART) procedures are not covered. This includes but is not limited to:
   1. Embryo transfer (except for IVF).
   2. Gamete intra-fallopian transfer (GIFT), and zygote intra-fallopian transfer (ZIFT).
   3. Services and supplies related to ART procedures except for IVF.

J. Services of a surrogate or gestational carrier.

K. Gonadotropins for infertility are not covered without an authorization for infertility services.

L. Infertility treatment medications are not reimbursed for members who do not meet our guidelines for infertility coverage or for anonymous donors.
IV. Administrative Guidelines

A. Precertification is required. To precertify, complete the In Vitro Fertilization Precertification and mail or fax the form, or use iExchange as indicated. Appropriate documentation to support a clinical diagnosis should be submitted with the precertification request. Precertification is valid for one year.

1. Patients over 44 years old requesting IVF services will require demonstration of ovarian reserve. Labs that are required are as follows:
   a. Day 3 FSH
   b. Day 3 Estradiol
   c. Antral Follicle Count within 6 months
   d. Anti- Mullerian hormone (AMH) level within 6 months

2. Follistim AQ is preferred gonadotropin. If prescribing Gonal-F, an additional precertification is required through CVS Caremark.

3. Maximum gonadotropin units is limited to 4500 IU per cycle attempt.

4. Maximum menotropin units is limited to 1500 IU per cycle attempt.

B. For claims filing instructions, see Billing Instructions and Code Information. HMSA reserves the right to perform retrospective reviews to validate if services rendered met coverage criteria.

C. Applicable codes for gonadotropins:

<table>
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<tr>
<th>Drug name</th>
<th>HCPCS Codes</th>
<th>Description</th>
<th>NDC</th>
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<tbody>
<tr>
<td>Gonal-F</td>
<td>S0126</td>
<td>Injection, follitropin beta, 75 IU</td>
<td>Yes</td>
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<tr>
<td>Follistim-AQ</td>
<td>S0128</td>
<td>Injection, Follitropin Alfa, 75 IU</td>
<td>Yes</td>
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D. The chart above identifies the HCPCS code that must be submitted on the claim form with NDC information to identify drug administration for In Vitro Fertilization.

E. Annual data reporting to SART and CDC is required.

V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.
VI. References