

**Subject: Infertility Services - Massachusetts****Background:**

Infertility is the condition of an individual who is unable to conceive or produce conception during a period of one year (if the female is age 35 years or younger), or during a period of 6 months (if the female is over age 35).

- For purposes of meeting HPHC criteria, if a woman conceives but is unable to carry the pregnancy to live birth, the period of time spent attempting to conceive prior to achieving that pregnancy is included in the calculation of the one year (for females age 35 or younger) or 6-month (for females over age 35 years) period described above.

For women without male partners or exposure to sperm, infertility is the inability to conceive after 6 cycles of Artificial Insemination or Intrauterine Insemination performed by a qualified specialist using normal quality Donor Sperm.

- These 6 cycles (including Donor Sperm) are not covered by HPHC as a diagnosis of infertility cannot be established until after the AI/IUI cycles have been completed.

**Authorization:**

Prior authorization is required for the following infertility services provided to eligible members enrolled in commercial (HMO, POS and PPO) products:

- Artificial Insemination (AI)
- Intrauterine Insemination (IUI)
- Collection, storage, cryopreservation, and banking of sperm, eggs (oocytes), or embryos
- Donor eggs
- Donor sperm
- Embryo Transfer/Frozen Embryo Transfer (FET)
- Gamete Intra-Fallopian Transfer (GIFT)
- Intra-Cytoplasmic Sperm Injection (ICSI)
- In-Vitro fertilization (IVF) including conversion from IUI to an IVF cycle
- Microsurgical Epididymal Sperm Aspiration (MESA)
- Single Embryo Transfer (SET)
- Testicular Sperm Extraction (TESE)
- Zygote intra-fallopian transfer (ZIFT)

Prior authorization is also required for out-of-network Assisted Hatching services provided to members enrolled in PPO/POS products.

**In-network providers should submit authorization requests on HPHC's Infertility Services Precert and IVF Cycle Summary forms. Forms can be found on HPHC's Provider Site:  
<https://www.harvardpilgrim.org>**

**Policy and Coverage Criteria:****HPHC Medical Review Criteria****Infertility Services- Massachusetts****Page 1 of 13**

*HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members' unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.*

*Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.*

Harvard Pilgrim Health Care (HPHC) Infertility benefits include coverage for non-experimental services that are medically necessary to diagnose and treat medical infertility when such treatment is likely (i.e., with greater than 5% probability) to result in viable offspring. Covered services include, but are not limited to:

- Specialist consultation (PCP referral required for HMO members)
- Diagnostic services (e.g., lab work, hysterosalpingogram, laparoscopy, ultrasound) that are medically necessary to assess infertility.
- Infertility services and procedures including Artificial Insemination, Intrauterine Insemination, Frozen Embryo Transfer (FET), Gamete Intra-Fallopian Transfer, and In-Vitro Fertilization.
- Medically necessary prescription drugs
  - Self-administered drugs including ovulatory injections (e.g., HCG) are covered only for members with HPHC prescription drug coverage, who are in an active, authorized cycle of infertility treatment.

**See HPHC's Medical Review Criteria for Preimplantation Genetic Testing (PGT) for information regarding coverage and authorization requirements for PGT.**

HPHC does not authorize infertility treatment (including Donor Egg or cryopreservation procedures) or related services for female members age 44 or older unless clinical documentation clearly demonstrates the individual woman has a greater than 5% chance of achieving a positive birth outcome using her own eggs.

- **The age of the female is the most important clinical factor affecting the chances of a live birth when her own eggs are used. As noted in data from the United States Centers for Disease Control and Prevention (CDC), "overall, 40% of cycles started in 2011 among women younger than 35 resulted in live births. This percentage decreased to 32% among woman 35-37 years of age, 22% among woman aged 38-40, 12% among women aged 41-42, 5% among women aged 43-44, and 1% among women older than age 44." Further stratification of live birth cycle shows 22.2% among women 38-40 years of age, 11.7 % among women age 41-42, 4.5% among women age 43-44, and 1.8 % among women age>44.**

Under most HPHC plans with Infertility benefits, coverage is limited to a maximum of 6 IVF cycles (including cancelled cycles), regardless of whether the member's egg or a donor egg is used, and regardless of whether or not previous cycles were covered by HPHC. Fewer than 6 IVF cycles may be authorized when medically appropriate (e.g., in situations where additional cycles are unlikely [less than 5% probability] to result in a live birth).

- The cycle coverage limit does not include prior IVF cycles that resulted in a livebirth, Frozen Embryo thaw cycles that do not include gonadotropin therapy, or AI or IUI cycles.

Infertility Services are authorized for eligible members in whom fertility would naturally be expected who meet applicable General Eligibility Criteria and relevant Service-Specific criteria (listed below).

1. The member has a documented history of Infertility (as defined above);
2. Documentation (i.e., clinical history including diagnosis, menopausal status, response to and outcomes of previous infertility treatment) confirms at least a 5% probability that infertility treatment using the female partner's eggs will result in a live birth.
  - For women with a diagnosis of premature ovarian failure (POF), premature diminished ovarian reserve, or premature menopause, documentation must confirm that, absent such a diagnosis, the member would be an individual in whom fertility would naturally be expected, and infertility treatment would have >5% probability of success.

## **HPHC Medical Review Criteria**

### **Infertility Services- Massachusetts**

**Page 2 of 13**

*HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members' unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.*

*Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.*

3. Documentation of Ovarian Reserve Assessment results (i.e., day 3 Follicle-Stimulating Hormone [FSH] test and Estradiol levels) obtained within the past year are submitted.
  - For women aged 40 and older, documentation of adequate ovarian reserve, confirmed by ANY of the following is required:
    - Clomiphene Citrate Challenge Test (CCCT) performed within the past 6 months with BOTH:
      - Day 3 and Day 10 FSH levels less than 15 milli international units per milliliter (mIU/ml) and
      - Day 3 Estradiol level less than 100 picograms per milliliter (pg/ml)
    - CCCT performed within the past 12 months with ALL:
      - Day 3 and Day 10 FSH levels less than 15mIU/ml and
      - Day 3 Estradiol level <100 pg/ml and
      - Day 3 FSH level <15 mIU/ml and
      - Day 3 Estradiol level <100 pg/m within the past 6 months
  - Normal Anti-Mullerian Hormone (AMH) level, and documentation confirming the member is unable to take (or tolerate) Clomid.

**Women over age 40 with ANY history of Day 3 or Day 10 FSH >15 remain eligible for coverage of the transfer of frozen embryos created prior to the abnormal test finding, but are not eligible for ANY further assisted reproduction treatments.**

4. Documentation confirms adequate ovarian response to stimulation (i.e., 2 follicles >12 mm diameter for IUI, or at least 3 follicles >12 mm diameter for IVF) to any monitored, medicated-stimulated infertility treatments provided within the past six months.
5. The female member's Body Mass Index (BMI) is submitted with the request for infertility services.
  - If reported BMI is  $\geq 30$ , prior to authorization of infertility services, the member must be counseled to lose weight, and educated about the adverse effects of an elevated BMI (e.g., impact on fertility and fertility treatment success, obstetrical risks including diabetes and hypertension, potential anesthesia complications, poorer fetal outcomes).
  - If reported BMI is 35 or higher, documentation of a nutrition consult within the past 6 months and history of previous weight loss attempts is required.
6. If there is a male partner, results of a semen analysis (performed within the past year) demonstrating normal fertility threshold, must be submitted prior to initial authorization of infertility services.
  - If the initial semen analysis is abnormal, a second sample (obtained within the past year) must be submitted; if the second sample is abnormal, the REI specialist may request a urology consult for further evaluation
  - If the male partner has previously undergone vasectomy reversal, results of 2 consecutive semen analyses demonstrating a normal fertility threshold, and performed within 3 months of the initial request must be submitted. The couple must also meet Service-Specific Criteria for Reversal of Prior Sterilization (below).

#### **Service-Specific Criteria**

<b>Service</b>	<b>Criteria</b>
<b>Artificial Insemination (AI) Intrauterine Insemination (IUI)</b>	Medically necessary AI/IUI services are authorized when applicable General Eligibility Criteria are met, and documentation includes:

#### **HPHC Medical Review Criteria**

#### **Infertility Services- Massachusetts**

*HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members' unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.*

*Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.*

Service	Criteria
	<ol style="list-style-type: none"> <li>1. Results of hysterosalpingogram, laparoscopic chromotubation with hysteroscopy, or definitive sonohysterosalpingogram (e.g., FemVue, HyCoSy) <u>within the past 4 years</u> confirming presence of ALL the following: <ul style="list-style-type: none"> <li>• At least one patent Fallopian tube</li> <li>• Normal ipsilateral ovary</li> <li>• Normal endometrial cavity</li> </ul> </li> <li>2. Confirmation of spontaneous ovulation, or normal ovarian reserve testing;</li> <li>3. Any of the following: <ul style="list-style-type: none"> <li>• Unexplained infertility</li> <li>• Polycystic Ovary Syndrome (PCOS), anovulation, or oligoovulation</li> <li>• Mild to moderate endometriosis</li> <li>• Cervical factors</li> <li>• Mild to moderate male factor infertility <ul style="list-style-type: none"> <li>○ Documentation of urology consult must be submitted, and include evidence that infertility cannot be improved through standard conservative treatment.</li> </ul> </li> <li>• Use of stored sperm from male members who, subsequent to active infertility treatment, required sperm banking/storage as a result of medical treatment (e.g., cancer treatment) likely to cause infertility.</li> </ul> </li> </ol> <p>Results of prior IUI cycles must be submitted with each request, and demonstrate:</p> <ul style="list-style-type: none"> <li>• Adequate ovarian response to stimulation (i.e. at least 2 follicles &gt;12 mm diameter for any monitored IUI using standard medication doses); and</li> <li>• Adequate fresh semen and post wash semen parameters in order to continue with IUI.</li> </ul>
<b>IUI After In Vitro Fertilization (IVF)</b>	<ul style="list-style-type: none"> <li>• In the absence of an intervening live birth, subsequent IUI cycles are not authorized for members who have already undergone IVF if further IVF cycles do not meet HPHC's IVF criteria. IUI after IUI-to-IVF conversion for hyperstimulation if the stimulation that was initially given is reduced.</li> <li>• IUI after IVF/ICSI/Preimplantation Genetic Testing (PGT) may be authorized for couples with a male genetic disorder who opt to use donor sperm after IVF/ICSI/PGT if the female member meets IUI criteria. (Coverage for IUI is limited to 6 cycles with documented ovulation.)</li> </ul>
<b>Conversion from IUI to IVF</b>	<p>Authorized when the current IUI cycle has resulted in ALL:</p> <ol style="list-style-type: none"> <li>1. Estradiol level of <math>\geq 800</math> pg/ml; AND</li> <li>2. Production of at least 5 follicles &gt;12 mm in diameter.</li> </ol>
<b>In Vitro Fertilization</b>	<p>Results of prior IUI cycles must be submitted with each IVF request (initial and subsequent requests).</p>

**HPHC Medical Review Criteria**

**Infertility Services- Massachusetts**

*HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members' unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.*

*Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.*

Service	Criteria
<p><b>NOTE: IVF cycles using a member's own eggs are not authorized for members who have undergone previous donor egg cycles.</b></p>	<p>Results must demonstrate an adequate response to each cycle (i.e., at least 3 follicles &gt;12 mm diameter for IVF, and adequate embryo numbers and quality for transfer), and adequate fresh semen and post wash semen parameters.</p> <ul style="list-style-type: none"> <li>• In addition, there must be documentation confirming the female member requesting IVF has undergone hysterosalpingogram, sonohystogram, <b>or</b> hysteroscopy (to establish uterine contours) within the past 4 years is required.</li> <li>• Members &lt; 35 years of age are required to have SET during the first two IVF treatment cycles with more than one top-quality embryo available for transfer;</li> <li>• Members 35 to 38 years of age are required to have SET for the first IVF cycle if there is more than one top-quality embryo available for transfer from a fresh cycle, OR 1 top-quality frozen embryo after thawing;</li> <li>• Members &lt;38 years of age with a documented live birth from IVF treatment are required to have SET for one treatment/cycle if there are more than one top-quality embryos available from a fresh cycle, OR 1 top-quality frozen embryo after thawing;</li> <li>• Members 38 years of age and older undergoing authorized IVF cycles are NOT required to undergo SET as the risk for multiples is low.</li> </ul> <p>IVF services are authorized when relevant General Eligibility Criteria (above) are met, and there is documentation of ANY of the following:</p> <ul style="list-style-type: none"> <li>• Documented history of failed medicated IUI cycles (as follows) when IUI criteria (above) have been met: <ul style="list-style-type: none"> <li>○ For female members under 40 years-old, there must be documentation confirming a history of 2 failed medicated IUI cycles</li> <li>○ For female members age 40 or older, documentation of failed medicated IUI cycles is not required.</li> </ul> </li> <li>• The female member has ANY of the following: <ul style="list-style-type: none"> <li>○ Bilateral Fallopian tube absence (excluding prior elective sterilization) or bilateral Fallopian tube obstruction due to prior tubal disease. (Documentation confirming failure of conventional therapy is required.)</li> <li>○ Severe endometriosis. (Documentation confirming failure of surgical and medical therapy is required.)</li> </ul> </li> <li>• The male member has severe male factor infertility, and has been evaluated by a urologist who confirms condition cannot be improved by standard conservative treatment(s), and cannot be addressed via IUI.</li> </ul>
<p><b>IVF for Women Without Male Partners or Exposure to Sperm</b></p>	<p>Documentation confirms a female without a male partner or exposure to sperm has failed 6 consecutive AI/IUI cycles using normal donor</p>

**HPHC Medical Review Criteria**

**Infertility Services- Massachusetts**

*HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members' unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.*

*Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.*

Service	Criteria
	<p>sperm.</p> <p>To qualify for IVF services, the woman must also meet Service-Specific Criteria for IVF including documentation of an age-specific number of failed medicated IUI cycles:</p> <ul style="list-style-type: none"> <li>For female members up to 40 years-old, there must be documentation confirming a history of 2 failed medicated IUI cycles;</li> <li>For female members age 40 or older, documentation of failed medicated IUI cycles is not required.</li> <li>Age-related embryo transfer requirements outlined in the Service-specific criteria for IVF also apply</li> </ul>
<p><b>Gamete Intrafallopian Transfer (GIFT)</b></p> <p><b>Zygote intrafallopian transfer (ZIFT)</b></p>	<p>Authorized for members who have one normal patent Fallopian tube, and meet IVF criteria (above).</p>
<p><b>Donor Egg (Donor Oocyte)</b></p> <p><b>Non-medical services related to donor egg procurement (e.g., finder fees, broker fees, legal fees) are not covered.</b></p>	<p>Donor egg procedures are authorized for women under age 44 years when General Eligibility Criteria (above) are met, and there is documentation of ANY of the following:</p> <ul style="list-style-type: none"> <li>Congenital or surgical absence of ovaries</li> <li>Premature ovarian failure or premature menopause in women under age 40 years</li> <li>Premature diminished ovarian reserve (i.e., FSH <math>\geq</math>15 in women under age 40 years</li> <li>Inadequate ovarian response (i.e., fewer than 3 follicles &gt;12 mm diameter), or inadequate embryo numbers and quality, during authorized IVF cycles within the prior 6 months.</li> </ul> <p>When donor egg criteria are met, a donor egg cycle is authorized for up to 6 months.</p> <ul style="list-style-type: none"> <li>A SET is required for members &lt; 35 years of age for the first two approved donor egg IVF treatment cycles with more than one top-quality embryo available for transfer;</li> <li>If the donor egg procedure is not performed within 6 months, the member must be reevaluated and continue to meet HPHC criteria for infertility services and donor egg procedures before additional services are authorized.</li> </ul> <p>For female members (embryo recipients) without HPHC prescription drug coverage, coverage for the egg donor is limited to monitoring (up to egg retrieval), and the egg retrieval procedure.</p> <ul style="list-style-type: none"> <li>For embryo recipients with HPHC prescription drug coverage, medications to stimulate the donor’s ovaries, and to induce ovulation, are covered.</li> </ul> <p>After proceeding to a donor egg cycle, further IVF cycles using the</p>

**HPHC Medical Review Criteria**

**Infertility Services- Massachusetts**

*HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members’ unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.*

*Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.*

Service	Criteria
	member's eggs are not authorized.
<p><b>Intracytoplasmic Sperm Injection (ICSI)</b></p> <p><b>ICSI is not authorized for any IVF cycle involving use of donor sperm, or solely to perform Preimplantation Genetic Testing (PGT) when HPHC's PGT criteria are not met.</b></p>	<p>Authorized (in conjunction with IVF) to treat sperm-related infertility problems in the male partner when the use of ICSI is expected (with a greater than 5% probability) to result in a live birth, and there is documentation of ANY of the following:</p> <ul style="list-style-type: none"> <li>• Severe male factor infertility that cannot be overcome by IVF</li> <li>• Less than 50% fertilization (for mature eggs) on a prior IVF cycle with drop insemination</li> <li>• Obstruction of the male reproductive tract unrelated to prior sterilization or sterilization reversal, and not amenable to repair (necessitating sperm retrieval via Microsurgical Epididymal Sperm Aspiration)</li> <li>• Non-obstructive azospermia (necessitating sperm retrieval via Testicular Sperm Extraction)</li> </ul>
<p><b>Assisted Hatching (AH)</b></p>	<p>Authorized as part of an IVF or Frozen Embryo Transfer (FET) procedure when documentation confirms ANY of the following:</p> <ul style="list-style-type: none"> <li>• 2-3 failed IVF cycles that produced 3 or more morphologically high quality embryos, with failure to implant after embryo transfer; OR</li> <li>• Prior pregnancy resulting from IVF that required assisted hatching; OR</li> <li>• Planned transfer of a frozen-thawed embryo; OR</li> <li>• Thick Zonae in prior IVF for a woman over age 35.</li> </ul>
<p><b>Donor Sperm</b></p>	<p>Normal quality donor sperm is authorized when documentation (by ANY of the following) confirms male factor infertility:</p> <ul style="list-style-type: none"> <li>• Bilateral congenital absence of vas deferens (BCAVD)</li> <li>• Non-obstructive Azoospermia confirmed through MESA/TESE results</li> <li>• Previous radiation or chemotherapy treatment resulting in abnormal semen analyses</li> <li>• Two or more abnormal semen analyses at least 30 days apart</li> <li>• Inadequate fertilization rates despite use of ICSI</li> </ul> <p>Normal quality donor sperm may also be authorized <u>in lieu of Preimplantation Genetic Testing (PGT)</u> for couples who meet HPHC's PGT Medical Review Criteria due to the male partner's genetic abnormality. A diagnosis of infertility is not required if PGT criteria are met.</p>
<p><b>Microsurgical Epididymal Sperm Aspiration (MESA)</b></p>	<p>Authorized for male members with documented congenital absence or obstruction, or traumatic obstruction, of the vas deferens.</p> <ul style="list-style-type: none"> <li>• Excludes obstruction resulting from prior sterilization or sterilization reversal procedures.</li> </ul>
<p><b>Testicular Sperm Extraction (TESE) or Micro-TESE</b></p>	<p>Authorized when documentation confirms male members has documented non-obstructive azoospermia, or has failed a prior MESA</p>

**HPHC Medical Review Criteria**

**Infertility Services- Massachusetts**

*HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members' unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.*

*Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.*

Service	Criteria
<b>Sperm Collection and Cryopreservation</b>	<p>procedure.</p> <p>Authorized for male members when documentation confirms ANY of the following:</p> <ul style="list-style-type: none"> <li>• Need for frozen back-up sperm because of unreliable ability to produce adequate or useful sperm on the day of ovulation; or</li> <li>• Sperm was recovered through MESA or TESE; or</li> <li>• Documentation confirms that the member is undergoing medical treatment (e.g., cancer treatment) that is likely to result in infertility.</li> </ul>
<b>Cryopreservation of Eggs and/or Embryos</b>	<p>For a woman in active (authorized) infertility treatment: HPHC covers retrieval, cryopreservation, and up to one year of storage, of any embryos remaining after an authorized IVF cycle, <u>or</u> cryopreservation, and up to one year of storage, of mature eggs from an authorized IVF cycle when there is an unexpected lack of sperm for fertilization.</p> <ul style="list-style-type: none"> <li>• The member’s cryopreserved embryos (or eggs) must be used before additional (fresh) IVF cycles using the member's or another woman’s/donor’s eggs are authorized if: <ul style="list-style-type: none"> <li>○ Member up to age 35 years has 2 or more cryopreserved embryos or eggs; or</li> <li>○ Member age 35 years or older has 4 or more cryopreserved embryos or eggs.</li> </ul> </li> </ul> <p>Requests for authorization of a Thaw Cycle (using frozen eggs or embryos) must meet General Eligibility Criteria (above) at the time of the request.</p> <p>For women who are not in active infertility treatment: HPHC covers retrieval, cryopreservation, and storage (up to one year) of eggs or embryos when documentation confirms a female member who is not in active treatment for infertility will be undergoing medical treatment (e.g., chemotherapy, radiation therapy) that is likely to result in infertility.</p> <ul style="list-style-type: none"> <li>• The member is not required to meet HPHC’s General Eligibility Criteria for Infertility Services.</li> </ul> <p>For women or couples not in active infertility treatment, who are requesting fertilization of eggs and cryopreservation of embryos:</p> <ul style="list-style-type: none"> <li>• Results of ovarian testing, and the male partner’s semen analysis, must be submitted to assess the likelihood of embryo creation.</li> </ul>
<b>Cryopreservation of Eggs or Sperm (including retrieval and up to one year of storage) for Members Undergoing Gender Reassignment</b>	<p>Covered when documentation confirms a member with Gender Dysphoria will be undergoing covered Gender Reassignment treatment that is likely to result in infertility.</p> <ul style="list-style-type: none"> <li>• Documentation must confirm that member and provider(s)</li> </ul>

**HPHC Medical Review Criteria**

**Infertility Services- Massachusetts**

*HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members’ unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.*

*Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.*

Service	Criteria
<b>Treatment</b>	have discussed the impact of Gender Reassignment treatment on fertility and family planning.
<b>Reversal of Prior Sterilization</b>	<p>Authorized for members who have undergone previous sterilization procedures (e.g., tubal ligation or vasectomy) and subsequent surgical reversal, only when there is clinical documentation confirming ALL the following:</p> <ol style="list-style-type: none"> <li>1. The member/couple meets all applicable medical necessity criteria in this policy, and the member has undergone a successful reversal procedure;</li> <li>2. The member's infertility is independent of the previous sterilization procedure, and the successful reversal procedure has been followed by at least 6 months of attempting natural conception;</li> <li>3. There is documentation of either: <ul style="list-style-type: none"> <li>• For males, two consecutive semen analyses within 3 months of the request for infertility services demonstrating a normal fertility threshold (as noted in General Eligibility Criteria) and continued success of the reversal;</li> <li>• For females, post-surgery hysterosalpingogram (HSG) or chromotubation demonstrate unilateral or bilateral free spill tubal patency, and results of an HSG or chromotubation performed within the six months of the request for infertility services demonstrate that post-operative scarring and tubal blockage have not occurred.</li> </ul> </li> </ol>
<p><b>Surrogacy/Gestational Carriers</b></p> <p><b>HPHC does not cover:</b></p> <ul style="list-style-type: none"> <li>• <b>Use of donor egg with a gestational carrier as the HPHC member is not treated in this situation; or</b></li> <li>• <b>Cost(s) of implantation or other services (e.g., transfer, pre-pregnancy costs, cryopreservation of embryos) provided to a gestational carrier, regardless of whether or not the gestational carrier is an HPHC member.</b></li> </ul>	<p>One cycle of oocyte stimulation, retrieval, and fertilization is authorized for female members who:</p> <ul style="list-style-type: none"> <li>• Meet General Eligibility Criteria for Infertility Services, but are unable to carry a pregnancy due to an uncorrectable structural uterine abnormality or a life-threatening condition that precludes a safe pregnancy; AND</li> <li>• Are using their own oocytes and self-paying for a gestational carrier.</li> </ul>

**Exclusions:**

Harvard Pilgrim Health Care (HPHC) does not cover Infertility Services when criteria above are not met.

In addition, HPHC does not cover Infertility services for ANY of the following:

- Members without HPHC Infertility benefits

**HPHC Medical Review Criteria**

**Infertility Services- Massachusetts**

*HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members' unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.*

*Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.*

- Members who are not medically infertile unless the member meets other HPHC criteria (e.g., PGT, sperm/egg banking and storage for a member who is undergoing medical treatment that is likely to result in infertility);
- Individuals who are not members (including partners, dependents, or other third parties), or services in which the member is not treated, or is not the intended recipient of the infertility services
- Infertility services (including but not limited to consultations, labs, radiology studies, infertility drugs, ART cycles, and other services to assess and/or treat infertility in a member or a member's partner) requested as a result of a prior voluntary sterilization or unsuccessful sterilization reversal procedure unless there is documentation that criteria (above) are met
- Infertility services requested to treat effects that are due to natural aging, or for women who are menopausal
- Donor sperm:
  - In the absence of documented male factor infertility, or for genetic sperm defects in the male partner when the male partner is not an HPHC member
  - In the absence of a male partner
  - When the male partner has undergone vasectomy reversal and fails to meet the medical necessity criteria for infertility services for males with prior vasectomy with reversal
- Chromosome studies of a donor (sperm or egg)
- Infertility services in cases in which normal embryos have been or will be discarded because of gender selection
- ICSI for any IVF cycle involving use of donor sperm
- Any Advanced Reproductive Technology requested solely for PGT (e.g., IVF, ICSI) when PGT is not a covered benefit, or PGT criteria (above) are not met.
  - When PGT is not covered or not authorized, medically necessary Infertility services (including IVF and ICSI) may be authorized for members with Infertility benefits if service-specific criteria (above) are met.
- Treatments requested solely for the convenience, lifestyle, personal or religious preference of the member in the absence of medical necessity
- Treatment to reverse voluntary sterilization, or MESA/TESE, for a member who has undergone prior sterilization
- Supplies that may be purchased without a physician's written order (e.g., ovulation test kits)
- Monitoring of non-authorized IUI cycles
- Services related to achieving pregnancy through a surrogate or gestational carrier except as described above
- Implantation or other services provided to a gestational carrier, including, but not limited to transfer, impending pregnancy costs or cryopreservation of embryos, whether or not the gestational carrier is an HPHC member
- Use of donor egg with gestational carrier even when the surrogate is a member of the health plan
- Charges for the storage of eggs, sperm or embryos that remain in storage after the completion of an approved series of infertility cycles, or more than 1 year after the cryopreservation (whichever is shorter)
- Service fees, charges or compensation for the recruitment of egg donors
  - This exclusion does not include the charges related to the medical procedure of removing an egg for the purpose of donation when the recipient is a member of the Plan.
- Infertility services when clinical documentation confirms an individual or couple are using illicit substances or abusing substances known to negatively interfere with fertility or fetal development (e.g. marijuana, opiates, cocaine, or alcohol).
  - Results of serum or urine drug screening may be requested before infertility services are authorized.

## **Coding:**

**Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.**

### **HPHC Medical Review Criteria**

#### **Infertility Services- Massachusetts**

**Page 10 of 13**

*HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members' unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.*

*Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.*

<b>CPT® Codes</b>	<b>Description</b>
<b>89250</b>	Culture of oocyte(s)/embryo(s), less than 4 days
<b>89251</b>	Culture of oocyte(s)/embryo(s), less than 4 days; with co-culture of oocyte(s)/embryos
<b>89253</b>	Assisted embryo hatching, microtechniques (any method)
<b>89254</b>	Oocyte identification from follicular fluid
<b>89255</b>	Preparation of embryo for transfer (any method)
<b>89258</b>	Cryopreservation; embryo(s)
<b>89259</b>	Cryopreservation; sperm
<b>89343</b>	Storage (per year); sperm/semens
<b>89346</b>	Storage (per year): oocyte(s)
<b>89352</b>	Thawing of cryopreserved; embryo(s)

<b>HCPCS Codes</b>	<b>Description</b>
<b>S4011</b>	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
<b>S4013</b>	Complete cycle, gamete intrafallopian transfer (GIFT), case rate
<b>S4014</b>	Complete cycle, zygote intrafallopian transfer (ZIFT), case rate
<b>S4015</b>	Complete in vitro fertilization cycle, not otherwise specified, case rate
<b>S4016</b>	Frozen in vitro fertilization cycle, case rate
<b>S4017</b>	Incomplete cycle, treatment cancelled prior to stimulation, case rate
<b>S4018</b>	Frozen embryo transfer procedure cancelled before transfer, case rate
<b>S4020</b>	In vitro fertilization procedure cancelled before aspiration, case rate
<b>S4021</b>	In vitro fertilization procedure cancelled after aspiration, case rate
<b>S4022</b>	Assisted oocyte fertilization, case rate
<b>S4026</b>	Procurement of donor sperm from sperm bank
<b>S4028</b>	Microsurgical epididymal sperm aspiration (MESA)

### State Mandate Information

<b>State/Mandate</b>	<b>Members Covered</b>
<b>Massachusetts:</b> <b>176G §4 211 CMR 37.00</b>	All MA residents enrolled through Fully Insured Employer groups.  Please see Infertility Services Medical Review Criteria (above) for UM and coverage information.
<b>Connecticut</b> • <b>Bill No. 508 / Public Act No. 05-196</b> • <b>Connecticut State Mandate: Sec. 38a-536.</b>	Members enrolled through CT employer groups in CT HMO (Open Access), PPO, and HDHP products.  Please see CT Infertility Medical Review Criteria for state-specific UM and coverage information.
<b>Maine</b>	No mandate.
<b>New Hampshire</b>	No mandate.

### References:

1. Anesthesia for the morbidly obese parturient Curr Opin Anaesthesiol. 2009 Jun;22(3):341-6. <http://www.ncbi.nlm.nih.gov/pubmed/19412095> Clin Exp Obstet Gynecol. 2011;38(1):14-20.
2. Barbara Luke, Morton Brown, Ethan Wantman, et. al.; Cumulative Birth Rates with Linked Assisted Reproductive Technology Cycles, New England Journal of Medicine. 2012 June, 366:2483-2491

### HPHC Medical Review Criteria

#### Infertility Services- Massachusetts

*HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members' unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.*

*Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.*

3. Boulet, SL., Mehta, M., Kissin, DM., et al. Trends in use of and reproductive outcomes associated with intracytoplasmic sperm injection. JAMA. 2015; 313(3): 255-263.
4. Clin Exp Obstet Gynecol. 2011;38(1):14-20. Maternal obesity and pregnancy outcome. <http://www.ncbi.nlm.nih.gov/pubmed/21485717>
5. Effect of obesity on oocyte and embryo quality in women undergoing in vitro fertilization. Obs and Gyn. 2011:118:63-70
6. Female age-related Fertility Decline. The American College of Obstetrics and Gynecologists Committee on Gynecologic Practice and the Practice Committee of the American Society for Reproductive Medicine. [http://www.asrm.org/uploadedFiles/ASRM\\_Content/News\\_and\\_Publications/Practice\\_Guidelines/Committee\\_Opinions/Age-related\\_fertility.pdf](http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Practice_Guidelines/Committee_Opinions/Age-related_fertility.pdf)
7. Kawwass, JF., Monsour, M., Crawford, S., et al. Trends and outcomes for donor oocyte cycles in the United States, 2000-2010. JAMA. 2013; 310(22): 2426-2434.
8. Massachusetts State Mandate: M.G.L. 175 §47H, 211 CMR 37.00
9. National Center for Chronic Disease Prevention (CDC): Assisted Reproductive Technology (ART): Annual Art Success Rates Reports. <http://www.cdc.gov/art/ARTReports.htm> (Accessed July 27, 2017).
10. Practice Committee for the Society for Assisted Reproductive Technology and Practice Committee of the American Society for Reproductive Medicine. Elective single-embryo transfer. Fertil Steril. 2012: 97(4); 835-842.
11. Smith, A., Tilling, K., Nelson, S., et al. Live-birth rate associated with repeat in vitro fertilization treatment cycles. JAMA. 2015; 314(24): 2654-2662.
12. Society for Assisted Reproductive Technology: National Summary. [http://sart.org/find\\_frm.html](http://sart.org/find_frm.html)
13. The effect of body mass index on the outcomes of first assisted reproductive technology cycles. Fertility and Sterility 2012. <http://www.ncbi.nlm.nih.gov/pubmed/22584023>
14. WHO laboratory manual for the examination and processing of human semen-5th ed. WHO Press, World Health Organization. 2010. Geneva, Switzerland.

### Summary of Changes

Date	Revisions
9/17	Background updated
9/28/16	Added requirements for SET
4/27/16	Revise footnote re: cryopreservation and storage. (Approved off-line 5/2/16) Clarify that, for women without male partners or exposure to sperm seeking authorization for IVF, documentation must confirm failure after 6 <u>consecutive</u> AI/IUI cycles using normal donor sperm.
4/13/16	Added footnote clarifying coverage of cryopreserved eggs, sperm and embryos
2/24/16	Formatting updates. Minor language clarifications.
3/11/15	Clarify coverage for cryopreservation services for members undergoing Gender Reassignment treatment that is likely to render them infertile.
2/25/15	Language changes for clarity. Updated AMH parameters under Ovarian Reserve Assessment. Add criteria re: cryopreservation of eggs or sperm for members undergoing Gender Reassignment treatment. Clarify coverage for ART when PGT is excluded or not covered. Add mandate summary.

#### HPHC Medical Review Criteria

#### Infertility Services- Massachusetts

*HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members' unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.*

*Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.*

**Approved by UMPC: 9/13/17**

**Reviewed/Revised: 8/03, 8/04, 10/04, 1/05, 12/05, 6/06, 6/07, 3/08, 4/09, 6/10, 8/10, 3/11, 7/11, 9/11, 9/12, 10/13, 12/13, 2/15, 3/15; 2/16; 4/16; 5/16; 9/16; 9/17**

**Initiated: 12/02**

#### **HPHC Medical Review Criteria**

##### **Infertility Services- Massachusetts**

**Page 13 of 13**

*HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members' unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations.*

*Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.*