Subject: In Vitro Fertilization (IVF) and Other Fertility Services CT

Contents

Background:
This policy addresses fertility treatments and their uses. These services include in vitro fertilization (IVF), intrauterine insemination (IUI), gamete intrafallopian transfer, zygote intrafallopian transfer, tubal embryo transfer, gamete, embryo, and sperm cryopreservation, use of frozen embryos or eggs, oocyte and embryo donation, and gestational surrogacy. Infertility under age 35 is defined as the failure to achieve live birth when fertility would naturally be expected after 12 months or more of regular contraceptive-free sexual intercourse between an individual with ovaries/eggs and an individual with testes/sperm. Infertility over age 35 is defined as the failure to achieve a live birth after 6 months or more of regular contraceptive-free sexual intercourse between an individual with ovaries/eggs and an individual with testes/sperm. In cases where insemination is being used in lieu of intercourse, infertility is defined as the failure to achieve a live birth after 6 months of assisted inseminations.

Prior Authorization:
- Prior authorization is required for the following fertility services provided to eligible members enrolled in commercial (HMO, POS and PPO) products:
  - Stimulated 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) or Zygote intra-fallopian transfer (ZIFT)
  - Intra-Cytoplasmic Sperm Injection (ICSI)
  - In-Vitro fertilization (IVF) including conversion from IUI to an IVF cycle
  - Microsurgical Epidydimal Sperm Aspiration (MESA) and/or Testicular Sperm Extraction (TESE)
  - Single Embryo Transfer (SET)
- Prior authorization is required for out-of-network Assisted Hatching services provided to members enrolled in PPO/POS products.

Authorization of Preimplantation Genetic Diagnosis (PGD)
Prior authorization is required for members seeking IVF to select embryos free of known, carried genetic disorder.

- This process requires two authorizations, the first from AIM Specialty Health Medical Review and the second from Harvard Pilgrim Health Care (HPHC) UM.
- See AIM Specialty Health Clinical Appropriateness Guidelines for Genetic Testing for Reproductive Carrier Screening and Prenatal Diagnosis for information regarding coverage and authorization requirements. See IVF criteria and limitations for IVF in conjunction with PGD.
- HPHC considers 1 cycle of IVF as medically necessary (without the need for a documented medical infertility) when it is in order to perform a previously approved PGD.
    - Note: prescription drugs associated with approved IVF treatments are not covered the member's medical benefit.
- Normal quality donor sperm may also be authorized in lieu of Preimplantation Genetic Testing (PGD) for couples who are approved for PGD due to the HPHC member's sperm-producing partner's genetic abnormality but decide to use therapeutic donor insemination (TDI) instead of IVF and PGD.

POLICY AND COVERAGE CRITERIA FOR MEMBERS WITH UTERI/EGGS:
Harvard Pilgrim Health Care (HPHC) fertility 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 fertility.
- Fertility support services and procedures, including Intrauterine Insemination (IUI), In-Vitro Fertilization (IVF), Frozen Embryo Transfer (FET), and Gamete/zygote Intra-Fallopian Transfer (GIFT/ZIFT).
    - Note: prescription drugs associated with approved fertility treatments are not covered the member's medical benefit.
        - Authorized cycle of fertility treatment.

HPHC does not cover fertility support or fertility treatment (including Donor Egg or cryopreservation procedures) or related services for members with uteri/eggs with a lower than 5% chance of achieving a positive birth outcome using member's own eggs or for whom ART would be unsafe or unethical (see guidelines and benchmarks).

Covered fertility treatment or procedures must be performed at facilities that conform to standards and guidelines developed by the American Society of Reproductive Medicine or the Society of Reproductive Endocrinology and Infertility.

Coverage for medically necessary fertility services is limited to the following maximum benefit cycles:

- Coverage for Ovulation Induction is limited to a benefit maximum of 4 cycles.
- Coverage for Intrauterine Insemination (IUI) services is limited to a benefit maximum of 3 cycles.
- Coverage for IVF services (including in-vitro fertilization, gamete intra-fallopian transfer, zygote intra-fallopian transfer or low tubal ovum transfer) is limited to a benefit maximum of 2 cycles.
    - HPHC covers no more than 2 embryo implantations per cycle; each such fertilization or transfer shall be credited toward such maximum as one cycle.

General eligibility criteria for Members with Uteri/Eggs
Fertility support services are authorized for eligible members with uteri/eggs in whom fertility would naturally be expected who meet applicable General Eligibility Criteria and relevant Service-Specific criteria (listed below).

- An at least a 5% probability, as per guidelines and benchmarks, that fertility treatment for the member with uterus/eggs using her own eggs will result in a live birth that is confirmed with medical record documentation (i.e., clinical history including diagnosis, menopausal status, response to and outcomes of previous infertility fertility treatment).

Ib. Assessment of ovary/uterus function:

- Medical record documentation of Ovarian Reserve Assessment results (i.e., day 3 Follicle-Stimulating Hormone [FSH] test and Estradiol levels) obtained within the past three months must be submitted prior to the initiation of new fertility services. If the member is continuing with a previously used service, assessment of ovarian reserve must be within 6 months of the next treatment.
  - For members aged 40 and older, documentation of adequate ovarian reserve, confirmed by ANY of the following is required:
    - Clomiphene Citrate Challenge Test (CCCT) 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)

    OR
    - Normal Anti-Mullerian Hormone (AMH) level within the past 3 months, and documentation confirming the member is unable to take (or tolerate) Clomid.

Members with uteri/eggs over age 40 with ANY history of Day 3 or Day 10 FSH greater than 15 remain eligible for coverage of the transfer of frozen embryos either created or from frozen eggs dated prior to the abnormal test finding but are not eligible for ANY further assisted reproduction treatments.

- Medical record 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 fertility treatments provided within the past six months.

- Medical record documentation of the member with uterus/eggs' Body Mass Index (BMI) is submitted with the request for fertility services.
  - If reported BMI is $\geq$30, prior to authorization of fertility services, the medical record documentation must contain notations that the member has been 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, medical recommendation documentation of a nutrition consult within the past 3 months and history of previous weight loss attempts is required.
  - If the BMI is >40, then weight loss must be accomplished to bring it below 40 before fertility treatment will be covered.

Ic. Assessment of contributory testicles/sperm:

- If member with uterus/eggs has a partner with testicles/sperm with whom member has been trying to conceive through contraceptive-free intercourse, results of a semen analysis (performed within the past three months) demonstrating normal fertility threshold must be submitted prior to initial authorization of fertility services (see guidelines for normal levels).
  - If the initial semen analysis is abnormal, a second sample (obtained within the past three months) must be submitted; if the second sample is abnormal, the partner with testes/sperm should be evaluated for infertility. This evaluation is covered when the partner with testes/sperm is a HPHC member.
  - If the partner with testicles/sperm has previously undergone vasectomy reversal, documentation must confirm 2 consecutive semen analyses demonstrating a normal fertility threshold and performed within 3 months of the initial request. The couple must also meet Service-Specific Criteria for Reversal of Prior Sterilization (below).

II. Intrauterine Insemination (IUI)

IIa. Initiation to IUI

Harvard Pilgrim Health Care (HPHC) considers IUI services as medically necessary when applicable General Eligibility Criteria are met, and medical record documentation includes ALL the following:

- Results of hysterosalpingogram, laparoscopic chromotubation with hysteroscopy, or definitive sonohysterosalpingogram (e.g., FemVue, HyCoSy) within the past year confirming presence of ALL the following:
  - At least one normal and patent Fallopian tube
  - Normal ipsilateral ovary

- Normal endometrial cavity
- Confirmation of spontaneous ovulation, or normal ovarian reserve testing; and
- Any of the following:
  - Unexplained failure to successfully conceive with regular sperm exposure using unprotected vaginal intercourse for at least
    - Twelve months if younger than 35 years of age or
    - Six months if 35 years of age or older;
  - Member has failed to successfully conceive after at least six consecutive cycles of artificial insemination

***** Member-provided sperm must be of high quality and has, if necessary, received washing.

IIb. Continuing IUI

Coverage for IUI is limited to 3 cycles with documented ovulation for members with uteri/eggs. Note: Future IVF coverage would require at least three cycles of IUI be medicated for members under 40.

Results of prior IUI cycles must be submitted with each request, and demonstrate:

- Adequate ovarian response to stimulation (i.e. at least 2 follicles >12 mm diameter for any monitored IUI using standard medication doses); and
- Adequate fresh semen and post wash semen parameters in order to continue with IUI.

IIc. IUI after in vitro fertilization

IUI after IUI-to-IVF conversion for hyperstimulation may be authorized if the stimulation that was initially given is reduced.

IUI after or in lieu of IVF/ICSI/Preimplantation Genetic Diagnosis (PGD) may be authorized for couples with a sperm-side genetic disorder who opt to use donor sperm instead of IVF/ICSI/PGD IUI is limited to one cycle.

IId. Conversion to IVF from IUI with hyper-response

Harvard Pilgrim Health Care (HPHC) considers conversion from IUI to IVF as medically necessary when the current IUI cycle has resulted in BOTH of the following:

- Estradiol level of ≥800 pg/ml; AND
- Production of at least 5 follicles >12 mm in diameter.

III. Fertility services

IIIa. In Vitro Fertilization (IVF) services

In vitro fertilization service-specific criteria

Harvard Pilgrim Health Care (HPHC) considers IVF services as reasonable and medically necessary when relevant delivery protocols (below) are being followed, infertility has been confirmed (Tubal factor infertility, Premature ovarian insufficiency, Severe Endometriosis, Pelvic adhesive disease, Congenital absence or anomaly of reproductive organs, or infertility (primary or secondary) of unknown cause), and there is documentation of EITHER of the following:

- Infertility was confirmed by a positively identified infertility-causing disorder or sperm factor that cannot be addressed via IUI or
- Failure to achieve a successful pregnancy with at least
  - Three medicated cycles of intrauterine insemination, with stimulated ovulation induction if anovulation is documented despite follicle stimulation, if member is younger than 40 years of age or
  - An age greater than forty years (no failed IUI cycles are required).

Cycle specifications and limitations

Delivery protocols

Results of prior IUI and IVF cycles must be submitted with each IVF request (initial and subsequent requests).

Results must demonstrate an adequate response to each cycle (i.e., at least 2 follicles >12 mm diameter for IUI and 3 follicles >12 mm diameter for IVF, and adequate embryo numbers and quality for transfer), and adequate fresh semen and post wash semen parameters. • The collection of member eggs or acquisition of donor eggs is only authorized if member does not already have adequate eggs in storage as outlined above.

Repeat cycle documentation

- Documentation must confirm the uterus/egg-possessing member requesting IVF has undergone hysterosalpingogram, sonohystogram, **or** hysteroscopy (to establish uterine contours) within the past year.
- Members with eggs < 35 years of age are required to have Single Embryo Transfer (SET) during the first two IVF treatment cycles with more than one top-quality embryo available for transfer;
- Members with uteri/eggs 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;
- Members with uteri/eggs <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;
- Members 38 years of age and older with uteri/eggs undergoing authorized IVF cycles are NOT required to undergo SET.
- IVF cycles using a member's own eggs are not authorized for members who have undergone previous donor egg cycles
- The collection of member eggs or acquisition of donor eggs is only authorized if member does not already have adequate eggs in storage as outlined above

Service maximum

Under most HPHC plans with fertility benefits, coverage is limited to a maximum of 2 In-Vitro Fertilization 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 2 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 leading to a livebirth, frozen embryo thaw cycles that do not include gonadotropin therapy, or AI or IUI cycles.

Gamete and Zygote Intrafallopian Transfer (GIFT & ZIFT)

Harvard Pilgrim Healthcare (HPHC) considers Gamete and Zygote Intrafallopian Transfer (G/ZIFT) for members who meet ALL the following

- Have one normal patent Fallopian tube,
- Meet IVF criteria (above), and
- Have none of the following contraindications:
  - Severe uterine factor,
  - Irreparable distortion of the uterine cavity,
  - Active tubal disease

IIIb. Donor egg (donor oocyte)

Requirements

Harvard Pilgrim Health Care (HPHC) considers donor egg procedures as medically necessary for members with uterus years when fertility service requirements are met, and there is documentation of ANY of the following:

- Congenital or surgical absence of ovaries;
- Premature ovarian failure or premature menopause under age 40 years as demonstrated by CCCT
- Inadequate ovarian response (i.e., fewer than 3 follicles >12 mm diameter), or inadequate embryo numbers in prior IVF attempts for members with uteri under where fertility would be expected.

If the donor egg procedure is not performed within 6 months, the member must be reevaluated and continue to meet HPHC criteria for fertility services and donor egg procedures before additional services are authorized.

Egg donors must follow all SET and induction requirements as members of the same age.

For members with eggs without HPHC prescription drug coverage, coverage for the egg donor is limited to monitoring (up to egg retrieval), and the egg retrieval procedure. In these cases, coverage for infertility drugs is provided through employer's prescription drug plan

After proceeding to a donor egg cycle, further IVF cycles using the member's eggs are not authorized. Non-medical services related to donor egg procurement (e.g., finder fees, broker fees, legal fees) are not included in coverage.

The collection of member eggs or acquisition of donor eggs is only authorized if member does not already have adequate eggs in storage as outlined above

IIIc. Assisted Hatching (AH)
Harvard Pilgrim Health Care (HPHC) considers assisted hatching as part of an IVF or Frozen Embryo Transfer (FET) procedure as medically necessary when documentation confirms ANY of the following:

- 2-3 failed IVF cycles that produced 3 or more morphologically high-quality embryos, with failure to implant after embryo transfer; OR
- Prior pregnancy resulting from IVF that required assisted hatching; OR
- Thick Zonae in prior IVF for a member over age 35.
- Use of frozen eggs.

IIId. Reversal of prior sterilization
Harvard Pilgrim Health Care (HPHC) considers fertility coverage after successful reversal of prior sterilization as medically necessary 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:

- The member meets all applicable medical necessity criteria for fertility treatment in this policy, and the member has undergone a successful reversal procedure;
- 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;
- There is documentation of either:
    - For members with uteri/eggs, post-surgery hysterosalpingogram (HSG) or chromotubation demonstrate unilateral or bilateral free spill tubal patency, and results of an HSG or chromotubation performed within the three months of the request for fertility services demonstrate that post-operative scarring and tubal blockage have not occurred.

IIIe. Oocyte stimulation, retrieval, and fertilization
Harvard Pilgrim Health Care (HPHC) considers one cycle of oocyte stimulation, retrieval, and fertilization as medically necessary for members with uteri/eggs who:

- Meet general eligibility criteria for fertility 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
- Are using their own oocytes and self-paying for a gestational carrier.

IIIf. Intracytoplasmic Sperm Injection (ICSI)
Harvard Pilgrim Health Care (HPHC) considers Intracytoplasmic Sperm Injection (ICSI) as medically necessary 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:

- Sperm factor infertility that cannot be overcome by IVF
- Less than 40% fertilization (for mature eggs) on an IVF cycle with drop insemination
- Obstruction of the sperm reproductive tract unrelated to prior sterilization or sterilization reversal, and not amenable to repair (necessitating sperm retrieval via Microsurgical Epididymal Sperm Aspiration)
- Non-obstructive azoospermia (necessitating sperm retrieval via MESA/TESE)
- Use of frozen eggs.

ICSI is not authorized for any IVF cycle involving use of donor sperm, or solely to perform Preimplantation Genetic Diagnosis (PGD) when PGD has not been approved.

IV. Cryopreservation of eggs and/or embryos

IVa. Cryopreservation of eggs or sperm (including retrieval and up to one year of storage) for a member in active (authorized) fertility treatment:
Harvard Pilgrim Health Care (HPHC) considers retrieval, cryopreservation, and up to one year of storage, of any embryos remaining after an authorized IVF cycle or 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 as medically necessary.

- The member's cryopreserved embryos (or eggs) must be used before additional (fresh) IVF cycles using the member's or donor's eggs are authorized if:
  - Member up to age 35 years has 2 or more cryopreserved embryos or 8 or more eggs; or
  - Member age 35 years or older has 4 or more cryopreserved embryos or 12 or more eggs.

Requests for authorization of a Thaw Cycle (using frozen eggs or embryos) must meet General Eligibility Criteria (above) at the time of the request.

IVb. Cryopreservation of eggs or sperm (including retrieval and up to one year of storage) anticipatory to medical treatment expected to impact fertility:
Harvard Pilgrim Health Care (HPHC) considers retrieval, cryopreservation, and storage (up to one year) of eggs or embryos as medically necessary when documentation confirms that a member with eggs who is not in active treatment for infertility will in the next three months be undergoing medical treatment (e.g., chemotherapy, radiation therapy) that is likely to result in infertility.

- The member is not required to meet HPHC's General Eligibility Criteria for Fertility Services, but, at time of recovery request, results of ovarian testing, and, if applicable, partner's semen analysis must be submitted to assess the likelihood of embryo creation.
- Only 1 cycle of IVF will be covered for egg recovery.

IVc. Cryopreservation of eggs or sperm (including retrieval and up to one year of storage) for members undergoing gender reassignment treatment:
Harvard Pilgrim Health Care (HPHC) covers one cycle of retrieval, cryopreservation, and storage (up to one year) of sperm or eggs when documentation confirms an eligible member with gender dysphoria/gender incongruence will be undergoing gender reassignment treatment that is likely to result in infertility. This is limited to 1 cycle for sperm or egg recovery.

POLICY AND COVERAGE CRITERIA FOR MEMBERS WITH TESTICLES/SPERM:

Harvard Pilgrim Health Care (HPHC) fertility benefits include coverage for non-experimental services that are medically necessary to diagnose and treat medical fertility failure 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., sperm testing) that are medically necessary to assess fertility.
- Fertility support services and procedures, including Microsurgical Sperm Aspiration (MESA) and Testicular Sperm Extraction (TESE).
- 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 fertility treatment.

Covered fertility treatment or procedures must be performed at facilities that conform to standards and guidelines developed by the American Society of Reproductive Medicine or the Society of Reproductive Endocrinology and Infertility.

Coverage for medically necessary fertility services is limited to the following maximum benefit cycles:

- Coverage for Intrauterine Insemination (IUI) services is limited to a benefit maximum of 3 cycles.

I. Fertility services

Ia. Fertility confirmation requirement

Fertility Services are authorized for eligible members in whom infertility has been confirmed who meet applicable General Eligibility Criteria and relevant service criteria.

Infertility is considered to be confirmed when documentation confirms at least two separate semen sample analyses showing severe testicle/sperm factor infertility according to WHO classification guidelines (see guidelines) and a urologist evaluation confirms condition cannot be improved by standard conservative treatment(s) and cannot be addressed via use of IUI.

Ib. Intracytoplasmic Sperm Injection (ICSI)

Harvard Pilgrim Health Care (HPHC) considers Intracytoplasmic Sperm Injection (ICSI) as medically necessary 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:

- Testicle/sperm factor infertility that cannot be overcome by IVF
- Less than 40% fertilization (for mature eggs) on an IVF cycle with drop insemination
- Obstruction of the testicle/sperm reproductive tract unrelated to prior sterilization or sterilization reversal, and not amenable to repair (necessitating sperm retrieval via Microsurgical Epididymal Sperm Aspiration)
- Non-obstructive azoospermia (necessitating sperm retrieval via MESA/TESE)
- Use of frozen eggs.

ICSI is not authorized for any IVF cycle involving use of donor sperm, or solely to perform Preimplantation Genetic Diagnosis (PGD) when PGD has not been approved.

Ic. Donor sperm

Harvard Pilgrim Health Care considers the acquisition of normal quality donor sperm (no more than one vial per IUI or IVF cycle) as medically necessary when documentation (by ANY of the following) confirms testicle/sperm factor infertility:

- Bilateral congenital absence of vas deferens (BCAVD)
- Non-obstructive Azoospermia confirmed through MESA/TESE results
- Previous radiation or chemotherapy treatment resulting in severely abnormal semen analyses.
- Two or more severely abnormal semen analyses at least 30 days apart
- Inadequate fertilization rates despite use of ICSI

Normal quality donor sperm may also be authorized in lieu of Preimplantation Genetic Testing (PGD) for couples who are approved for PGD due to the member's genetic abnormality but decide to use therapeutic donor insemination (TDI) instead. A diagnosis of infertility is not required if PGD criteria are met.

Id. Microsurgical Epididymal Sperm Aspiration (MESA)

Harvard Pilgrim Health Care (HPHC) considers Microsurgical Epididymal Sperm Aspiration (MESA) as medically necessary for members with sperm with documented congenital absence or obstruction, or traumatic obstruction, of the vas deferens, excluding obstruction resulting from prior sterilization or sterilization reversal procedures.

Ie. Testicular Sperm Extraction (TESE) or Micro-TESE

Harvard Pilgrim Health Care (HPHC) considers testicular sperm extraction (TESE) or micro-TESE as medically necessary when documentation confirms members with testicles/sperm has documented non-obstructive azoospermia or has failed a prior MESA procedure.

If. Reversal of prior sterilization
Harvard Pilgrim Health Care (HPHC) considers fertility coverage after successful reversal of prior sterilization as medically necessary 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:

- The member meets all applicable medical necessity criteria for fertility treatment in this policy, and the member has undergone a successful reversal procedure;
- 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;
- There is documentation of:
  - For members with testicles/sperm, two consecutive semen analyses within 3 months of the request for fertility services demonstrating a normal fertility threshold (as noted in Guidelines below) and continued success of the reversal;

II. Sperm collection and cryopreservation

IIa. Cryopreservation related to fertility or medical treatment
Harvard Pilgrim Health Care (HPHC) considers sperm collection and up to one year of cryopreservation as medically necessary for members with sperm when documentation confirms ANY of the following:

- Need for frozen back-up sperm because of unreliable ability to produce adequate or useful sperm on the day of ovulation; or
- Sperm was recovered through MESA or TESE; or
- Documentation confirms that the member is undergoing medical treatment in the next three months (e.g., cancer treatment) that is likely to result in infertility.

IIIb. Cryopreservation of eggs or sperm (including retrieval and up to one year of storage) for members undergoing gender reassignment treatment
Harvard Pilgrim Health Care (HPHC) covers retrieval, cryopreservation, and storage (up to one year) of sperm or eggs when documentation confirms an eligible member with gender dysphoria/gender incongruence will be undergoing gender reassignment treatment that is likely to result in infertility. This is limited to 1 cycle for sperm or egg recovery.

Exclusions:
Harvard Pilgrim Health Care (HPHC) considers Fertility Services as not medically necessary for all other indications. In addition, HPHC does not cover fertility services for ANY of the following:

- Members without HPHC Fertility benefits
- Members who are not medically infertile unless the member meets other HPHC criteria (e.g., PGD, 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 fertility services
- Fertility 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
- Fertility services requested to treat effects that are due to natural aging, or for members who are menopausal
- Immunoassay for serum inhibin B measurement
- Donor sperm:
  - In the absence of documented sperm issue, or for genetic sperm defects in the partner with sperm when the partner is not an HPHC member
  - In the absence of a partner with testes/sperm.
  - When the member or partner has undergone vasectomy reversal and fails to meet the medical necessity criteria for fertility services for members with prior vasectomy with reversal
- Chromosome studies of a donor (sperm or egg)
- Fertility 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 PGD (e.g., IVF, ICSI) when PGD is not a covered benefit, or PGD has not been approved.
    - When PGD is not covered or not authorized, medically necessary fertility services (including IVF and ICSI) may be authorized for members with fertility 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 insemination 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.
- Fertility 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 fertility services are authorized.
- Stimulation for and retrieval of eggs whose use or preservation has not been approved by Harvard Pilgrim Healthcare

Guidelines and benchmarks:
According to 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 individuals with uteri 38-40 years of age, 11.7 % among individuals with uteri age 41-42, 4.5% among individuals with uteri age 43-44, and 1.8 % among individuals with uteri age>44. (National Center for Chronic Disease Prevention (CDC): Assisted Reproductive Technology (ART): Annual Art Success Rates Reports)

Abnormal Clomiphene Citrate Challenge Test (CCCT) results in members with uteri/eggs aged 40 years and older includes when:

- Day 3 estradiol (basal labs or CCCT) is found to be over 100 pg/mL, and all follicle-stimulating hormone (FSH) values are under 15.0 mIU/ml, the Day 3 Estradiol and FSH should be repeated prior to determining eligibility for IVF or other fertility treatment. To meet criteria, repeat values must meet the criteria above, AND
- At any time when any Day 3 or Day 10 FSH is ≥ 15 mIU/ml, fertility services are not authorized.

According to the World Health Organization (WHO, 2010) classification, normal fertility threshold is defined as semen volume 1.5 ml, sperm concentration 15 million/ml, sperm total 40 million, 40% motility, and 4% normal morphology by Krüger classification, or morphology of 30% by WHO.

Mild-to-moderate testicle/sperm factor infertility is defined as abnormal semen analysis with at least a sperm concentration 10 million/mL, total sperm 20 million, motility 20%, morphology 2% by Krüger classification or morphology 20% by WHO, total motile sperm concentration of at least 10 million, and at least 5 million on a washed sample (if performed).

Severe testicle/sperm factor infertility is demonstrated by sperm concentration less than 10 million/mL, sperm number less than 20 million, motility less than 20%, morphology less than 2% by Krüger classification or less than 10%, total motile sperm count of less than 10 million (less than 5 million on a washed sample if performed).

State Mandate Information

State/Mandate	Members Covered
Massachusetts: **176G §4 211 CMR 37.00**	All MA residents enrolled through Fully Insured Employer groups Please see MA Fertility Services Medical Review Criteria for UM and coverage information
Connecticut · **Bill No. 508 / Public Act No. 05-196** · **Connecticut State Mandate: Sec. 38a-536.**	Members enrolled through CT employer groups in CT HMO (Open Access), PPO, and HDHP products Please see above Fertility Medical Review Criteria for state-specific UM and coverage information
Maine	No mandate
New Hampshire · **Senate Bill 279**	All NH residents enrolled through NH fully insured large and small groups Please see NH Fertility Services Medical Review Criteria for UM and coverage information

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.

Note addition of fraction/step codes for procedures, case rate (episode-of-care) codes

CPT® Codes	Description
58321	Artificial insemination; intra-cervical
58322	Artificial insemination; intra-uterine
58970	Follicle puncture for oocyte retrieval, any method
58974	Embryo transfer, intrauterine
58976	Gamete, zygote, or embryo intrafallopian transfer, any method
76948	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation
89250	Culture of oocyte(s)/embryo(s), less than 4 days;
89251	Culture of oocyte(s)/embryo(s), less than 4 days; with co-culture of oocyte(s)/embryos
89253	Assisted embryo hatching, micro techniques (any method)
89254	Oocyte identification from follicular fluid
89255	Preparation of embryo for transfer (any method)
89258	Cryopreservation; embryo(s)
89259	Cryopreservation; sperm
89268	Insemination of oocytes
89272	Extended culture of oocyte(s)/embryo(s), 4-7 days
89280	Assisted oocyte fertilization, micro technique; less than or equal to 10 oocytes
89281	Assisted oocyte fertilization, micro technique; greater than 10 oocytes
89290	Biopsy, oocyte polar body or embryo blastomere, micro technique (for pre-implantation genetic diagnosis); less than or equal to 5 embryos
89337	Cryopreservation, mature oocyte(s)
89342	Storage (per year); embryo(s)
89343	Storage (per year); sperm/semen

89346	Storage (per year); oocyte(s)
89352	Thawing of cryopreserved; embryo(s)
89356	Thawing of cryopreserved; oocytes, each aliquot

HCPCS Codes	Description
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
S4037	Cryopreserved embryo transfer, case rate

Billing Guidelines:

Member's medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

References:

1. Connecticut Chapter 700c §38a-509 : Health Insurance Contracts – Mandatory Coverage For Infertility Diagnosis and Treatment: https://www.cga.ct.gov/current/pub/chap_700c.htm#sec_38a-536
2. Fertility treatment when the prognosis is very poor or futile: a committee opinion. ASRM. Fertil Steril_ 2012; 98:e6–e9. Accessed at https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/ethics-committee-opinions/fertility_treatment_when_the_prognosis_is_very_poor_or_futile.pdf, on September 14, 2022
3. Luke B, Brown MB, Wantman E, et al. A prediction model for live birth and multiple births within the first three cycles of assisted reproductive technology. Fertil Steril. 2014;102(3):744-752. doi:10.1016/j.fertnstert.2014.05.020
4. Starosta A, Gordon CE, Hornstein MD. Predictive factors for intrauterine insemination outcomes: a review. Fertil Res Pract. 2020;6(1):23. Published 2020 Dec 11. doi:10.1186/s40738-020-00092-1
5. Cai H, Xie J, Shi J, Wang H. Efficacy of intrauterine insemination in women with endometrioma-associated subfertility: analysis using propensity score matching. BMC Pregnancy Childbirth. 2022;22(1):12. Published 2022 Jan 4. doi:10.1186/s12884-021-04342-y
6. Harris BS, Acharya KS, Weber JM, Truong T, Eaton JL. Can high antimüllerian hormone mitigate some of the age-related decline in live birth rates? The association between antimüllerian hormone and live birth among women over 40 undergoing in vitro fertilization. F S Rep. 2021 Sep 8;2(4):440-447. doi: 10.1016/j.xfre.2021.08.009. PMID: 34934985; PMCID: PMC8655414
7. Pregnancy and Rubella. Center for Disease Control and Prevention. https://www.cdc.gov/rubella/pregnancy.html. Published 2022. Accessed September 19, 2022.
8. Practice Committee of the American Society for Reproductive Medicine. Electronic address: asrm@asrm.org; Practice Committee of the American Society for Reproductive Medicine. Smoking and infertility: a committee opinion. Fertil Steril. 2018;110(4):611-618. doi:10.1016/j.fertnstert.2018.06.016

9. Practice Committee of the American Society for Reproductive Medicine. Aging and infertility in women: a committee opinion. Fertil Steril. 2002 Jul;78(1):215-9. doi: 10.1016/s0015-0282(02)03212-0. PMID: 12095531.
10. Gu P, Yang X, Zhao X, Xu D. The value of transvaginal 4-dimensional hysterosalpingo-contrast sonography in predicting the necessity of assisted reproductive technology for women with tubal factor infertility. Quant Imaging Med Surg. 2021;11(8):3698-3714. doi:10.21037/qims-20-1193
11. Schlegel PN, Sigman M, Collura B, et al. Diagnosis and Treatment of Infertility in Men: AUA/ASRM Guideline Part I. J Urol. 2021;205(1):36-43. doi:10.1097/JU.0000000000001521
12. Wald G, Punjani N, Hayden R, Feliciano M, Dudley V, Goldstein M. Assessing the clinical value of the Kruger strict morphology criteria over the World Health Organization fourth edition criteria. F S Rep. 2021;2(2):176-180. Published 2021 Apr 19. doi:10.1016/j.xfre.2021.04.003
13. Practice Committee of the American Society for Reproductive Medicine. Diagnostic evaluation of the infertile female: a committee opinion. Fertil Steril. 2015;103(6):e44-e50. doi:10.1016/j.fertnstert.2015.03.019
14. Teranishi A, Kuwata A, Fumino T, Hamai H, Shigeta M. A theoretical model for single blastocyst transfer. J Assist Reprod Genet. 2009;26(6):327-334. doi:10.1007/s10815-009-9321-y
15. Aboulghar M, Mansour R, Serour G, Abdrazek A, Amin Y, Rhodes C. Controlled ovarian hyperstimulation and intrauterine insemination for treatment of unexplained infertility should be limited to a maximum of three trials. Fertil Steril. 2001;75(1):88-91. doi:10.1016/s0015-0282(00)01641-1
16. Luke B, Brown MB, Wantman E, et al. Application of a validated prediction model for in vitro fertilization: comparison of live birth rates and multiple birth rates with 1 embryo transferred over 2 cycles vs 2 embryos in 1 cycle. Am J Obstet Gynecol. 2015;212(5):676.e1-676.e6767. doi:10.1016/j.ajog.2015.02.005
17. Practice Committee of American Society for Reproductive Medicine. Multiple gestation associated with infertility therapy: an American Society for Reproductive Medicine Practice Committee opinion. Fertil Steril. 2012;97(4):825-834. doi:10.1016/j.fertnstert.2011.11.048
18. Penzias, Bendikson, K., Butts, S., Coutifaris, C., Fossum, G., Falcone, T., Gitlin, S., Gracia, C., Hansen, K., La Barbera, A., Mersereau, J., Odem, R., Paulson, R., Pfeifer, S., Pisarska, M., Rebar, R., Reindollar, R., Rosen, M., Sandlow, J., & Vernon, M. (2017). Guidance on the limits to the number of embryos to transfer: a committee opinion. Fertility and Sterility, 107(4), 901–903.https://doi.org/10.1016/j.fertnstert.2017.02.107
19. 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
20. Practice Committee of the American Society for Reproductive Medicine; Practice Committee of the Society for Assisted Reproductive Technology. Role of assisted hatching in in vitro fertilization: a guideline. Fertil Steril. 2014;102(2):348-351. doi:10.1016/j.fertnstert.2014.05.034
21. Ramasamy R, Lin K, Gosden LV, Rosenwaks Z, Palermo GD, Schlegel PN. High serum FSH levels in men with nonobstructive azoospermia does not affect success of microdissection testicular sperm extraction. Fertil Steril. 2009;92(2):590-593. doi:10.1016/j.fertnstert.2008.07.1703
22. van Wely M, Barbey N, Meissner A, Repping S, Silber SJ. Live birth rates after MESA or TESE in men with obstructive azoospermia: is there a difference?. Hum Reprod. 2015;30(4):761-766. doi:10.1093/humrep/dev03
23. Practice Committee of the American Society for Reproductive Medicine. Electronic address: asrm@asrm.org. Evidence-based outcomes after oocyte cryopreservation for donor oocyte in vitro fertilization and planned oocyte cryopreservation: a guideline. Fertil Steril. 2021;116(1):36-47. doi:10.1016/j.fertnstert.2021.02.024

Summary of Changes

Date	Changes
5/23	Annual review, no changes
9/22	Annual review; coding and references updated
9/21	Annual review; no changes
10/20	IVF language clarified
4/20	IVF requirement language clarified, AIM nomenclature updated
11/19	Policy and criteria reorganized and updated
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 consecutive AI/IUI cycles using normal donor sperm.
4/13/16	Added footnote clarifying coverage of cryopreserved eggs, sperm and embryos
2/24/16	Minor updates for compliance. Added age-related criteria for Ovarian Reserve Assessment
10/28/15	Removed language related to age and lifetime maximums; effective 1/1/16
5/27/15	Removed requirement that member to be treated must have maintained coverage under their HPHC policy for at least twelve months.
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. Add criteria re: cryopreservation of eggs or sperm for members undergoing GRS. Clarify coverage for ART when PGT is excluded or not covered. Add mandate summary.

Approved by Medical Policy Committee: 05/17/2023
Approved by Clinical Policy Operational Committee: 2/15, 3/15, 10/15; 2/16; 5/16; 9/16; 9/17; 11/19; 5/20; 10/20; 9/21; 10/22; 7/23
Policy Effective Date: 8/1/2023
Initiated: 12/02