INFERTILITY PROTOCOL

☐ Corporate ☒ Comm – FF ☒ Comm – SF ☒ Medicare ☐ Medicaid ☐ MedSupp

Procedure:

Medical Criteria Disclaimer

 The treating physician or primary care provider must submit to Health New England the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Health New England will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how Health New England determines whether certain services or supplies are medically necessary. Health New England established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). Health New England expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by Health New England, as some programs exclude coverage for services or supplies that Health New England considers medically necessary. If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage and Medicaid members. Health New England has adopted the herein policy in providing management, administrative and other services to its Health Plan.

Infertility Services

Massachusetts mandates certain health insurance coverage of non-experimental infertility procedures recognized by the American Society for Reproductive Medicine (ASRM) or the American College of Obstetrics and Gynecology (ACOG). In accordance with these mandates, HNE will provide infertility benefits to medically infertile members with the goal of restoring normal reproductive capacity. Coverage for infertility services is available to members who meet the residency requirements, individual plan limitations, medical necessity and eligibility criteria outlined in this protocol.

Definition

Infertility is defined as ONE of the following:

- The inability of opposite-sex partners under the age of 35 to achieve conception after at least one year of unprotected intercourse
- The inability of opposite-sex partners to achieve conception after six months of unprotected intercourse when the biological female partner trying to conceive is age 35 or older
- The inability of a biological female, with or without an opposite sex partner, to achieve conception after at least six trials of medically supervised artificial insemination
- The inability of a biological female, with or without an opposite-sex partner, to achieve conception after at least three trials of medically supervised artificial insemination over a six month period of time when the biological female partner trying to conceive is age 35 or older.

Policy:

A. HNE Infertility benefits include coverage for non-experimental services that are medically necessary to diagnose and treat medical infertility for members with uteri/eggs when such treatment is likely to result in viable offspring. Covered services include, but are not limited to:

1. Specialist consultation

2. Diagnostic services (e.g., lab work, hysterosalpingogram, laparoscopy, and ultrasound) that are medically necessary to assess infertility

3. Assisted Reproductive Technology (ART) services including Artificial Insemination, Intrauterine Insemination, Frozen Embryo Transfer, Gamete Intra-Fallopian Transfer, and In-Vitro Fertilization

4. Prescription fertility drugs that are FDA approved that can be self-administered (e.g., ovulatory injections including HCG) are covered only for members with HNE prescription drug coverage who are in an active, authorized cycle of infertility treatment.

B. **See HNE's Medical Review Criteria for Preimplantation Genetic Diagnosis (PGD) for information regarding coverage and authorization requirements for PGD.**

C. **Medical Necessity:** Those Covered Services and supplies that are consistent with generally accepted principles of professional and medical practice as determined by whether the service is:

1. The most appropriate available supply or level of service for the Member in question, considering potential benefits and risks to the individual

2. Known to be effective, based on scientific evidence, professional standards and expert opinion, in improving health outcomes

3. Based on scientific evidence if the services and interventions are not in widespread use

I. What is Covered:

- Artificial Insemination (AI) Intrauterine Insemination (IUI)
- Assisted Hatching
- 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)
- Pre-implantation Genetic Diagnosis (please see separate policy)

- Testicular Sperm Extraction (TESE)
- Zygote Intra-Fallopian Transfer (ZIFT)

In-network providers should submit authorization requests utilizing HNE's Infertility Treatment Prior Approval Request Form. Forms can be found on HNE's Provider Site:

https://healthnewengland.org/Portals/_default/Shared%20Documents/providers/InfertilityPAdoc.pdf

(The link to the new form will be updated and available on 9/1/21.)

II. General Eligibility Criteria

A. Coverage for required infertility benefits will not be limited arbitrarily, but may be limited according to reasonable consideration of the individual member's medical history, hormone levels and age, medical necessity guidelines, provider standards and protocols, and legal requirements or limitations. Unless ineligible for reasons unrelated to this provision, and based upon the recommendation of the patient's clinician specialist, members who meet the residency requirements, the above definition of infertility, and the following criteria (where relevant) are eligible for ART services.

B. For a member with uteri/eggs to be considered for cycle initiation of a covered ART service:

1. The member must meet the definition of medical infertility (as defined above) and infertility may not be the result of a previous sterilization or unsuccessful reversal.

2. Treatment is likely (i.e., with greater than 5% probability) to result in viable offspring.

3. Documentation (i.e., clinical history including: diagnosis, menopausal status, response to and outcomes of previous infertility treatment) confirms that infertility treatment using the female partner's eggs will result in a live birth.

    a. 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.

C. Evaluation Requirements

1. Baseline hormonal blood work (including FSH and Estradiol) done within the past year

2. Rubella testing-all non-immune members must be vaccinated and wait 30 days before requesting infertility treatment.

3. TSH (thyroid stimulating hormone) must be done yearly.

4. HSG/tubal patency eval (unless going directly to IVF)

5. For members going directly to IVF:

a. Uterine Cavity eval: HSG/hysteroscopy, Sonohysterogram, 3D ultrasound or hysterosalpingo contrast sonography (HyCoSy)

b. Testing must be done every two years or after a pregnancy loss

6. Semen analysis done yearly

D. Testing of the Female

Members <40 years old
- Members with premature ovarian insufficiency may qualify for IVF treatment, or may qualify for donor egg/embryo
- A repeat FSH/estradiol is not needed if a member <39 years of age has already been diagnosed with premature ovarian insufficiency

Diminished ovarian reserve occurs below age 40 and is defined as:
- A day 3 FSH >15 mIU/ml, OR
- A day 3 estradiol >100 pg/ml and no medical reason is documented (i.e. ovarian cyst)

Members without diminished ovarian reserve who are ≥40 and <44 years old must meet ALL of the following criteria:
- Yearly clomiphene citrate challenge test (CCCT)
- If 6 months have elapsed since the CCT, a basal FSH and estradiol are required prior to the next fresh cycle
- A new CCT or repeat FSH/estradiol is not required for FET's from an approved IVF cycle

Lab values needed for infertility services coverage (highest ever value) for age 40-44
- All day 3 or day 10 FSH must be <15
- All day 3 estradiol must be ≤100 pg/ml
- Day 10 estradiol >100 pg/ml

Alternate testing options only for those members not able to do CCCT:
For members with a documented contraindication to clomiphene or ovulation disorder (i.e., PCOS, hypothalamic amenorrhea) a combination of tests would be accepted:
- Basal FSH and estradiol done on the same day, AND
- Anti-mullerian hormone (AMH) and antral follicle count (AFC) drawn within 1 month of labs
- Lab values needed for infertility services coverage:
  - AMH >1.0 NG/ML, and
  - AFC >6, and
  - Day 3 FSH <15
  - Estradiol ≤ 100 pg/ml

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.

E. Evaluation of the Male:

1. Results of a semen analysis performed within the past year demonstrating normal fertility must be submitted.

    a. 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 3rd edition classification (based on World Health Organization 5th edition 2010).

        i If the initial semen analysis demonstrates a sperm total of less than 3 million (washed) or concentration of less than 10 million/ml or Kruger morphology <4%, a second sample must be submitted.

        ii If the second sample is abnormal, work-up by a urologist or other specialist in male reproduction (to evaluate and treat reversible causes) is recommended and referrals will be at the discretion of the infertility specialist.

2. Medical records for a member who was covered under a different insurer will be requested for review to determine male infertility status.

3. Medical and reproductive history (including any substance use) must be submitted.

4. If the biological male has previously undergone vasectomy reversal, 2 post reversal semen analyses (6 months apart) showing ≥20 million total motile sperm AND ≥3% normal forms, AND

    Member has a normal semen analysis 6 months prior to the infertility service request.

F. Substance Use/Contraindications for Fertility Treatments

1. Tobacco / Electronic Cigarettes (Vaping) - Due to the toxic effects of tobacco/nicotine on female and male fertility and in pregnancy, both members of the couple must be non-smokers of traditional or electronic cigarettes and are not exposed to second hand smoke on a regular basis. If either member of the couple has smoked within the past 6 months: Urine or serum cotinine levels, obtained within the month of the requested service, for all members and their partners who acknowledged smoking within the past six months.

    a. No infertility services will be approved if cotinine is found in the member or the member's partner.

2. Other Substances – Due to the known negative effects related to fertility and/or fetal development, if either member of a couple

    a.. has an alcohol related disorder- due to known negative effects related to fertility and/or fetal development if either member of the couple has used alcohol within the past 6 months and need to maintain sobriety OR

    b. is consuming substances that are against medical advice OR

c. is using illegal substances, such as marijuana, opiates, cocaine OR

d.. marijuana (medical or recreational), cannabinoid products (edibles, CDB oil, topicals, etc.) AND

e.. serum or urine drug screening results may be requested before infertility services are authorized. Positive results may result in a denial of the request.

Substance Use disorder (SUD): Members and partners in medication assisted therapy (MAT) programs must have been enrolled for 1 year, and receiving MAT with buprenorphine, buprenorphine/naloxone, methadone or naltrexone may be considered for infertility services. Documentation of continued participation in a program including monitoring and provision of cognitive behavioral therapy (CBT) is required.

Service-Specific Criteria

SERVICE	CRITERIA
Advanced Maternal Age **Women >42 yrs. and up to member's 44th birthday**	Advanced Maternal Age will be considered in the following way: A. A single ART cycle may be approved for coverage using her own eggs based on her history and prior ART attempts including: 1. Normal CCCT 2. Development of 3 or more follicles (>15mm) and Estradiol >500 m IU/ml following gonadotropin stimulation or prior ART cycle with transfer of at least 1 embryo of reasonable quality For women ages ≥44: Fertility is not considered a natural state due to age-related decline in oocyte number and quality at or beyond age 44 regardless of hormonal testing.

Intrauterine Insemination (IUI)	Medically necessary AI or IUI services are authorized when applicable eligibility criteria are met, and documentation includes: A. Results of a uterine cavity evaluation (sonohysterogram, hysterosalpingogram, or hysteroscopy) within the past 2 years confirming the presence of ALL the following: • At least one patent Fallopian tube • Normal ipsilateral ovary • Normal endometrial cavity AND B. Confirmation of spontaneous ovulation, or normal ovarian reserve testing; AND C. Evidence of ANY of the following: • Unexplained failure to successfully conceive with regular sperm exposure using unprotected vaginal intercourse • Polycystic Ovary Syndrome (PCOS), anovulation, or oligo ovulation • Mild to moderate endometriosis • Cervical factors • Mild to moderate male factor infertility (abnormal semen analysis with at least a sperm concentration 10 million/ml) • 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. **IUI is not indicated for the following**: • Bilateral tubal factor infertility • Recurrent pregnancy loss-defined by 2 or more failed pregnancies (absent an ovulatory disorder) • Severe endometriosis **A uterine cavity evaluation is required after a pregnancy or pregnancy loss.**
Assisted Hatching (AH)	Assisted Hatching may be authorized as part of an IVF or Frozen Embryo Transfer (FET) when there is documentation of ANY of the following: A. Women with a history of 2 or more embryo transfers without a pregnancy OR

	B. History of a prior pregnancy as a result of IVF and AH OR C. Planned transfer of a frozen-thawed embryo; OR D. Thick Zonae in prior or current IVF. **Assisted hatching will not be authorized if preimplantation genetic diagnosis (PGD) is being performed as this process includes opening the zona pellucida.**
Conversion from IUI to IVF	Conversion from IUI to IVF cycle may be authorized when the current IUI cycle has resulted in an Estradiol level of ≥800 pg/ml and production of at least 5 follicles >13 mm in diameter.
Cryopreservation of Eggs and/or Embryos	For women in **active** (authorized) infertility treatment: A. HNE covers retrieval, cryopreservation, and up to one year of storage, of any embryos. The storage is for a member in an active fertility cycle when there is an unexpected lack of sperm for fertilization. 1. Cryopreserved embryos (or eggs) must be used before additional (fresh) IVF cycles. 2. Requests for authorization of a Thaw Cycle (using frozen eggs or embryos) must meet General Eligibility Criteria (above) at the time of the request. For women who are **not in active** infertility treatment: A. HNE 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) or other treatment that is expected to render them permanently infertile (excluding voluntary sterilization):

	1. The member is not required to meet HNE's General Eligibility Criteria for Infertility Services. 2. For members not in active infertility treatment, who are requesting fertilization of eggs and cryopreservation of embryos: a. Results of ovarian testing, and the male partner's semen analysis, must be submitted to assess the likelihood of embryo creation. **No more than 1 cycle of IVF will be covered for members who will undergo treatment that is expected to render them infertile.**
Cryopreservation and Sperm Collection	Sperm collection, cryopreservation (including up to one year of storage) is authorized for male members when: A. There is a need for frozen back-up sperm because of unreliable ability to produce adequate or useful sperm on the day of ovulation; or B. Sperm was recovered through MESA or TESE for members in active infertility treatment; or C. Documentation confirms that the member is undergoing medical treatment (e.g., cancer treatment) or other treatment that is expected to render them infertile
Cryopreservation of Eggs or Sperm (including retrieval and up to one year of storage) for members undergoing Gender Reassignment Treatment **Cryopreservation is limited to one cycle only**	Covered when documentation confirms a member with Gender Dysphoria will be undergoing covered Gender Reassignment treatment that is likely to result in infertility. A. Documentation must confirm that member and provider(s) have discussed the impact of Gender Reassignment treatment on fertility and family planning. B. No coverage for costs associated with any form of Surrogacy including gestational carriers.

Donor Eggs (Donor Oocyte) **Donor egg is covered for medical illness which causes a natural loss of egg quantity and/or quality.**	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: A. Congenital or surgical absence of ovaries OR B. Premature ovarian failure or premature diminished ovarian reserve (i.e., - FSH ≥15) in women under age 40 years C. Inadequate ovarian response (i.e., at least two IVF treatments cycles where <6 eggs were retrieved with maximum ovarian stimulation) Medications for the member recipient will only be covered if the member has an HNE pharmacy benefit. Medication for the anonymous or designated donor in an approved cycle will not be covered. Donor egg is not authorized for women aged 44 or greater as they are experiencing an age-related decline in fertility that is normal and expected, and not consistent with disease process. While these individuals may require donor egg/embryo to achieve a positive birth outcome, the need is secondary to an age-related decline in fertility that is normal and expected. **After proceeding to a donor egg cycle, further IVF cycles using the member's eggs are not authorized**.
Donor Sperm **One vial per IVF/IUI cycle** Donor sperm is not covered for biological females without a biological male partner.	Normal quality donor sperm (from an accredited sperm bank) is authorized when there is documentation (by ANY of the following) confirming male factor infertility: A. Bilateral Congenital Absence of Vas Deferens (BCAVD) OR B. Non-obstructive Azoospermia confirmed through MESA/TESE results OR C. Previous radiation or chemotherapy treatment resulting in abnormal semen analyses

	OR D. Two or more abnormal semen analyses demonstrating severe male factor infertility (<10 million total motile sperm in unwashed specimen or <3 million total motile sperm in washed specimen or <2% normal forms using Kruger strict morphology) at least 30 days apart E. Inadequate fertilization rates (<50%) despite use of ICSI. Normal quality donor sperm may also be authorized in lieu of PGD for couples who meet HNE's PGD Medical Review Criteria due to the male partner's genetic abnormality. A diagnosis of infertility is not required if PGD criteria are met.
Frozen Embryo Transfer (FET)	FET will be approved for members who meet the definition of infertility, expect fertility as a natural state, and have a normal uterine cavity evaluation within two years. A normal uterine cavity evaluation is required after a pregnancy or pregnancy loss. **Frozen embryos must be used prior to authorization for additional fresh cycles**
Gamete-Intra-Fallopian Transfer (GIFT)	GIFT procedures are authorized for members who have one normal patent Fallopian tube, and meet IVF criteria above.
Intra-Cytoplasmic Sperm Injection (ICSI) **ICSI is not authorized for any IVF cycle involving use of donor sperm, or solely to perform PGD when HNE's PGD criteria are not met.**	ICSI using the male partner's fresh or frozen sperm is authorized (in conjunction with IVF) to treat sperm-related infertility problems in the male partner when the use of ICSI is expected to result in a live birth, and there is documentation of ANY of the following: A. Severe male factor infertility (<10 million total motile sperm in unwashed specimen or <3 million total motile sperm in washed specimen or <4% normal forms using Kruger strict morphology) that cannot be overcome by IVF OR B. Less than 50% fertilization (for mature eggs) or failed fertilization on a prior IVF OR

	C. Sperm retrieved via Microsurgical Epididymal Sperm Aspiration (MESA) or Testicular Sperm Extraction (TESE). OR D. With use of frozen eggs

In-Vitro Fertilization (IVF) **NOTE: IVF cycles using a member's own eggs are not authorized for members who have undergone previous donor egg cycles.** **Members of any age will be required to follow ASRM (American Society for Reproductive Medicine) guidelines for embryo transfers.** **For members <35 years of age** **With favorable prognosis (1st IVF cycle, previous IVF success, good quality embryos/excess embryos available for freezing), 1 blastocyst** **Others-≤2** **For members age 35-37** **With favorable prognosis-1 blastocyst** **Others-≤2** **For members age 38-40** **With favorable prognosis-≤2 blastocysts** **Others-≤3** **For members age 41 and greater** **With favorable prognosis-≤3** **All others-≤3**	IVF services are authorized when relevant General Eligibility Criteria (above) are met, and there is documentation of ANY of the following: A. Documented history of failed medicated IUI cycles (as follows) when IUI criteria have been met: OR • For female members under 40 years-old, there must be documentation confirming a history of 3 failed medicated IUI cycles • For female members age 40 or older, documentation confirming a history of 2 failed medicated IUI cycles OR B. The female member has ANY of the following: • 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.) • Severe endometriosis. (Documentation confirming failure of surgical and medical therapy is required.) • Recurrent pregnancy loss-defined by 2 or more failed pregnancies (absent an ovulatory disorder) OR C. The male member has severe male factor infertility, (<10 million total motile sperm in unwashed specimen or <3 million total motile sperm in washed specimen or <4% normal forms using Kruger strict morphology) D. Results of prior 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 3 follicles >12 mm diameter for ICD, and adequate embryo numbers and quality for

	transfer), and adequate fresh semen and post-wash semen parameters. • Documentation confirming the female member requesting IVF has undergone hysterosalpingogram, sonohystogram, or hysteroscopy (to establish uterine contours) within the past 2 years is required. E. An IVF cycle will be approved one cycle at a time to determine that the probability of a live birth remains using one's own eggs. If the ART cycle does not demonstrate the attainment of at least one (1) embryo suitable for transfer an additional cycle may be considered when there is a significant change in the treatment protocol such as a change in dosage, a change in protocol or a change in the clinical presentation. The chances of a live birth after greater than 6 consecutive unsuccessful IVF cycles in women age 40 and over is typically less than 5%. **Cryopreserved embryos (or oocytes) must be used prior to an additional fresh cycle.**
IVF FOR Women Without Male Partners or Exposure to Sperm	To establish a diagnosis of infertility, there must be documentation confirming the woman without a male partner or exposure to sperm has failed to conceive after 6 AI/IUI cycles, performed by a qualified specialist, using normal donor sperm. 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: A. For female members 35 to 40 years old, there must be documentation confirming a history of 3 failed medicated IUI cycles; B. For female members ages 40 or older, documentation confirming 2 failed medicated IUI cycles.

IUI After In-Vitro Fertilization (IVF)	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.) 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 HNE's IVF criteria.
Microsurgical Epididymal Sperm Aspiration (MESA)	Microsurgical Epididymal Sperm Aspiration is authorized for male members with documented congenital absence or obstruction, or traumatic obstruction, of the vas deferens. A. This does not include obstruction resulting from prior sterilization or sterilization reversal procedures.
Reversal of Sterilization	For members who have undergone previous sterilization procedures (e.g., tubal ligation or vasectomy) and subsequent surgical reversal, infertility services are authorized only when there is clinical documentation confirming ALL the following: A. The member/couple meets all applicable medical necessity criteria in this policy, and the member has undergone a successful reversal procedure; AND B. 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; AND C. There is documentation of either: 1. 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 a normal semen analysis 6 months prior to the infertility service request 2. 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 postoperative scarring and tubal blockage have not occurred.
Testicular Sperm Extraction (TESE)	Testicular Sperm Extraction or Micro-TESE is authorized for male members with documented nonobstructive azoospermia, or those who have failed a MESA procedure.
Zygote Intra-Fallopian Transfer (ZIFT)	ZIFT procedures are authorized for members who have one normal patent Fallopian tube, and meet IVF criteria above.

III. Residency Requirements and Individual Plan Limitation

A. **Fully Funded health plan members:** HNE covers infertility services in accordance with the terms of this protocol for Massachusetts and Connecticut residents only. A Connecticut resident is covered for infertility benefits only until her 40th birthday, as is specified by the Connecticut state infertility mandate. A Connecticut resident is limited to up to 4 cycles of ovulation induction, a maximum of 3 intrauterine insemination (IUI) cycles, and up to 2 in-vitro fertilization (IVF) cycles with a maximum of 2 embryos transferred per cycle, as specified by the Connecticut state infertility mandate. For members who reside in Connecticut and are age 40 years or older, infertility services are not covered. (Infertility services for Connecticut residents may end when the member turns 40 years old regardless of where the member is in the treatment cycle.)

B. The total number of approved ART cycles is calculated per lifetime of member and is independent of the insurance coverage

   * For policies issued or renewed after January 1, 2016, the Connecticut Mandate has removed the age limits on infertility benefits.

C. **State members (Group Insurance Commission [GIC] members):** HNE covers infertility services in accordance with the terms of this protocol regardless of whether the member resides in Massachusetts or Connecticut.

D. **Self-Funded Group members:** Self-funded plans are not required to provide mandated infertility services. If a self-funded group offers infertility coverage, benefits will be provided to all members subject to the defined plan limitations, regardless of their state of residency, as outlined in the group's Summary Plan Description, which may reference this protocol.

Codes:

HCPC Code	Description
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
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 (to CPT codes)
CPT Code	
89253	Assisted embryo hatching, microtechniques (any method)
89258	Cryopreservation; embryos
58323	Sperm washing for artificial insemination

IV. What is Not Covered?

HNE does not cover Infertility Services when criteria above are not met.

A. In addition, HNE does not cover Infertility services for ANY of the following:

1. Members without HNE Infertility benefits

2. Members who are not medically infertile unless the member meets other HNE criteria (e.g., PGD, sperm/egg banking and storage for a member who is undergoing medical treatment that is likely to result in infertility)

3. 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

4. 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

5. Infertility services requested to treat effects that are due to natural aging, or for women who are menopausal. Any elevation in FSH level (>15) is considered infertility as a natural state and therefore infertility services are not covered for members >40 years and over.

6. Donor sperm is not covered:

    a. In the absence of documented male factor infertility, or for genetic sperm defects in the male partner when the male partner is not an HNE member

b. In the absence of a male partner

c. For biological females without a biological male partner

d. 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

e. Chromosome studies of a donor (sperm or egg)

7. Infertility services in cases in which normal embryos have been or will be discarded because of gender selection

8. Cryopreservation of embryos or eggs for reciprocal IVF is not covered

9. ICSI for any IVF cycle involving use of donor sperm

10. Any Advanced Reproductive Technology requested solely for PGD (e.g., IVF, ICSI) when PGD is not a covered benefit, or PGT criteria (above) are not met

11. Treatments requested solely for the convenience, lifestyle, personal or religious preference of the member in the absence of medical necessity

12. Treatment to reverse voluntary sterilization, or MESA/TESE, for a member who has undergone prior sterilization

13. Supplies that may be purchased without a physician's written order (e.g., ovulation test kits)

14. Monitoring of non-authorized IUI cycles

15. Services related to achieving pregnancy through a surrogate or gestational carrier

16. 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 HNE member

17. Use of donor egg with gestational carrier even when the surrogate is a member of the health plan

18. 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)

19. Service fees, charges or compensation for the recruitment of egg donors

20. 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.

21. 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., cigarettes, marijuana, opiates, cocaine, or alcohol)

22. Shipping costs for donor egg or donor sperm

23. Endometrial receptivity testing

24. Infertility services for women who are not Rubella immune

25. More than one cycle of IVF, for members who will undergo treatment that is expected to render them infertile

26. Voluntary male sterilization (chemical or procedural) ends coverage for IVF, ICSI and donor sperm based on male factor or unexplained infertility. Any abnormal semen analysis post a reversal ends eligibility for coverage of infertility services.

REFERENCES:

NCQA Standard, UM2, Clinical Criteria for Utilization Management Decisions, Element A

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