Priority Health

MEDICAL POLICY
No. 91163-R12

INFERTILITY DIAGNOSIS AND TREATMENT/ ASSISTED REPRODUCTION

Effective Date: September 1, 2024	**Review Dates: 1/93, 12/99, 12/01, 11/02, 11/03, 11/04, 10/05, 10/06, 7/07, 6/08, 6/09, 6/10, 6/11, 6/12, 6/13, 8/14, 5/15, 5/16, 5/17, 5/18, 5/19, 5/20, 2/21, 2/22, 8/22, 8/23, 8/24**
Date of Origin: July 7, 1989	**Status: Current**

Note:
This policy incorporates previously separate policy Sperm & Oocyte Retrieval and Storage #91393.

Please refer to a member's plan documents, including riders if available, for specific pharmacy or medical benefits availability and the terms and conditions of coverage.

Summary of Changes

Clarification:

- I.A. 2 –Treatment services in this policy refers to services for the underlying medical cause of infertility.

Deletion:

- I.A.2 – Deleted list of specific drugs. Directed members to consult benefit documents for applicable coverage.
- Removed "artificial conception" from title of policy and references in policy.

I. POLICY/CRITERIA

See SPECIAL NOTES section below for specific information regarding Medicaid and Healthy Michigan plan members.

A. Infertility

1. **Diagnostic Services:** Diagnostic evaluation of infertility is medically necessary if the procedure is appropriate for establishing the underlying cause of infertility. Examples include:
    a. Hysterosalpingogram;
    b. Huhners' test;
    c. Endometrial biopsy;
    d. Diagnostic Laparoscopy or Hysteroscopy.
    e. Hormone evaluation;
    f. Semen analysis;
    g. Hamster egg penetration assay.
2. **Treatment** for the underlying medical cause infertility is medically necessary if the member is diagnosed as infertile, and has not had an elective sterilization. The individual on whom the procedure is being performed must be a member to be

eligible for coverage. For example, coverage for semen analysis would require that they are a member of Priority Health. Medically necessary procedures include:

a. Laparoscopy for surgical intervention;
b. Tuboplasty for scarring/blockage (tuboplasty for the reversal of elective sterilization is not covered);
c. Varicocelectomy;
d. Testicular hypothermia device (see policy: *Durable Medical Equipment* #91110);
e. Endocrine management;
f. Pharmacologic intervention: Limitations may apply. Please check benefit plan descriptions and formularies for details on which specific medications are covered if any. The medications may not be covered for members without pharmacy benefit plans; in addition, some pharmacy benefit plans may exclude or limit coverage of some or all of these medications.

B. Assisted reproduction services

Care and services related to Assisted Reproduction and Artificial Insemination are not a covered benefit unless the group/member has purchased a rider or supplemental coverage for these services. Unless provided by plan amendment, all services and supplies related to assisted reproduction services are excluded from coverage. Some examples of this exclusion are:

- Any service done in preparation for the assisted reproduction procedure or done to determine optimal timing of the procedure (e.g., lab work, ultrasounds).
- Immunological testing (e.g., antiprothrombin antibodies, embryotoxicity assay, circulating natural killer cell measurement, antiphospholipid antibodies, reproductive immunophenotype [RIP], cytokine assay and Th1/Th2 cytokine ratio).
- Any concomitant procedure or service done with the assisted reproduction (e.g. laparoscopy).
- Any post-operative or follow-up service or procedure (e.g., testing to determine success of procedure, such as ultrasonography).

C. Sperm and Oocyte Retrieval and Storage

1. All services for retrieval, preservation, storage or thawing of semen, oocytes, or ovaries are not covered benefit.
2. The retrieval and storage of semen, oocytes or ovarian tissue prior to cancer treatment are not a covered benefit.

D. Pre-implantation genetic diagnosis (PGD) Please refer to the medical policy *Genetics: Counseling, Testing and Screening #91540*.

SPECIAL NOTES:

Maternity care for a pregnancy resulting from infertility treatment is covered for members only.

Medicaid/Healthy Michigan Plan members: The Medicaid and Healthy Michigan Plan Certificates of Coverage (COC) state that all services and supplies relating to treatments for infertility including, among other things, artificial insemination, in-vitro fertilization, embryo or ovum transfer procedures, any other assisted reproduction procedure, fees to a surrogate or gestational carrier, prescription drugs designed to achieve pregnancy, harvest preservation and storage of eggs or sperm and services to reverse voluntary sterilizations are **not a covered benefit**. Diagnostic services are covered as described in the Medicaid COC Section 5.B. (16), and the Healthy Michigan Plan COC Section 6.B. (14).

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between***

this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IV. BACKGROUND

For the intent of this section, the terms female and male are used to identify sex assigned at birth and not gender identity. Definitions of infertility are not stated in this section as medical criteria for services in this policy. Please refer to the member's specific plan documents and any applicable riders for benefit coverage.

The World Health Organization defines infertility is a disease of the male or female reproductive system defined by the failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse (WHO, 2024). The American College of Obsterics & Gynecology defines infertility as failure to achieve pregnancy within 12 months of unprotected intercourse or therapeutic donor insemination in women younger than 35 years or within 6 months in women older than 35 years (ACOG, 2019). In a 2023 update, the American Society of Reproductive Medicine's (ASRM), states that one compotent of of their definition of infertility is "the inability to achieve a successful pregnancy based on a patient's medical, sexual, and reproductive history, age, physical findings, diagnostic testing, or any combination of those factors" (ASRM, 2023).

Infertility may be caused by a number of different factors. In the female reproductive system, infertility may be caused by tubal disorders such as blocked fallopian tubes, uterine disorders (e.g., endometriosis, fibroids, septate uterus), disorders of the ovaries (e.g.,polycystic ovarian syndrome), follicular disorders, and disorders of the endocrine system causing imbalances of reproductive hormones. In the male reproductive system, infertility may be caused by obstruction of the reproductive tract causing dysfunctionalities in the ejection of semen, hormonal disorders, testicular failure to produce sperm, or abnormal sperm function and quality. Other factors include lifestype and environmental exposure to pollutants and toxins (WHO, 2024). The ASRM states that in the absence of exigent history or physical findings, evaluation should and treatment may be initiated at 12 months in women <35 years of age and at 6 months in women aged >35 years. In women >40 years of age, more immediate evaluation and treatment may be warranted (ASRM, 2021). ACOG states that the essential components of an initial workup include a review of the medical history, physical examination, and additional tests as indicated. For the female partner, tests will focus on ovarian reserve, ovulatory function, and structural abnormalities. Imaging of the reproductive organs provides valuable information on conditions

that affect fertility. Imaging modalities can detect tubal patency and pelvic pathology and assess ovarian reserve (ACOG, 2019). For the initial evaluation of the male partners, the American Urological Association (AUA) and ASRM recommends a step-wise process of evaluation and consultation regarding treatment options, beginning with the review of reproductive history and one or more semen analyses (Schlegel, 2020). The AUA and ASRM recommends proceeding with evaluation for the male and female partners in parallel to optimize treatment success.

Assisted Reproductive Technology (ART) refers to treatments and procedures that aim to achieve pregnancy.The Center for Disease Control (CDC) defines ART as any fertility-related treatments in which eggs or embryos are manipulated. Procedures where only sperm are manipulated, such as intrauterine inseminations, are not considered under the CDC's definition. Additionally, procedures in which ovarian stimulation is performed without a plan for egg retrieval are also excluded from their definition (CDC, 2019). In vitro fertilization (IVF) is a method of assisted reproduction in which eggs are removed from a woman's ovary and combined with sperm outside the body to form embryos. The embryos are grown in the laboratory for several days and then either placed in a woman's uterus or cryopreserved (frozen) for future use (NCI). The steps in an IVF treatment cycle are ovarian stimulation, egg retrieval, fertilization, embryo culture, and embryo transfer. Intrauterine insemination (IUI) is a procedure that bypasses the cervix and places sperm into the uterus around the time of ovulation. IUI is most commonly used when the male partner has a low sperm count or if the movement of the sperm (motility) is less than ideal. IUI is also helpful when a cervix has scarring that prevents the sperm from entering the uterus from the vagina (ASRM, 2012). Gamete intrafallopian transfer (GIFT) is similar to IVF, but the gametes (egg and sperm) are transferred to the woman's fallopian tubes rather than her uterus, and fertilization takes place in the tubes rather than in the lab. Another difference is that laparoscopy, a surgical procedure, is necessary to transfer the sperm and egg to the tubes. GIFT is an option only for women who have normal fallopian tubes. Another ART procedure similar to GIFT is is zygote intrafallopian transfer (ZIFT). The fertilized egg is transferred to the fallopian tube rather than the uterus, but unlike GIFT the fertilization takes place in the lab. This procedure also requires a laparoscopy (ASRM, 2016).

V. CODING INFORMATION

A. Infertility:

ICD-10 Codes that apply to this policy:

N46.01 – N46.9	Male infertility
N97.0 – N97.9	Female infertility
Z31.41	Encounter for fertility testing
Z31.49	Encounter for other procreative investigation and testing

CPT/HCPCS Codes (*List should not be considered inclusive*):
All procedures billed with the diagnoses above may be subject to the plan's Fertility benefit limitations, including but not limited to:

- Anesthesia
- DME
  - E1399 Durable medical equipment, miscellaneous – *if billed for testicular hypothermia device (Explanatory notes must accompany claim)*

- Medication
  - J0725 Injection, Chorionic Gonadotropin, Per 1,000 Usp Units
  - J1620 Injection, Gonadorelin Hydrochloride, Per 100 Mcg (*no active NDC for this code)*
  - J1950 Injection, leuprolide acetate (for depot suspension), per 3.75 mg
  - J3355 Injection, urofollotropin, 75IU
  - S0126 Injection, follitropin alfa, 75 IU
  - S0128 Injection, follitropin beta, 75 IU

- Radiology
  - 74740 Hysterosalpingography, radiological supervision and interpretation
  - 74742 Transcervical catheterization of fallopian tube, radiological supervision and interpretation
  - 74440 Vasography, vesiculography, or epididymography, radiological supervision and interpretation

- Lab/Path
  - 0255U Andrology (infertility), sperm-capacitation assessment of ganglioside GM1 distribution patterns, fluorescence microscopy, fresh or frozen specimen, reported as percentage of capacitated sperm and probability of generating a pregnancy score
  - 89300 Semen analysis; presence and/or motility of sperm including Huhner test (post coital)
  - 89310 Semen analysis; motility and count (not including Huhner test)
  - 89320 Semen analysis; complete (volume, count, motility, and differential)
  - 89321 Semen analysis, presence and/or motility of sperm
  - 89322 Semen analysis; volume, count, motility, and differential using strict morphologic criteria (e.g., Kruger)
  - 89325 Sperm antibodies
  - 89329 Sperm evaluation; hamster penetration test
  - 89330 Sperm evaluation; cervical mucus penetration test, with or without spinnbarkeit test
  - 89331 Sperm evaluation, for retrograde ejaculation, urine (sperm concentration, motility, and morphology, as indicated)
  - 89398 Unlisted reproductive medicine laboratory procedure (*Explanatory notes must accompany claim)*

  - G0027 Semen analysis; presence and/or motility of sperm excluding huhner
  - Q0115 Post-coital direct, qualitative examinations of vaginal or cervical mucous

- Surgery

52010	Cystourethroscopy, with ejaculatory duct catheterization, with or without irrigation, instillation, or duct radiography, exclusive of radiologic service
52402	Cystourethroscopy with transurethral resection or incision of ejaculatory ducts
54692	Laparoscopy, surgical; orchiopexy for intra-abdominal testis
54900	Epididymovasostomy, anastomosis of epididymis to vas deferens; unilateral
54901	Epididymovasostomy, anastomosis of epididymis to vas deferens; bilateral
55200	Vasotomy, cannulization with or without incision of vas, unilateral or bilateral (separate procedure)
55300	Vasotomy for vasograms, seminal vesiculograms, or epididymograms, unilateral or bilateral
58100	Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method (separate procedure)
58110	Endometrial sampling (biopsy) performed in conjunction with colposcopy (List separately in addition to code for primary procedure
58340	Catheterization and introduction of saline or contrast material for saline infusion sonohysterography (SIS) or hysterosalpingography
58345	Transcervical introduction of fallopian tube catheter for diagnosis and/or re-establishing patency (any method), with or without hysterosalpingography
58350	Chromotubation of oviduct, including materials
58578	Unlisted laparoscopy procedure, uterus *(Explanatory notes must accompany claim)*
58660	Laparoscopy, surgical; with lysis of adhesions (salpingolysis, ovariolysis) (separate procedure)
58662	Laparoscopy, surgical; with fulguration or excision of lesions of the ovary, pelvic viscera, or peritoneal surface by any method
58672	Laparoscopy, surgical; with fimbrioplasty (*not covered for Medicaid)*
58752	Tubouterine implantation (*not covered for Medicaid)*
58760	Fimbrioplasty (*not covered for Medicaid)*
58673	Laparoscopy, surgical; with salpingostomy (salpingoneostomy)
58679	Unlisted laparoscopy procedure, oviduct, ovary *(Explanatory notes must accompany claim)*
58752	Tubouterine implantation (*not covered for Medicaid)*
58760	Fimbrioplasty (*not covered for Medicaid)*
58770	Salpingostomy (salpingoneostomy)
58999	Unlisted procedure, female genital system (nonobstetrical)

B. Assisted reproduction or artificial conception procedures
Any services billed with the following diagnoses *are not covered:*

(Check plan rules for any coverage exceptions)

ICD-10 Codes that are required for billing these services:

Z31.81	Encounter for male factor infertility in female patient
Z31.83	Encounter for assisted reproductive fertility procedure cycle
Z31.89	Encounter for other procreative management
Z31.9	Encounter for procreative management, unspecified
Z52.810	Egg (Oocyte) donor under age 35, anonymous recipient
Z52.811	Egg (Oocyte) donor under age 35, designated recipient
Z52.812	Egg (Oocyte) donor age 35 and over, anonymous recipient
Z52.813	Egg (Oocyte) donor age 35 and over, designated recipient
Z52.819	Egg (Oocyte) donor, unspecified

CPT/HCPCS Codes:

All procedures billed with the diagnoses above will be denied as not covered (unless plan specifies coverage), including but not limited to:

- Anesthesia
- Medication
- Radiology
- Lab/Path

80414	Chorionic gonadotropin stimulation panel; testosterone response This panel must include the following: Testosterone (84403 x 2 on 3 pooled blood samples)
80415	Chorionic gonadotropin stimulation panel; estradiol response This panel must include the following: Estradiol (82670 x 2 on 3 pooled blood samples)
80426	Gonadotropin releasing hormone stimulation panel This panel must include the following: Follicle stimulating hormone (FSH) (83001 x 4) Luteinizing hormone (LH) (83002 x 4)
82626	Dehydroepiandrosterone (DHEA)
82627	Dehydroepiandrosterone-sulfate (DHEA-S)
82670	Estradiol
82671	Estrogens; fractionated
82672	Estrogens; total
82679	Estrone
82681	Estradiol; free, direct measurement
82757	Fructose, semen
83001	Gonadotropin; follicle stimulating hormone (FSH)
83002	Gonadotropin; luteinizing hormone (LH)
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, microtechniques (any method)
89254	Oocyte identification from follicular fluid
89255	Preparation of embryo for transfer (any method)
89257	Sperm identification from aspiration (other than seminal fluid)
89258	Cryopreservation; embryo(s)
89259	Cryopreservation; sperm

89260	Sperm isolation; simple prep (e.g., sperm wash and swim-up) for insemination or diagnosis with semen analysis
89261	Sperm isolation; complex prep (e.g., Percoll gradient, albumin gradient) for insemination or diagnosis with semen analysis
89264	Sperm identification from testis tissue, fresh or cryopreserved
89268	Insemination of oocytes
89272	Extended culture of oocyte(s)/embryo(s), 4-7 days
89280	Assisted oocyte fertilization, microtechnique; less than or equal to 10 oocytes
89281	Assisted oocyte fertilization, microtechnique; greater than 10 oocytes
89335	Cryopreservation, reproductive tissue, testicular
89337	Cryopreservation, mature oocyte(s)
89342	Storage, (per year); embryo(s)
89343	Storage, (per year); sperm/semen
89344	Storage, (per year); reproductive tissue, testicular/ovarian
89346	Storage, (per year); oocyte(s)
89352	Thawing of cryopreserved; embryo(s)
89353	Thawing of cryopreserved; sperm/semen, each aliquot
89354	Thawing of cryopreserved; reproductive tissue, testicular/ovarian
89356	Thawing of cryopreserved; oocytes, each aliquot

- Physician Services
- Office Visits
- Surgery/Procedures

58321	Artificial insemination; intra-cervical
58322	Artificial insemination; intra-uterine
58323	Sperm washing for artificial insemination
58970	Follicle puncture for oocyte retrieval, any method
58974	Embryo transfer, intrauterine
58976	Gamete, zygote, or embryo intrafallopian transfer, any method

C. Sperm and Oocyte Retrieval and Storage

ICD-10 Codes that apply to this policy:

Z52.810	Egg (Oocyte) donor under age 35, anonymous recipient
Z52.811	Egg (Oocyte) donor under age 35, designated recipient
Z52.812	Egg (Oocyte) donor age 35 and over, anonymous recipient
Z52.813	Egg (Oocyte) donor age 35 and over, designated recipient
Z52.819	Egg (Oocyte) donor, unspecified

Z31.81	Encounter for male factor infertility in female patient
Z31.83	Encounter for assisted reproductive fertility procedure cycle
Z31.84	Encounter for fertility preservation procedure
Z31.89	Encounter for other procreative management
Z31.9	Encounter for procreative management, unspecified

CPT/HCPCS Codes

Basic services billed with the above diagnoses are not covered including but not limited to: Office Visits, Surgery, Medicine services, Anesthesia, Lab/Pathology, Pharmacy, and Radiology covered (unless plan specifies coverage).

The following services are Not Covered *(unless plan specifies coverage*)

55870 Electroejaculation
58970 Follicle puncture for oocyte retrieval, any method

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
89258 Cryopreservation; embryo(s)
89259 Cryopreservation; sperm
89264 Sperm identification from testis tissue, fresh or cryopreserved
89268 Insemination of oocytes
89272 Extended culture of oocyte(s)/embryo(s), 4-7 days
89335 Cryopreservation, reproductive tissue, testicular
89337 Cryopreservation, mature oocyte(s)
89342 Storage, (per year); embryo(s)
89343 Storage, (per year); sperm/semen
89344 Storage, (per year); reproductive tissue, testicular/ovarian
89346 Storage, (per year); oocyte(s)
89352 Thawing of cryopreserved; embryo(s)
89353 Thawing of cryopreserved; sperm/semen, each aliquot
89354 Thawing of cryopreserved; reproductive tissue, testicular/ovarian
89356 Thawing of cryopreserved; oocytes, each aliquot

S4027 Storage of previously frozen embryos
S4030 Sperm procurement and cryopreservation services; initial visit
S4031 Sperm procurement and cryopreservation services; subsequent visit
S4037 Cryopreserved embryo transfer, case rate
S4040 Monitoring and storage of cryopreserved embryos, per 30 days

Any service billed with the following diagnoses are ***not covered***
Z31.0 Encounter for reversal of previous sterilization
Z31.7 Encounter for procreative management and counseling for gestational carrier
Z31.42 Aftercare following sterilization reversal

The following services are ***not covered*** *regardless of diagnosis billed:*
0664T Donor hysterectomy (including cold preservation); open, from cadaver donor
0665T Donor hysterectomy (including cold preservation); open, from living donor
0668T Backbench standard preparation of cadaver or living donor uterine allograft prior to transplantation, including dissection and removal of surrounding soft tissues and preparation of uterine vein(s) and uterine artery(ies), as necessary
0669T Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; venous anastomosis, each
0670T Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; arterial anastomosis, each

55400 Vasovasostomy, vasovasorrhaphy
57292 Construction of artificial vagina; with graft

58750 Tubotubal anastomosis

S4011 In vitro fertilization; including but not limited to identification and incubation of mature oocytes, fertilization with sperm, incubation of embryo(s), and subsequent visualization for determination of development
S4013 Complete cycle, gamete intrafallopian transfer (GIFT), case rate
S4014 Complete cycle, zygote intrafallopian transfer (ZIFT), case rate
S4015 Complete in vitro fertilization cycle, not otherwise specified, case rate
S4016 Frozen in vitro fertilization cycle, case rate
S4017 Incomplete cycle, treatment cancelled prior to stimulation, case rate
S4018 Frozen embryo transfer procedure cancelled before transfer, case rate
S4020 In vitro fertilization procedure cancelled before aspiration, case rate
S4021 In vitro fertilization procedure cancelled after aspiration, case rate
S4022 Assisted oocyte fertilization, case rate
S4023 Donor egg cycle, incomplete, case rate
S4025 Donor services for in vitro fertilization (sperm or embryo), case rate
S4026 Procurement of donor sperm from sperm bank

S4028 Microsurgical epididymal sperm aspiration (MESA)
S4035 Stimulated intrauterine insemination (IUI), case rate

S4042 Management of ovulation induction (interpretation of diagnostic tests and studies, nonface-to-face medical management of the patient), per cycle

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