INFERTILITY DIAGNOSIS AND TREATMENT

Policy Number: INFERTILITY 008.6 T2 Effective Date: June 1, 2018

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Related Policies

- Follicle Stimulating Hormone (FSH) Gonadotropins
- Human Menopausal Gonadotropins (hMG)

Related Optum Clinical Guideline

- Fertility Solutions Medical Necessity Clinical Guideline: Infertility

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

CONDITIONS OF COVERAGE

Applicable Lines of Business/ Products

This policy applies to Oxford Commercial plan membership.

Benefit Type

- General benefits package
- Infertility benefit
- Pharmacy benefit

Referral Required

(Does not apply to non-gatekeeper products)

Yes

Authorization Required

(Precertification always required for inpatient admission)

Yes

Precertification with Medical Director Review Required

No

Applicable Site(s) of Service

(If site of service is not listed, Medical Director review is required)

Outpatient, Office
Special Considerations

1. Precertification through Optum is required.
2. Refer to member’s benefit plan document/Certificate of Coverage for information on advanced Infertility benefits, out-of-network treatment, and injectable Infertility medications.
3. Referral is ONLY required if the treating physician is NOT the OBGYN of record.
4. For Commercial plans, precertification is not required, but is encouraged for out-of-network services performed in the office that are covered under the member’s General Benefits package. If precertification is not obtained, Oxford may review for medical necessity after the service is rendered.

Note:
- Oxford has engaged Optum to perform reviews of requests for pre-certification. To pre-certify a procedure related to the treatment of Infertility, please call Optum at 877-512-9340.
- The Optum Infertility Clinical Guidelines may be found on Optum’s website: https://www.myOptumcomplexmedical.com/gateway/public/infertility/productsAndServices.jsp
- Oxford continues to be responsible for decisions to limit or deny coverage and for appeals.

**BENEFIT CONSIDERATIONS**

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Infertility services are always subject to mandate review. Several states mandate benefit coverage for certain Infertility services, but the requirements for coverage vary from state to state. Legislative mandates and the member-specific benefit plan document must be reviewed when determining benefit coverage for Infertility services. Where legislative mandates exist, they supersede benefit plan design. Benefit coverage for testing and treatment of Infertility are available only for the person(s) who are covered under the benefit document, and only when the member's specific plan provides benefits for Infertility diagnosis and/or treatment. The member-specific benefit plan document should be reviewed for applicable benefits, limitations and/or exclusions.

Services related to an insured member’s use of a third party surrogate/gestational carrier in pregnancy, whether the member is infertile or otherwise, are not related to medical treatment of the infertile woman and are therefore not covered as part of an insured member’s Infertility benefit. However, if a woman who is an insured member is pregnant, her prenatal, delivery and postnatal pregnancy care are a covered health service, regardless of whether she is functioning as a surrogate/gestational carrier.

Therapeutic (medical or surgical) procedures to correct a physical condition, which is the underlying cause of the Infertility, are a covered health service (e.g., for the treatment of a pelvic mass or pelvic pain, thyroid disease, pituitary lesions, etc.). Interventions to reverse elective sterilization may be explicitly excluded in the benefit document. Legislative mandates and the member-specific benefit plan document should be reviewed for mandates of benefits, limitations and/or exclusions.

Assisted reproductive technologies (ART) for the prevention of disease in offspring are not covered as an Infertility benefit since this service is not a treatment for Infertility. For ART services in other circumstances, legislative mandates and the member-specific benefit plan document should be reviewed for applicable benefits, limitations and/or exclusions.

Cryopreservation services are subject to the limitations and/or exclusions of Infertility benefits, if they exist. In most benefit documents, storage after cryopreservation of sperm, oocytes (eggs), embryos or ovarian tissue is excluded, as it does not meet the definition of a covered health service. However, some states mandate benefit coverage for certain Infertility services, including cryopreservation.

**Essential Health Benefits for Individual and Small Group**

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be...
removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

**COVERAGE RATIONALE**

**Diagnostic Procedures**

**Females**

The following tests or procedures are proven and/or medically necessary for diagnosing Infertility in female patients:

- Antral follicle count
- Clomiphene citrate challenge test
- The following hormone level tests:
  - Antimüllerian hormone (AMH)
  - Estradiol
  - Follicle-stimulating hormone (FSH)
  - Luteinizing hormone (LH)
  - Progesterone
  - Prolactin
  - Thyroid-stimulating hormone (TSH)
- Hysterosalpingogram (HSG)
- Diagnostic hysteroscopy
- Diagnostic laparoscopy with or without chromatubation
- Pelvic ultrasound (transabdominal or transvaginal)
- Sonohysterogram or saline infusion ultrasound

The following tests are unproven and/or not medically necessary for diagnosing Infertility in female patients:

- Inhibin B
- Uterine/endometrial receptivity testing

There is insufficient evidence to permit conclusions regarding the use of these tests. More studies are needed to support improved outcomes (i.e., increased successful pregnancies with delivery of liveborn children) with use of these diagnostic tests.

**Males**

The following tests or procedures are proven and/or medically necessary for diagnosing Infertility in male patients:

- Antisperm antibodies
- The following genetic screening tests:
  - Cystic fibrosis gene mutations
  - Karyotyping for chromosomal abnormalities
  - Y-chromosome microdeletions testing
- The following hormone level tests:
  - LH
  - FSH
  - Prolactin
  - Testosterone (total and free)
- Leukocyte count in semen
- Post-ejaculatory urinalysis
- Scrotal, testicular or transrectal ultrasound
- Semen analysis
- Testicular biopsy
- Vasography

The following tests are unproven and/or not medically necessary for diagnosing Infertility in male patients:

- Computer-assisted sperm analysis (CASA)
- Hyaluronan binding assay (HBA)
- Postcoital cervical mucus penetration test
- Reactive oxygen species (ROS) test
- Sperm acrosome reaction test
• Sperm DNA integrity/fragmentation tests (e.g., sperm chromatin structure assay (SCSA), single-cell gel electrophoresis assay (Comet), deoxynucleotidyl transferase-mediated dUTP nick end labeling assay (TUNEL), sperm chromatin dispersion (SCD) or Sperm DNA Decondensation™ Test (SDD))

• Sperm penetration assays

There is insufficient evidence to permit conclusions regarding the use of these tests. More studies are needed to support improved outcomes (i.e., increased successful pregnancies with delivery of liveborn children) with use of these diagnostic tests.

**Therapeutic Procedures**

For medical necessity reviews, refer to the Optum [Fertility Solutions Medical Necessity Clinical Guideline: Infertility](#).

**The following procedures are unproven and/or not medically necessary for treating Infertility:**

• Co-culture of embryos

• EmbryoGlue®

• In vitro maturation (IVM) of oocytes

Studies describe different techniques of co-culture of embryos, but no standardized method of co-culturing has been defined. The use of co-cultures may improve blastocyst development but may not result in an improved pregnancy or delivery rate.

There is inadequate published scientific data to permit conclusions regarding the use of EmbryoGlue.

Although preliminary results with IVM are promising, studies to date show that implantation and pregnancy rates are significantly lower than those achieved with standard IVF. Further evidence from well-designed trials is needed to determine the long-term safety and efficacy of the procedure.

**Cryopreservation**

Cryopreservation of sperm, semen or embryos is proven and/or medically necessary for individuals who are undergoing treatment with assisted reproductive technologies or are planning to undergo therapies that threaten their reproductive health, such as cancer chemotherapy.

Cryopreservation of *mature* oocytes (eggs) is proven and/or medically necessary for women, under the age of 42, who are undergoing treatment with assisted reproductive technologies or are planning to undergo therapies that threaten their reproductive health, such as cancer chemotherapy.

Cryopreservation of *immature* oocytes (eggs) is unproven and/or not medically necessary. Further evidence from well-designed trials is needed to determine the long-term safety and efficacy of cryopreserving immature oocytes for future in vitro maturation.

Cryopreservation of ovarian or testicular tissue is unproven and/or not medically necessary.

Ovarian tissue banking remains a promising clinical technique because it avoids ovarian stimulation and provides the opportunity for preserving gonadal function in prepubertal, as well as adult patients. However, this procedure has produced very few live births.

Testicular tissue or testis xenografting are in the early phases of experimentation and have not yet been successfully tested in humans.

**DEFINITIONS**

**Infertility:** A disease (an interruption, cessation, or disorder of body functions, systems, or organs) of the reproductive tract which prevents the conception of a child or the ability to carry a pregnancy to delivery (American Society for Reproductive Medicine (ASRM), 2012d). It is a disease defined by the failure to achieve a successful pregnancy after 12 months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination. Earlier evaluation and treatment may be justified based on medical history and physical findings and is warranted after 6 months for women over age 35 years. (ASRM 2013d)

**Preimplantation Genetic Diagnosis (PGD):** A laboratory test performed on an embryo prior to transfer when one or both genetic parents carry a gene mutation or a balanced chromosomal rearrangement to determine whether that specific mutation or an unbalanced chromosomal complement has been transmitted to the oocyte or embryo (Society for Assisted Reproductive Technology. (SART) and ASRM, 2008)
Preimplantation Genetic Screening (PGS): A laboratory test performed on an embryo prior to transfer when the genetic parents are known or presumed to be chromosomally normal to determine if the embryo has a genetic or chromosomal disorder. (SART and ASRM, 2008)

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

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<tr>
<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>0058T</td>
<td>Cryopreservation; reproductive tissue, ovarian</td>
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<tr>
<td>0357T</td>
<td>Cryopreservation; immature oocyte(s)</td>
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<td>52402</td>
<td>Cystourethroscopy with transurethral resection or incision of ejaculatory ducts</td>
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<td>54500</td>
<td>Biopsy of testis, needle (separate procedure)</td>
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<tr>
<td>54505</td>
<td>Biopsy of testis, incisional (separate procedure)</td>
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<tr>
<td>55300</td>
<td>Vasotomy for vasograms, seminal vesiculograms, or epididymograms, unilateral or bilateral</td>
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<tr>
<td>55530</td>
<td>Excision of varicocele or ligation of spermatic veins for varicocele; (separate procedure)</td>
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<tr>
<td>55535</td>
<td>Excision of varicocele or ligation of spermatic veins for varicocele; abdominal approach</td>
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<tr>
<td>55550</td>
<td>Laparoscopy, surgical, with ligation of spermatic veins for varicocele</td>
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<tr>
<td>55870</td>
<td>Electroejaculation</td>
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<tr>
<td>58140</td>
<td>Myomectomy, excision of fibroid tumor(s) of uterus, 1 to 4 intramural myoma(s) with total weight of 250 g or less and/or removal of surface myomas; abdominal approach</td>
</tr>
<tr>
<td>58145</td>
<td>Myomectomy, excision of fibroid tumor(s) of uterus, 1 to 4 intramural myoma(s) with total weight of 250 g or less and/or removal of surface myomas; vaginal approach</td>
</tr>
<tr>
<td>58146</td>
<td>Myomectomy, excision of fibroid tumor(s) of uterus, 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g, abdominal approach</td>
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<td>58321</td>
<td>Artificial insemination; intra-cervical</td>
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<td>58322</td>
<td>Artificial insemination; intra-uterine</td>
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<td>58323</td>
<td>Sperm washing for artificial insemination</td>
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<td>58340</td>
<td>Catheterization and introduction of saline or contrast material for saline infusion sonohysterography (SIS) or hysterosalpingography</td>
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<td>58345</td>
<td>Transcervical introduction of fallopian tube catheter for diagnosis and/or re-establishing patency (any method), with or without hysterosalpingography</td>
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<td>58350</td>
<td>Chromotubation of oviduct, including materials</td>
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<tr>
<td>58545</td>
<td>Laparoscopy, surgical, myomectomy, excision; 1 to 4 intramural myomas with total weight of 250 grams or less and/or removal of surface myomas</td>
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<td>58546</td>
<td>Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 grams</td>
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<td>Hysteroscopy, diagnostic (separate procedure)</td>
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<td>58559</td>
<td>Hysteroscopy, surgical; with lysis of intrauterine adhesions (any method)</td>
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<td>Laparoscopy, surgical; with lysis of adhesions (salpingolysis, ovariolysis) (separate procedure)</td>
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<td>58662</td>
<td>Laparoscopy, surgical; with fulguration or excision of lesions of the ovary, pelvic viscera, or peritoneal surface by any method</td>
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<td>58670</td>
<td>Laparoscopy, surgical; with fulguration of oviducts (with or without transection)</td>
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<td>58672</td>
<td>Laparoscopy, surgical; with fimbrioplasty</td>
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<td>58673</td>
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<td>58740</td>
<td>Lysis of adhesions (salpingolysis, ovariolysis)</td>
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<td>CPT Code</td>
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<tr>
<td>58752</td>
<td>Tubouterine implantation</td>
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<td>58760</td>
<td>Fimbrioplasty</td>
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<tr>
<td>58770</td>
<td>Salpingostomy (salpingoneostomy)</td>
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<td>58800</td>
<td>Drainage of ovarian cyst(s), unilateral or bilateral, (separate procedure); vaginal approach</td>
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<td>58805</td>
<td>Drainage of ovarian cyst(s), unilateral or bilateral, (separate procedure); abdominal approach</td>
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<td>58920</td>
<td>Wedge resection or bisection of ovary, unilateral or bilateral</td>
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<td>58970</td>
<td>Follicle puncture for oocyte retrieval, any method</td>
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<td>Embryo transfer, intrauterine</td>
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<td>58976</td>
<td>Gamete, zygote, or embryo intrafallopian transfer, any method</td>
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<td>74440</td>
<td>Vasography, vesiculography, or epididymography, radiological supervision and interpretation</td>
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<td>74740</td>
<td>Hysterosalpingography, radiological supervision and interpretation</td>
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<td>74742</td>
<td>Transcervical catheterization of fallopian tube, radiological supervision and interpretation</td>
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<tr>
<td>76830</td>
<td>Ultrasound, transvaginal</td>
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<td>76831</td>
<td>Saline infusion sonohysterography (SIS), including color flow Doppler, when performed</td>
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<tr>
<td>76856</td>
<td>Ultrasound, pelvic (nonobstetric), real time with image documentation; complete</td>
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<tr>
<td>76857</td>
<td>Ultrasound, pelvic (nonobstetric), real time with image documentation; limited or follow-up (e.g., for follicles)</td>
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<tr>
<td>76870</td>
<td>Ultrasound, scrotum and contents</td>
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<tr>
<td>76872</td>
<td>Ultrasound, transrectal</td>
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<tr>
<td>76948</td>
<td>Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation</td>
</tr>
<tr>
<td>80415</td>
<td>Chorionic gonadotropin stimulation panel; estradiol response This panel must include the following: Estradiol (82670 x 2 on 3 pooled blood samples)</td>
</tr>
<tr>
<td>80426</td>
<td>Gonadotropin releasing hormone stimulation panel This panel must include the following: Follicle stimulating hormone (FSH) (83001 x 4) Luteinizing hormone (LH) (83002 x 4)</td>
</tr>
<tr>
<td>81224</td>
<td>CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; intron 8 poly-T analysis (e.g., male infertility)</td>
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<tr>
<td>82397</td>
<td>Chemiluminescent assay</td>
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<td>82670</td>
<td>Estradiol</td>
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<tr>
<td>83001</td>
<td>Gonadotropin; follicle stimulating hormone (FSH)</td>
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<tr>
<td>83002</td>
<td>Gonadotropin; luteinizing hormone (LH)</td>
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<tr>
<td>83498</td>
<td>Hydroxyprogesterone, 17-d</td>
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<tr>
<td>83520</td>
<td>Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified</td>
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<tr>
<td>84144</td>
<td>Progesterone</td>
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<td>84146</td>
<td>Prolactin</td>
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<tr>
<td>84402</td>
<td>Testosterone; free</td>
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<tr>
<td>84403</td>
<td>Testosterone; total</td>
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<tr>
<td>84443</td>
<td>Thyroid stimulating hormone (TSH)</td>
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<tr>
<td>84830</td>
<td>Ovulation tests, by visual color comparison methods for human luteinizing hormone</td>
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<tr>
<td>88182</td>
<td>Flow cytometry, cell cycle or DNA analysis</td>
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<tr>
<td>88248</td>
<td>Chromosome analysis for breakage syndromes; baseline breakage, score 50-100 cells, count 20 cells, 2 karyotypes (e.g., for ataxia telangiectasia, Fanconi anemia, fragile X)</td>
</tr>
<tr>
<td>88261</td>
<td>Chromosome analysis; count 5 cells, 1 karyotype, with banding</td>
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<tr>
<td>CPT Code</td>
<td>Description</td>
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<tr>
<td>88262</td>
<td>Chromosome analysis; count 15-20 cells, 2 karyotypes, with banding</td>
</tr>
<tr>
<td>88263</td>
<td>Chromosome analysis; count 45 cells for mosaicism, 2 karyotypes, with banding</td>
</tr>
<tr>
<td>88273</td>
<td>Molecular cytogenetics; chromosomal in situ hybridization, analyze 10-30 cells (e.g., for microdeletions)</td>
</tr>
<tr>
<td>88280</td>
<td>Chromosome analysis; additional karyotypes, each study</td>
</tr>
<tr>
<td>88283</td>
<td>Chromosome analysis; additional specialized banding technique (e.g., NOR, C-banding)</td>
</tr>
<tr>
<td>88285</td>
<td>Chromosome analysis; additional cells counted, each study</td>
</tr>
<tr>
<td>89250</td>
<td>Culture of oocyte(s)/embryo(s), less than 4 days</td>
</tr>
<tr>
<td>89251</td>
<td>Culture of oocyte(s)/embryo(s), less than 4 days; with co-culture of oocyte(s)/embryos</td>
</tr>
<tr>
<td>89253</td>
<td>Assisted embryo hatching, microtechniques (any method)</td>
</tr>
<tr>
<td>89254</td>
<td>Oocyte identification from follicular fluid</td>
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<tr>
<td>89255</td>
<td>Preparation of embryo for transfer (any method)</td>
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<tr>
<td>89257</td>
<td>Sperm identification from aspiration (other than seminal fluid)</td>
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<tr>
<td>89258</td>
<td>Cryopreservation; embryo(s)</td>
</tr>
<tr>
<td>89259</td>
<td>Cryopreservation; sperm</td>
</tr>
<tr>
<td>89260</td>
<td>Sperm isolation; simple prep (e.g., sperm wash and swim-up) for insemination or diagnosis with semen analysis</td>
</tr>
<tr>
<td>89261</td>
<td>Sperm isolation; complex prep (e.g., Percoll gradient, albumin gradient) for insemination or diagnosis with semen analysis</td>
</tr>
<tr>
<td>89264</td>
<td>Sperm identification from testis tissue, fresh or cryopreserved</td>
</tr>
<tr>
<td>89268</td>
<td>Insemination of oocytes</td>
</tr>
<tr>
<td>89272</td>
<td>Extended culture of oocyte(s)/embryo(s), 4-7 days</td>
</tr>
<tr>
<td>89280</td>
<td>Assisted oocyte fertilization, microtechnique; less than or equal to 10 oocytes</td>
</tr>
<tr>
<td>89281</td>
<td>Assisted oocyte fertilization, microtechnique; greater than 10 oocytes</td>
</tr>
<tr>
<td>89290</td>
<td>Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); less than or equal to 5 embryos</td>
</tr>
<tr>
<td>89291</td>
<td>Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); greater than 5 embryos</td>
</tr>
<tr>
<td>89300</td>
<td>Semen analysis; presence and/or motility of sperm including Huhner test (post coital)</td>
</tr>
<tr>
<td>89310</td>
<td>Semen analysis; motility and count (not including Huhner test)</td>
</tr>
<tr>
<td>89320</td>
<td>Semen analysis; volume, count, motility, and differential</td>
</tr>
<tr>
<td>89321</td>
<td>Semen analysis; sperm presence and motility of sperm, if performed</td>
</tr>
<tr>
<td>89322</td>
<td>Semen analysis; volume, count, motility, and differential using strict morphologic criteria (e.g., Kruger)</td>
</tr>
<tr>
<td>89325</td>
<td>Sperm antibodies</td>
</tr>
<tr>
<td>89329</td>
<td>Sperm evaluation; hamster penetration test</td>
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<td>89330</td>
<td>Sperm evaluation; cervical mucus penetration test, with or without spinnbarkeit test</td>
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<tr>
<td>89331</td>
<td>Sperm evaluation, for retrograde ejaculation, urine (sperm concentration, motility, and morphology, as indicated)</td>
</tr>
<tr>
<td>89335</td>
<td>Cryopreservation, reproductive tissue, testicular</td>
</tr>
<tr>
<td>89337</td>
<td>Cryopreservation, mature oocyte(s)</td>
</tr>
<tr>
<td>89342</td>
<td>Storage, (per year); embryo(s)</td>
</tr>
<tr>
<td>89343</td>
<td>Storage, (per year); sperm/semen</td>
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<td>89344</td>
<td>Storage, (per year); reproductive tissue, testicular/ovarian</td>
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<td>Storage, (per year); oocyte(s)</td>
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<td>89352</td>
<td>Thawing of cryopreserved; embryo(s)</td>
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<td>89353</td>
<td>Thawing of cryopreserved; sperm/semen, each aliquot</td>
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### CPT Code | Description
---|---
89354 | Thawing of cryopreserved; reproductive tissue, testicular/ovarian
89356 | Thawing of cryopreserved; oocytes, each aliquot
89398 | Unlisted reproductive medicine laboratory procedure

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### HCPCS Code | Description
---|---
J0725 | Injection, chorionic gonadotropin, per 1,000 USP units
J3355 | Injection, urofollitropin, 75 IU
S0122 | Injection, menotropins, 75 IU
S0126 | Injection, follitropin alfa, 75 IU
S0128 | Injection, follitropin beta, 75 IU
S0132 | Injection, ganirelix acetate, 250 mcg
S3655 | Antisperm antibodies test (immunobead)
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, case rate not otherwise specified
S4016 | Frozen in vitro fertilization cycle, case rate
S4017 | Incomplete cycle, treatment canceled 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
S4027 | Storage of previously frozen embryos
S4028 | Microsurgical epididymal sperm aspiration (MESA)
S4030 | Sperm procurement and cryopreservation services; initial visit
S4031 | Sperm procurement and cryopreservation services; subsequent visit
S4035 | Stimulated intrauterine insemination (IUI), case rate
S4037 | Cryopreserved embryo transfer, case rate
S4040 | Monitoring and storage of cryopreserved embryos, per 30 days

### ICD-10 Diagnosis Code | Description
---|---
E23.0 | Hypopituitarism
N46.01 | Organic azoospermia
N46.021 | Azoospermia due to drug therapy
N46.022 | Azoospermia due to infection
N46.023 | Azoospermia due to obstruction of efferent ducts
N46.024 | Azoospermia due to radiation
N46.025 | Azoospermia due to systemic disease
N46.029 | Azoospermia due to other extratesticular causes
N46.11 | Organic oligospermia
N46.121 | Oligospermia due to drug therapy
N46.122 | Oligospermia due to infection
N46.123 | Oligospermia due to obstruction of efferent ducts
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**DESCRIPTION OF SERVICES**

Both male and female factors can contribute to infertility. Some underlying causes of infertility include ovulatory dysfunction, decreased ovarian reserve, cervical factors, uterine abnormalities, tubal disease and male factors. Once a diagnosis is made, treatment falls into 3 categories: medical treatment to restore fertility, surgical treatment to restore fertility or ART.

Cryopreservation is the process of cooling and storing cells, tissues or organs at very low or freezing temperatures to save them for future use. It is used to preserve sperm, semen, oocytes (eggs), embryos, ovarian tissue or testicular tissue as an option for men and women who wish to or must delay reproduction for various reasons, including the need to undergo therapies that threaten their reproductive health such as cancer treatment. Cryopreservation is also used to preserve unused gametes or zygotes produced through various artificial reproductive techniques for use at a later time.

**CLINICAL EVIDENCE**

**Diagnostic Procedures**

**Females**

An ASRM committee opinion on the diagnostic evaluation for infertility in women addresses several tests and procedures, starting with a comprehensive medical, reproductive and family history, as well as a thorough physical exam. Subsequent evaluation should be conducted in a systematic, expeditious and cost-effective manner so as to identify all relevant factors, with initial emphasis on the least invasive methods for detection of the most common causes of infertility. Diagnostic tests and procedures include evaluation for ovulatory dysfunction, ovarian reserve, cervical factors, uterine abnormalities, tubal disease and peritoneal factors (ASRM, 2015a).

A comprehensive National Institute for Health and Care Excellence (NICE) clinical guideline addresses the evaluation and management of infertility, including ART (NICE, 2013).

**Inhibin B**

An ASRM committee opinion on measures of ovarian reserve states that inhibin B is not a reliable measure of ovarian reserve and routine use is not recommended (ASRM, 2015b).

A NICE clinical guideline does not recommend the use of inhibin B testing for assessing ovarian reserve (NICE, 2013).

**Uterine Receptivity Testing**

Studies of uterine receptivity testing indicate that even though integrins may be important markers of endometrial receptivity and provide additional information, more study is needed before uterine receptivity testing can be considered a clinically useful test (Thomas et al., 2003; Lessey et al., 2000).

**Males**

Professional society guidelines on the diagnostic evaluation for infertility in men state that the initial screening evaluation should include a reproductive history and semen analysis. If the initial evaluation is abnormal, then a complete evaluation is recommended. This includes a complete medical history and physical examination. Other tests and procedures may include endocrine evaluation, post-ejaculatory urinalysis, ultrasound, additional tests on semen and sperm and genetic testing (ASRM, 2015c; American Urological Association (AUA), 2010a).
Computer-Assisted Sperm Analysis (CASA)
The evidence does not suggest that the predictive value of CASA is superior compared with conventional semen analysis. Only a very small proportion of the variance in fertility outcomes was explained by these variables, suggesting that other factors, not identified by semen analysis, are more important. Therefore, although CASA systems have the potential to reduce error in measurement and produce a larger array of semen variables, the literature to date does not demonstrate that these variables contribute clinically valuable information above and beyond the information already provided by conventional semen analysis (Hayes, 2011; updated 2015, archived 2017).

AUA guidelines state that specialized tests on semen, such as CASA, are not required for the diagnosis of male infertility. They may be useful in a small number of patients for identifying a male factor contributing to unexplained infertility, or for selecting therapy, such as ART (AUA, 2010a).

A meta-analysis by Oehninger et al. (2000) used data from 2906 patients in 34 prospective, controlled studies to evaluate the predictive value of four categories of sperm functional assays, including CASA, for IVF outcome. In this analysis, the combined results of 4 studies demonstrated a large degree of variability indicating a poor predictive power for sperm parameters assessed by CASA and IVF results. Predictive statistics demonstrated low specificity and sensitivity and a high rate of false positives.

Hyaluronan Binding Assay (HBA)
An ASRM committee opinion on the diagnostic evaluation for infertility in men states that hyaluronic acid binding tests have a very limited role in the evaluation of male fertility because they have limited clinical utility and typically do not affect treatment. (ASRM, 2015c)

A Cochrane systematic review by McDowell et al. (2014) evaluated the impact of advanced sperm selection techniques, including the ability to bind to hyaluronic acid, on ART outcomes. Two randomized controlled trials were included in the review. Both evaluated sperm selection by hyaluronic acid binding for ICSI, but only one reported live births. One study compared hyaluronic acid binding to conventional ICSI, but live births were not reported. Evidence was insufficient to determine whether sperm selected by hyaluronic acid binding improve live birth or pregnancy outcomes in ART. No clear data on adverse effects were available. Further studies of suitable quality are required to evaluate whether advanced sperm selection techniques, such as hyaluronic acid binding, can be recommended for use in clinical practice.

A systematic review of seven studies concluded that the use of hyaluronic acid binding sperm selection techniques yielded no improvement in fertilization and pregnancy rates. The results did not support routine use of hyaluronic acid binding assays in all ICSI cycles. Identification of patients that might benefit from this technique needs further study. (Beck-Fruchter et al., 2016)

A systematic review, conducted by Said and Land (2011), evaluated four advanced sperm selection methods: surface charge, apoptosis, membrane maturity (hyaluronic acid binding) and ultramorphology. The analysis focused on the anticipated benefits of sperm quality and ART outcomes. Sperm quality parameters included motility, morphology, viability, DNA integrity, apoptosis and maturity. ART outcomes assessed included fertilization, embryo quality, pregnancy, abortion and live birth rates. Forty-four studies were included. Preliminary results are encouraging; however, the authors concluded that more clinical studies on safety and efficacy are needed before the implementation of advanced sperm selection methods can be universally recommended in ART.

Ye et al. (2006) investigated the relationship between HBA and fertilization rate in conventional IVF in 175 IVF patients. Both the standard semen analysis and the HBA were performed on the same ejaculated sperm samples used for IVF treatments. While both normal sperm morphology and HBA scores were statistically significantly related to fertilization rates, the HBA was less significant than normal sperm morphology. The investigators concluded that the clinical predictive value of HBA for sperm-fertilizing ability in vitro is limited.

Postcoital Cervical Mucus Penetration Test
ASRM guidelines state that the postcoital test of cervical mucus is no longer recommended for evaluating infertility because the test is subjective, has poor reproducibility, rarely changes clinical management and does not predict the inability to conceive (ASRM, 2015a).

A NICE guideline does not recommend the routine use of postcoital testing of cervical mucus for evaluating infertility because the test has no predictive value on pregnancy rate. (NICE, 2013)
Reactive Oxygen Species (ROS) Test
An ASRM committee opinion on the diagnostic evaluation for infertility in men states that ROS tests have a very limited role in the evaluation of male fertility because they have limited clinical utility and typically do not affect treatment. (ASRM, 2015c)

AUA guidelines state that ROS testing has not been shown to be predictive of pregnancy independent of routine semen parameters nor are there any proven therapies to correct an abnormal test result. There is insufficient data to support the routine use of ROS testing in the management of the male partner of an infertile couple. (AUA, 2010a)

Chen et al. (2013) studied the influence of ROS on sperm physiology and pathology. Low levels of ROS serve a critical function in normal sperm physiology, such as fertilizing ability and sperm motility. Increased levels of ROS are considered to be a significant contributing factor to male infertility/subfertility due to sperm DNA damage and reduced motility. Some studies have shown that antioxidant therapy significantly improves sperm function and motility; however, the overall effectiveness remains controversial due to non-standardized assays for measuring levels of ROS and sperm DNA damage. Further development of standardized tests is needed.

Sperm Acrosome Reaction Test
An ASRM committee opinion on the diagnostic evaluation for infertility in men states that sperm acrosome reaction tests have a very limited role in the evaluation of male fertility because they have limited clinical utility and typically do not affect treatment. (ASRM, 2015c)

AUA guidelines state that less commonly used specialized tests on semen, such as acrosome reaction testing, are important investigative tools, but are not necessary for the routine evaluation of men with infertility. (AUA, 2010a)

Sperm DNA Integrity/Fragmentation Tests
After conducting a systematic review of the literature, ASRM developed a guideline stating that there is insufficient evidence to recommend the routine use of sperm DNA integrity tests as current assessment methods do not reliably predict treatment outcomes. The review did not identify any Level I (evidence from at least one properly designed randomized controlled trial) studies and few high quality prospective studies. Most studies were Level II-2 (evidence from well-designed cohort or case-control studies) or less. The majority of studies were hindered by small sample size, non-consecutive recruitment of patients, variable patient populations, lack of control for female factors, weak statistical methodology and use of several different methods for assessing DNA damage. (ASRM, 2013a)

AUA guidelines state that there is insufficient evidence in the literature to support the routine use of DNA integrity testing in the evaluation and management of the male partner of an infertile couple. Presently, there are no proven therapies to correct an abnormal DNA integrity test result. (AUA, 2010)

Sperm Penetration Assays (SPA)
An ASRM committee opinion on the diagnostic evaluation for infertility in men states that sperm penetration assays have a very limited role in the evaluation of male fertility. Since intracytoplasmic sperm injection (ICSI) is routinely used during IVF for male-factor infertility, this test is rarely of any clinical value. (ASRM, 2015c)

AUA guidelines state that specialized tests on semen, such as SPA, are not required for the diagnosis of male infertility. They may be useful in a small number of patients for identifying a male factor contributing to unexplained infertility, or for selecting therapy, such as ART. (AUA, 2010a)

A meta-analysis by Oehninger et al. (2000) used data from 2906 patients in 34 prospective, controlled studies to evaluate the predictive value of four categories of sperm functional assays, including SPA, for IVF outcome. In this analysis, the sperm-zona pellucida binding assay and the induced-acrosome reaction assay had a high predictive value for fertilization outcome. SPA had a relatively high positive predictive value (more than 70%), but the negative predictive value was variable, ranging from 11% to 100%, with most studies reporting NPV less than 75%. The authors noted that this assay was limited by the need for standardization.

Therapeutic Procedures
ASRM has published several documents, including a guide for patients that address available therapeutic options for infertility. (ASRM, 2013b, 2012a, 2012b, 2012c, 2015d and 2008b)

A comprehensive NICE clinical guideline addresses the evaluation and management of infertility, including ART. (NICE, 2013)

An AUA practice statement addresses surgical treatment options for males with obstructive azoospermia. The report also addresses sperm retrieval techniques and intracytoplasmic sperm injection. (AUA, 2010c)
**Co-Culturing of Embryos**

Studies describe different techniques of co-culture, but no standardized method of co-culturing has been defined.

In a meta-analysis of 17 prospective, randomized trials, Kattal et al. (2008) evaluated the role of co-culture in human IVF. Primary outcomes measured were implantation rates and pregnancy rates (clinical and ongoing). Secondary outcomes included evaluation of pre-embryo development based on average number of blastomeres per embryo. The pooled data of human trials on co-culture demonstrate a statistically significant improvement in blastomere number, implantation rates and clinical and ongoing pregnancy rates. However, the authors acknowledged that confounding factors such as heterogeneity of cell lines and variability in culture media used limit the conclusions.

A comparative study evaluated 517 women undergoing cumulus co-culture and cumulus-aided embryo transfer with those who underwent cumulus co-culture but did not undergo cumulus-aided embryo transfer. The study results demonstrated a significant increase in the implantation rate in the study group of 25.6% versus 14.5% in the control group and a significant increase in the pregnancy rate in the study group of 47.6% versus 34% in the control group. (Parikh et al., 2006)

Another study evaluated the effectiveness of autologous endometrial co-culture (AECC) in 1,030 consecutive cycles of in vitro fertilization-embryo transfer. Embryos were randomly grown on endometrial co-culture or conventional media if more than 6 oocytes were normally fertilized. Otherwise, all embryos were grown on AECC. The study results demonstrated a significant improvement in embryo quality with endometrial co-culture. (Spandorfer et al., 2004)

Johnson et al. (2008) evaluated whether culture of immature human oocytes with and without autologous cumulus cells (CCs) in standard culture medium would provide additional oocytes for use in IVF procedure in 61 women. This study demonstrated good maturation of metaphase I (MI) oocytes but poor maturation of germinal vesicle (GV) oocytes in standard culture medium. The investigators concluded that these extended culturing techniques were inefficient in maturing and providing additional oocytes/embryos for patient use.

Ebner et al. (2006) evaluated the influence of adhering CCs on further preimplantation development and concluded that co-culture of oocytes with attached CCs may enhance preimplantation development.

**EmbryoGlue**

A Cochrane systematic review by Bontekoe et al. (2014) assessed whether embryo transfer media containing adherence compounds improved live birth and pregnancy rates in ART. The adherence compounds identified for evaluation were hyaluronic acid (HA) and fibrin sealant. Seventeen studies with a total of 3898 participants were analyzed. One studied fibrin sealant, and the other 16 studied HA. No evidence was found of a treatment effect of fibrin sealant as an adherence compound. For HA, evidence suggests improved clinical pregnancy and live birth rates with the use of functional concentrations of HA as an adherence compound. However, the evidence obtained is of moderate quality. The multiple pregnancy rate was significantly increased in the high HA group. The increase may be the result of use of a combination of an adherence compound and a policy of transferring more than one embryo. Further studies of adherence compounds with single embryo transfer are needed.

In a single center, prospective randomized study (n=224), Hazlett et al. (2008) found that routine use of EmbryoGlue did not significantly improve pregnancy or implantation rates in nonselected patients receiving either a day 3 or day 5 embryo transfer compared with standard culture media. Future prospective randomized studies are needed to determine whether EmbryoGlue is beneficial in a selected patient population.

In a prospective randomized clinical trial, Valojerdi et al. (2006) evaluated the efficacy of EmbryoGlue. A total of 815 patients were randomly allocated to the test group (embryos were treated with EmbryoGlue prior to intrauterine transfer) (n=417) and the control group (embryos were not treated with EmbryoGlue) (n=398). The clinical pregnancy and implantation rate increased significantly in the test group compared to the control group. More studies are needed to evaluate the effectiveness and safety of EmbryoGlue.

**In Vitro Maturation of Oocytes**

An ASRM committee opinion on in vitro maturation (IVM) of oocytes states that initial results suggest the potential for clinical application. However, at this time, patients must be made aware that the implantation and pregnancy rates are significantly lower than with standard IVF. Because only a small number of children have been conceived with IVM, information on the safety of the procedure with regard to malformation and developmental outcomes cannot be accurately assessed. IVM should only be performed as an experimental procedure in specialized centers for carefully selected patients. (ASRM, 2013b)

A Cochrane review by Siristatidis et al. (2013) compared outcomes associated with in vitro maturation (IVM) followed by vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) versus conventional IVF or ICSI, in women with...
polycystic ovarian syndrome (PCOS) undergoing ART. Though results are promising, there is still no evidence from randomized controlled trials upon which to base any practice recommendations regarding IVM before IVF or ICSI for women with PCOS. Clinical trials are ongoing.

**Cryopreservation**

A Hayes analysis found insufficient evidence to draw definitive conclusions regarding the safety and efficacy of ovarian tissue cryopreservation for fertility preservation in patients undergoing gonadotoxic cancer treatment (Hayes, 2016).

An American Cancer Society (ACS) document on preserving fertility in women with cancer covers options to consider both before and after cancer treatment. Options prior to treatment include mature oocyte cryopreservation, embryo cryopreservation, fertility-saving surgery ovariian suppression, ovarian tissue cryopreservation, ovarian transplantation, radical trachelectomy and progesterone therapy for early-stage uterine cancer. ACS considers oocyte cryopreservation an established method of preserving fertility in women, although it has not been used as long as embryo cryopreservation, which is the most established and successful method of preserving a woman’s fertility. ACS considers ovarian suppression and cryopreservation of ovarian tissue experimental at this time. (ACS, 2016a)

An ACS document on preserving fertility in men with cancer covers options to consider both before and after cancer treatment. Options prior to treatment include radiation shielding and sperm banking. The success rates of infertility treatments using frozen sperm vary and depend on the quality of the sperm after it is thawed as well as the health and age of the female partner. In general, sperm collected before cancer treatment is just as likely to start a pregnancy as sperm from men without cancer. Sperm banking has resulted in thousands of pregnancies, without unusual rates of birth defects or health problems in the children. Once sperm is stored, it remains good for many years. (ACS, 2016b)

NICE makes the following recommendations for people with cancer who wish to preserve fertility:

- When using cryopreservation to preserve fertility in people diagnosed with cancer, use sperm, embryos or oocytes.
- Offer sperm cryopreservation to men and adolescent boys who are preparing for medical treatment for cancer that is likely to make them infertile.
- Offer oocyte or embryo cryopreservation as appropriate to women of reproductive age (including adolescent girls) who are preparing for medical treatment for cancer that is likely to make them infertile if:
  - They are well enough to undergo ovarian stimulation and egg collection and
  - This will not worsen their condition and
  - Enough time is available before the start of their cancer treatment
- In cryopreservation of oocytes and embryos, use vitrification instead of controlled-rate freezing if the necessary equipment and expertise is available. (NICE, 2013)

In a small, prospective, single center cohort study, Meirow et al. (2016) reported the results of cryopreserved ovarian tissue in twenty cancer survivors. Patient ages at tissue harvesting ranged from 14 to 39 years. Fifteen women had hematologic malignancies, and two had leukemia. Ten patients were exposed to nonsterilizing chemotherapy before ovarian tissue cryopreservation. After transplantation, the endocrine recovery rate was 93%. Fourteen patients underwent IVF treatments with a fertilization rate of 58%. Sixteen pregnancies were achieved (10 after IVF, 6 spontaneous), resulting in 10 live births, two (twins) after harvesting from the mother at the age of 37. After transplantation, 53% of patients conceived, and 32% delivered at least once. One patient conceived four times. Preharvesting chemotherapy exposure was not associated with inferior outcomes. This study is limited by small patient numbers. Further results from ongoing clinical trials are needed to confirm these findings.

Cil et al. (2013) conducted a meta-analysis to estimate age-specific probabilities of live birth with oocyte cryopreservation in infertile patients undergoing non-donor mature oocyte cryopreservation. Original data from 10 studies, including 2,265 cycles from 1,805 patients, was included. Live birth success rates declined with age regardless of the freezing technique. Despite this age-induced compromise, live births continued to occur as late as ages 42 and 44 years with slowly frozen and vitrified oocytes, respectively. Estimated probabilities of live birth for vitrified oocytes were higher than those for slowly frozen.

In a multicenter retrospective study, Harton et al. (2013) assessed the relationship between maternal age, chromosome abnormality, implantation and pregnancy loss in IVF patients undergoing chromosome screening. Results showed that aneuploidy rates increased with maternal age. Implantation and pregnancy rates were not significantly different between reproductively younger and older patients up to age 42 years. Mounting data suggests that the dramatic decline in IVF treatment success rates with female age is primarily caused by aneuploidy.

In a meta-analysis, Oktay et al. (2006) studied the efficiency of oocyte cryopreservation relative to IVF with unfrozen oocytes. Compared to women who underwent IVF after slow freezing (SF), IVF with unfrozen oocytes resulted in significantly better rates of fertilization. Although oocyte cryopreservation with the SF method appears to be justified for preserving fertility when a medical indication exists, its value for elective applications remains to be determined.
Pregnancy rates using a vitrification (VF) method appear to have improved, but further studies are needed to
determine the efficiency and safety of this technique.

Bedaiwy et al. (2008) performed a systematic review of reproductive function after ovarian tissue transplantation
(OTT) for fertility preservation in women at high risk of premature ovarian failure (POF). Women with follicle-
stimulating hormone (FSH) >30 IU/l at the time of OTT were included in a meta-analysis to evaluate the time to re-
establishment of ovarian function (ROF). Secondary outcomes included short-term (<12 months) and long-term (>12
months) ovarian function (OVF) and pregnancy after OTT. Transplantation of ovarian tissue can re-establish OVF after
POF; however, the efficacy of OTT using cryopreserved tissues is not yet equivalent to that of fresh grafts. A
prospective, controlled multicenter trial with sufficient follow-up is needed to provide valid evidence of the potential
benefit of this procedure.

Professional Societies

American Society for Reproductive Medicine (ASRM)

ASRM (2013e) recommends the following with regards to cryopreservation and fertility preservation:

- Sperm cryopreservation is an established method of fertility preservation in men
- Embryo cryopreservation is an established method of fertility preservation in women
- Cryopreservation of ovarian tissue remains investigational
- Cryopreservation of testicular tissue remains investigational

Mature Oocytes

After conducting a systematic review of the literature, ASRM developed guidelines (2013c) for mature oocyte
cryopreservation. Four randomized controlled trials comparing outcomes with cryopreserved and fresh oocytes in
IVF/ICSI cycles were included in the review (Cobo et al., 2008; Cobo et al., 2010; Rienzi et al., 2010; Parmegiani et
al., 2011). All studies used a similar open vitrification protocol. Two studies were conducted with oocyte donors and
two with infertile couples.

The guidelines state that there is good evidence that fertilization and pregnancy rates are similar to IVF/ICSI using
fresh oocytes when vitrified/warmed oocytes are used as part of IVF/ICSI in young infertility patients and oocyte
donors. No increases in chromosomal abnormalities, birth defects or developmental deficits have been noted in the
children born from cryopreserved oocytes. The guidelines also make the following recommendations:

- In patients facing infertility due to chemotherapy or other gonadotoxic therapies, oocyte cryopreservation is
  recommended with appropriate counseling (Level B).
- More data on the safety and efficacy of oocyte cryopreservation in donor populations is needed before universal
donor oocyte banking can be recommended (Level B).
- There is insufficient data to recommend oocyte cryopreservation for the sole purpose of circumventing
  reproductive aging in healthy women (Level B).
- More data is needed before oocyte cryopreservation should be used routinely in lieu of embryo cryopreservation
  (Level B).

Level B - at least fair scientific evidence suggests that the benefits of the clinical service outweigh the potential risks.

Success rates with oocyte cryopreservation, using either slow-freezing or vitrification, appear to decline with maternal
age consistent with the clinical experience with fresh oocytes. (ASRM, 2013c)

Ovarian Tissue

An ASRM committee opinion states that ovarian tissue cryopreservation is an option to preserve reproductive potential
in patients who must urgently undergo aggressive chemotherapy and/or radiotherapy or who have other medical
conditions requiring treatment that may threaten ovarian function and subsequent fertility. Ovarian tissue
cryopreservation may be the only option available to prepubertal girls undergoing such treatments. However, these
techniques are still considered to be experimental (ASRM, 2014).

American Society of Clinical Oncology (ASCO)

ASCO conducted a systematic review of the evidence on fertility preservation for adults and children with cancer. This
was an update to a previously published guideline (Lee et al., 2006). A total of 222 new publications met inclusion
criteria. A majority were observational studies, cohort studies and case series or reports, with few randomized clinical
trials. ASCO concluded that, with the exception of oocyte cryopreservation, no major, substantive revisions to the
2006 recommendations were warranted. Sperm, embryo and oocyte cryopreservation are considered standard
practice. Other fertility preservation methods, such as ovarian and testicular tissue cryopreservation, should be
considered investigational and should be performed by providers with the necessary expertise (Loren et al., 2013).

For tests regulated under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, premarket approval from the FDA is not required.

Products and media used for cryopreservation of reproductive tissue are too numerous to list. See the following website for more information (use product code MQL). Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed November 10, 2017)

REFERENCES

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2018T0270U]


**POLICY HISTORY/REVISION INFORMATION**

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