The Health Policy & Planning Subcommittee of the State Employee Benefits Committee

DELAWARE'S FERTILITY CARE & PRESERVATION LAW SB 139

February 7, 2019

Disclaimer

This presentation was prepared with research and citations provided by Stand Up for Delaware Fertility Coverage

Highmark and Aetna GHIP Infertility Benefit Coverage provided by Highmark and Aetna

Fertility Care and Preservation Law

Goal: to design comprehensive coverage that provides individuals diagnosed with infertility, access to affordable treatment options

Endorsed by National and Local Medical Organizations

- American Society of Reproductive Medicine
- RESOLVE: The National Infertility Association
- American College of Obstetricians and Gynecologists
- Alliance for Fertility Preservation
- Ulman Cancer Fund for Young Adults
- American Society for Clinical Oncology
- Delaware Section of the American Congress of Obstetricians and Gynecologists
- Delaware Society for Clinical Oncology
- Delaware Breast Cancer Coalition
- Support from local reproductive endocrinologists and oncologists

Passed Senate, March 27, 2018 – 21-0
Passed House, June 7, 2018 – 39-2
Signed into Law, June 30, 2018

What is Infertility?

The World Health Organization, American Medical Association and American Society for Reproductive Medicine define infertility as a disease of the reproductive system.

Lack of Access

- Of the 1 in 8 diagnosed with infertility, 3 in 4 never obtain treatment because of cost; including those with limited infertility coverage (RESOLVE, The National Infertility Association)

- Cost is the primary reason why adolescents and young adults with iatrogenic infertility (infertility as an unintended consequence of medical treatment, e.g. cancer) forgo fertility preservation (Ulman Cancer Fund for Young Adults)

Why Are We Here?

The SEBC is being asked to take up the issue, because the State Group Health Program (GHIP) is a self-insured plan and is therefore exempt from the requirements of the Delaware Fertility Care and Preservation law.

Understanding Treatment

- Delaware's Fertility Care and Preservation Law is not an in vitro fertilization law, because infertility does not always mean IVF
- Of those diagnosed with infertility, 3% will require IVF (National Survey of Family Growth, 1982-2010. Natl Health Stat Report. 2014; 22(73):1-21. 2014)

  Note: Delaware practices have estimated it is closer to 15% based on patient volumes
- Many men and women achieve successful pregnancy with less invasive interventions, such as medication, surgery and artificial insemination (Ibid.)
- Using US Census & National Survey of Family Growth data, it is estimated that 19,500 Delaware women have experienced physical difficulty in getting pregnant or carrying a pregnancy to live birth (RESOLVE State Report Card)

Medical Reasons for Coverage Adoption

- Delaware Fertility Care and Preservation Law defines infertility by medical diagnoses, allowing individuals to receive treatment that optimizes the chance for success as opposed to requiring that the individual first utilize lower cost interventions

- It is the first state fertility care and preservation law in the nation to recommend the use of Single Embryo Transfer (SET) and incorporate the latest medical technologies to encourage successful, healthy pregnancies

- Includes fertility preservation coverage for adolescents and young adults diagnosed with iatrogenic infertility, also extends eligibility to dependent children

Infertility Access in Delaware

Airbase Carpet and Tile Mart
Accenture
ADT
Aerotek
Amazon
AmWINS Brokerage
Anne Arundel County
Apple
ATI Physical Therapy
Baird Mandalas Brockstedt, LLC
Banister International
Bayhealth
Bank of America
Bank of New York
Barclays
Beacon Hill Staffing
Beebe Medical Center
Belfint, Lyons & Shuman, P.A.**
BlackRock
BNY Mellon
Boys & Girls Clubs of Delaware**
BrightView Landscaping
Brunswick
CACI International
Canon
Capital One
Carefirst
Catapult Learning
Cecil County Public Schools
Century Engineering
Chemours
Chimes
Chubb Insurance
Cigna
Citibank
Citizens Bank
Comcast
Connections**
Cowan Systems
CVS Corporation
Dassault Falcon**
Del-One Federal Credit Union**
Delaware Electric Cooperative
Delaware Orthopedic Specialists**
Delmarva
Dell
Deloitte
Dentsply LLC
Diamond Materials**
Dick's Sporting Goods
Discover Card
Discover
Dolben
Dover Downs Hotel & Casino**
Dow Chemical
Dupont
Easter Seals of Delaware**
Exelon
Facebook
FMC
Fox Chase Cancer Center
Fresenius Medical Care
Fusion
Glaxo Smith Kline
HBSC**
Hear Better Center
HERRS
Highmark BCBS
HomeGoods
Hydro East
IBM
Ikea
Incyte Corporation
Iron Mountain
Jack & Jill Ice Cream
Jet Blue Airways
Johnson & Johnson
JP Morgan Chase
Kimberly Clark
Kraft Foods
LabWare Holdings, Inc.**
Legg Mason
Marriott International
M&T Bank
McCormick & Company
Nanticoke Hospital
Northrop Grumman
Nucar Connection**
Orbital ATK
Pepco Holdings
Piedmont Airlines
Proctor and Gamble
PSEG
Quality Staffing
R&F Metals
Randstad Technologies
RSM
Rutgers University
Salem County Special Services
Sallie Mae
Sears Holdings
Simple
Sobi
Sprint
Stanley Black & Decker
Starbucks
State of Maryland
State of Delaware
Sussex County Government
Target
TD Bank
Team Health
Terumo Medical
The Archer Group**
The Mary Campbell Center**
ThoughtWorks
T Mobile
Tower Hill School**
T. Rowe Price
University of MD Eastern Shore
UTRS
Vanguard Group
Verizon
Visa
Walgreens
Washington College
Waters Corporation
Wawa
Wells Fargo
WSFS Bank**
Wicomico Board of Education
WL Gore
World Bank
Worcester County
Westside Family Healthcare**
Wyndham
XL America, Inc.
Young, Conaway, Stargatt & Taylor**

Source: Reproductive Associates of Delaware based on patient employer coverage verification. **Compliant with SB 139 (all others self-insure and infertility coverage benefits vary)

Fertility Care & Preservation Law

- No more than 3 cycles of Ovulation Induction (OI) or Intrauterine Insemination (IUI) may be required before In Vitro Fertilization (IVF) is covered[1]
- Examples when OI or IUI is appropriate include: unexplained infertility, poor cervical conditions, including scar tissue and male factor, including ejaculation and sperm mobility issues
- Medicated IUI – has a 20% success rate per cycle when performed each month for women under 35 for the first 3 tries, and then drops to 6% for tries 4 through 6. (Shady Grove Fertility Study)
  - Women over 40 will have a 2-5% chance of success (Ibid.)
  - Higher risk of multiples

Fertility Care & Preservation Law

- Up to 6 completed egg retrievals per lifetime, with unlimited embryo transfers
- Covered when “medically necessary” – examples include: moderate or severe endometriosis, damaged, blocked or absent fallopian tubes, genetic disease or condition, diminished ovarian reserve, multiple pregnancy loss, sexual dysfunction, severe male factor and fertility preservation
- IVF has a 40% success rate[2] per cycle, depending on a woman’s circumstance (CDC)
- Lower risk of multiples when Single Embryo Transfer[3] (SET) is used

Note: Natural conception has a 20-35% success rate per cycle. For each month that she tries, a healthy, fertile 30-year-old woman has a 20% chance of getting pregnant. (ASRM)

Age Limits

Retrievals Up To Age 45 And Transfers Up To Age 50

- While women at age 40 and above generally have reduced fertility potential compared to younger women, fertility doctors generally use a patient's health rather than age alone to evaluate whether they're good candidates for treatment (Mayo Clinic)
- While a 30-year-old woman has a 50% success with a non-genetically tested embryo from a fresh transfer, a 41-year-old woman has a 20% chance and 44-year-old woman has about a 10% chance (2014 SART data)
- However, each genetically tested embryo that has the normal number of chromosomes will have a 60-70% chance of success per-transfer no matter the age of the mother[4] (Reprogenetics Laboratories)
- Being able to identify and transfer "chromosomally normal embryos" also lowers the rate of miscarriage from 30-40% for a woman in her 30s/40s to 5% (Advanced Reproductive Medicine)

Age Limits

Donor Eggs & Embryos

- Many U.S. fertility clinics have an age limit for IVF treatment using non-donor eggs of 45 years of age based on standard medical practice (How old is too old? Challenges faced by clinicians concerning age cutoffs for patients undergoing in vitro fertilization, Robert L. Klitzman, M.D, Columbia University, New York, New York)

- Donor eggs are commonly used until age 49; the definition for reproductive age is generally considered between the ages of 12 and 49 or between menarche and menopause (WHO)

- The law states “for IVF services, retrievals are to be completed before the individual is 45 years old and transfers are to be completed before the individual is 50 years old. Additionally, the law states “in vitro fertilization, including IVF using donor eggs, sperm, or embryos and IVF where the embryo is transferred to a gestational carrier or surrogate must be covered

Why 6 IVF Cycles?

- To provide families diagnosed with the disease of infertility comprehensive coverage that provides access to affordable treatment options
- 32% of women age 40 and younger, using their own eggs, achieved a live birth greater than 20% of the time though the fourth cycle and six cycles achieved a cumulative prognosis-adjusted-live-birth rate of 68% (2015 study in the Journal for AMA (2015, 22/29)
- The same study found that women age 40 to 42 had a 12% live-birth rate for their first cycle, with 6 cycles achieving cumulative prognosis-adjusted live-birth rate of 31.5%

The more eggs produced from each IVF cycle, the better chance of live birth, up to13 eggs, after which can result in lower quality eggs (British Medical Journal)

Clinical Guidelines: Single Embryo Transfer

- The language in the law, regarding the use of SET “when recommended and medically appropriate” is intended to reduce safety risks to the mother, increase the chance for successful pregnancy and reduce the overall cost of health care now associated with multiple births

- This language reflects what is now widely accepted standard medical practice. Last year, the Practice Committee for ASRM issued recommendations for the clinical application of blastocyst transfer strongly endorsing SET, as the clinical norm

Clinical Guidelines: Single Embryo Transfer

- According to ASRM and SART, SET should be considered for women with favorable prognosis (i.e., women under 35 and those with good quality eggs or embryos)
- Limiting the high cost of multiple IVF treatment cycles can be viewed as a powerful incentive for individuals requesting the transfer of more than one embryo
- Pregnancies with the delivery of twins cost approximately 5 times as much when compared with singleton pregnancies, pregnancies with delivery of triplets or more cost nearly 20 times as much. (American Journal of Obstetrics and Gynecology, December 2013)[5]

Current GHIP Infertility Benefit

Highmark

- $25,000 lifetime cap - $10,000 medical and $15,000 prescription
- 25% coinsurance

Aetna

- $25,000 lifetime cap - $10,000 medical and $15,000 prescription
- 25% coinsurance

Specific Medical Policy Criteria

Highmark

- Retrievals must be completed before age 45
- Transfers must be completed before age 45

Aetna

- Retrievals must be completed before age 45
- Transfers must be completed before age 50

IVF Eligibility & Exceptions

Highmark

Eligibility

- Treating specialist submits “Request for IVF Coverage” for Approval[1]

Exceptions

- Each case is reviewed on an individual basis.

IVF Eligibility & Exceptions

Aetna

Eligibility

- No more than 3 cycles of ovulation induction or intrauterine inseminations may be required before in vitro fertilization services are covered
- Unmedicated day 3 FSH level must meet criteria in the Infertility Clinical Policy Bulletin (“CBC”)

Exceptions

- If IVF is medically necessary per CPB then a member would be able to proceed with IVF and would not have to first attempt less invasive procedures.

SEBC Concerns

- Unlimited embryo transfer and age limits defined in the law
- How adoption of law would be funded for GHIP participants
- What do subject matter experts and clinicians see as best practice?

Subcommittee Work

- Evaluate best practice plan design and coverage that is supported by medical evidence
- Propose GHIP infertility benefit plan design supported by medical evidence and best practice
  - Encourage treatment focused on patient safety and effectiveness
  - Limits multiple embryo transfers
  - Ensures high IVF success rates
  - Minimizes high risk pregnancy
  - Strives for single full term births
  - Reduces financial exposure to members and GHIP
- Reassess costs or savings
- Propose funding source and implementation plan

Next Steps & Considerations

Evaluate

- Average costs of services in Highmark and Aetna book of business
- Pros & cons of cost caps and service Limits (including limits on IVF treatment cycles)
- Pros & cons of age limits restrictions
- Requiring SET for women with favorable prognosis
- Coinsurance and cost sharing options

Questions?

Appendix

Footnotes

[1]Ovulation induction(OI) is a procedure in which medication is used to stimulate a woman's ovaries to produce multiple follicles and ova. (ASRM) Intrauterine insemination (IUI) is a fertility treatment that involves placing sperm inside a woman's uterus to facilitate fertilization. The goal of IUI is to increase the number of sperm that reach the fallopian tubes and subsequently increase the chance for fertilization. (ASRM)

[2]52% for a women under 35, 35.7% for women 35-37 and 36% for women 38-40 averages to 41% (CDC)

[3]Single embryo transfer (SET) is the transfer of a single embryo at either the cleavage or blastocyst stage of embryo development that is selected from a larger number of available embryos. (ASRM)

[4]Reprogenetics Laboratories, Study: Prevention of genetic disease before pregnancy, Santiago Munne, PhD

[5]Lemos, Elkin V., et al. Healthcare Expenses Associated With Multiple vs. Singleton Pregnancies in the United States (American Journal of Obstetrics & Gynecology, December 2013).

Highmark Infertility Policy

- Individual has a congenital absence or anomaly of reproductive organ(s); or
- Individual fulfills ONE of the following definitions of infertility:
  - Individual is less than the age of 35 years and has not achieved a successful pregnancy after at least twelve (12) months of appropriately timed unprotected vaginal intercourse or intrauterine insemination; or
  - Individual is 35 years of age or older and has not achieved a successful pregnancy after at least six (6) months of appropriately timed unprotected vaginal intercourse or intrauterine insemination;
- AND
- In the absence of known tubal disease and/or severe male factor problems (contraindications to insemination cycles), the individual has not achieved a successful pregnancy as described above which includes up to three (3) intrauterine insemination cycles; and

- Individual has at least ONE risk factor that includes, but is not limited to the following:
  - Tubal disease that cannot be corrected surgically; or
  - Diminished ovarian reserve; or
  - Irreparable distortion of the uterine cavity or other uterine anomaly (when using a gestational carrier); or
  - Male partner with severe male factor infertility; or
  - Unexplained infertility; or
  - Stage 4 endometriosis as defined by the American Society of Reproductive Medicine;
- AND
- Individual does not have EITHER of the following contraindications:
  - Ovarian failure: premature (i.e., ovaries stop working before age 40) or menopause (i.e., absence of menstrual periods for 1 year); or
  - Contraindication to pregnancy.

Aetna Infertility Policy

- Ovarian responsiveness is determined by measurement of an unmedicated day 3 FSH obtained within the prior 6 months if the woman is older than age 35 or within in the prior 12 months if the woman is 35 years of age or younger.
- Under these plans, for women who are less than age 40, the day 3 FSH must be less than 19 mIU/mL in their most recent lab test to use their own eggs.
- For women age 40 and older, their unmedicated day 3 FSH must be less than 19 mIU/mL in all prior tests to use their own eggs.
- In addition, infertility services for women with natural menopause in women age 40 years and older are not covered as such services are not considered treatment of disease.
- Women with ovarian failure who are less than 40 years of age are considered to have premature ovarian failure (also known as premature ovarian insufficiency, primary ovarian insufficiency, or hypergonadotropic hypogonadism).
- Advanced reproductive technology (in vitro fertilization) services are considered medically necessary for women with premature ovarian failure who are less than 45 years of age.

Aetna Infertility Policy

If IVF is medically necessary per CBP, a member would be able to proceed with IVF and would not have to attempt less invasive procedures. Those reasons would be:

- Couples for whom natural or artificial insemination would not be expected to be effective and ART would be expected to be the only effective treatment, including:
- Men with azoospermia or severe deficits in semen quality or quantity (see Appendix); or
- Women with tubal factor infertility:
    - Bilateral tubal disease (e.g., tubal obstruction, absence, or hydrosalpinges).
    - Endometriosis stage 3 or 4 (see appendix).
    - Failure to conceive after pelvic surgery with restoration of normal pelvic anatomy (see section I. E above for pelvic surgery procedures for infertility):
        - After trying to conceive for 6 months if less than 40 years of age;
        - After trying to conceive for 3 months if 40 years of age or older.
    - Infertility resulting from ectopic pregnancy
    - Ectopic pregnancy occurring during infertility treatment.
    - Unilateral hydrosalpinx with failure to conceive:
        - After trying to conceive for 12 months if less than 40 years of age;
        - After trying to conceive for 6 months if 40 years of age or older.
- Inadvertent ovarian hyperstimulation (estradiol level was greater than 1,000 pg/ml plus greater than 3 follicles greater than 16 mm or 4 to 8 follicles greater than 14 mm or a larger number of smaller follicles) during preparation for a planned stimulated cycle in women less than 40 years of age.

Thank You