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Fertility Preservation: Case for Coverage

Who needs fertility preservation?

- 160,000+ cancer patients diagnosed in reproductive years (up to 45)
  - Risk is treatment based, systemic, multi-factorial
  - Chemotherapy, radiation, and surgery can all cause infertility
    - Direct damage: can destroy gametes (sperm and eggs), damage/remove reproductive organs
    - Indirect affects: can cause heart, lung, uterine, endocrine damage, that may complicate pregnancy
- Others at risk:
  - Autoimmune diseases, sickle cell, genetic conditions
  - Prior to prophylactic surgery, e.g., oophorectomy; hysterectomy
  - Screening for hereditary diseases, e.g., BRCA

Carly K.,
Osteosarcoma, diagnosed at 23
Egg cryopreservation, no coverage

•I was diagnosed with osteosarcoma, while in law school, at age 23, after experiencing pain in my right knee. I quickly learned that treatment would require high doses of chemotherapy for eight months and a limb-salvage surgery to remove the tumor.

•A dear friend of mine, who had been diagnosed with Ewing Sarcoma while in her OB/GYN residency, informed me that my chemo often leaves women infertile. She encouraged me to preserve my eggs prior to treatment.

•My insurer denied my request since it deemed egg freezing unnecessary for cancer treatment. It cost me (and my parents) over $10,000 out of pocket, but I felt fortunate to be able to do it.

•Egg preservation allowed me to begin treatment with an unparalleled sense of security. While my future was in limbo, I knew the choice to have a family one day was safe as a result of this procedure.

Defining “Fertility Preservation”

- ***Iatrogenic Infertility***: An impairment of fertility by surgery, radiation, chemotherapy or other medical treatment or intervention affecting reproductive organs or processes.
- Medically-indicated – does not include “elective” egg freezing

Organization	Definition
AFP, NICHD	Fertility preservation is the process of saving or protecting eggs, sperm, or reproductive tissue so that a person can use them to have biological children in the future.
ASCO	Actions that can help you have a baby after cancer treatment, such as storing sperm or freezing eggs.
Oncofertility Consortium	Fertility preservation is the use of specific medical interventions to protect the fertility of individuals whose disease or disease treatment may lead to infertility.

Do patients want fertility preservation?

- **Patients desire parenthood**
  - Top concern for AYA patients, after mortality
  - Survivors express a desire to have children
  - Place an increased value on parenthood as a result of their experience with cancer
  - Preference is for biological children compared to third party reproductive options and adoption

Canada AL, et al, 2012
Schover LR, et al, 1999

- **Subsequent infertility causes distress**
  - Associated with depression
  - Survivors report poorer quality of life
  - Common themes: loss of control, threat to gender roles, complicates current/future intimate relationships

Ussher JM, et al, 2019
Benedict C, et al, 2020
Hawkey AJ, et al, 2021

Professional Guidelines

As part of education and informed consent **before cancer therapy**, health care providers **should address** the possibility of infertility with patients treated during their reproductive years and be prepared to **discuss possible fertility preservation options and/or to refer** all potential patients to appropriate reproductive specialists. Although patients may be focused initially on their cancer diagnosis, the Update Panel encourages providers to advise patients regarding potential threats to fertility **as early as possible** in the treatment process so as to allow for the widest array of options for fertility preservation.

Oktay K, et al, 2018

What are the costs (FP)?

FERTILITY PRESERVATION OPTION	SERVICE COST RANGE
Egg Freezing	$10,000-$15,000
Embryo Freezing	$11,000-15,000
Ovarian Tissue Freezing*	$10,000-$12,000
Ovarian Transposition	Cost unknown
Ovarian Suppression	$350-$500 monthly
Sperm banking	$500-$1,000
Testicular Sperm Extraction	$7500-$10000
Electroejaculation	$10,000-$12,000

**ASRM removed experimental label in 2019*

FP Legislative Summary

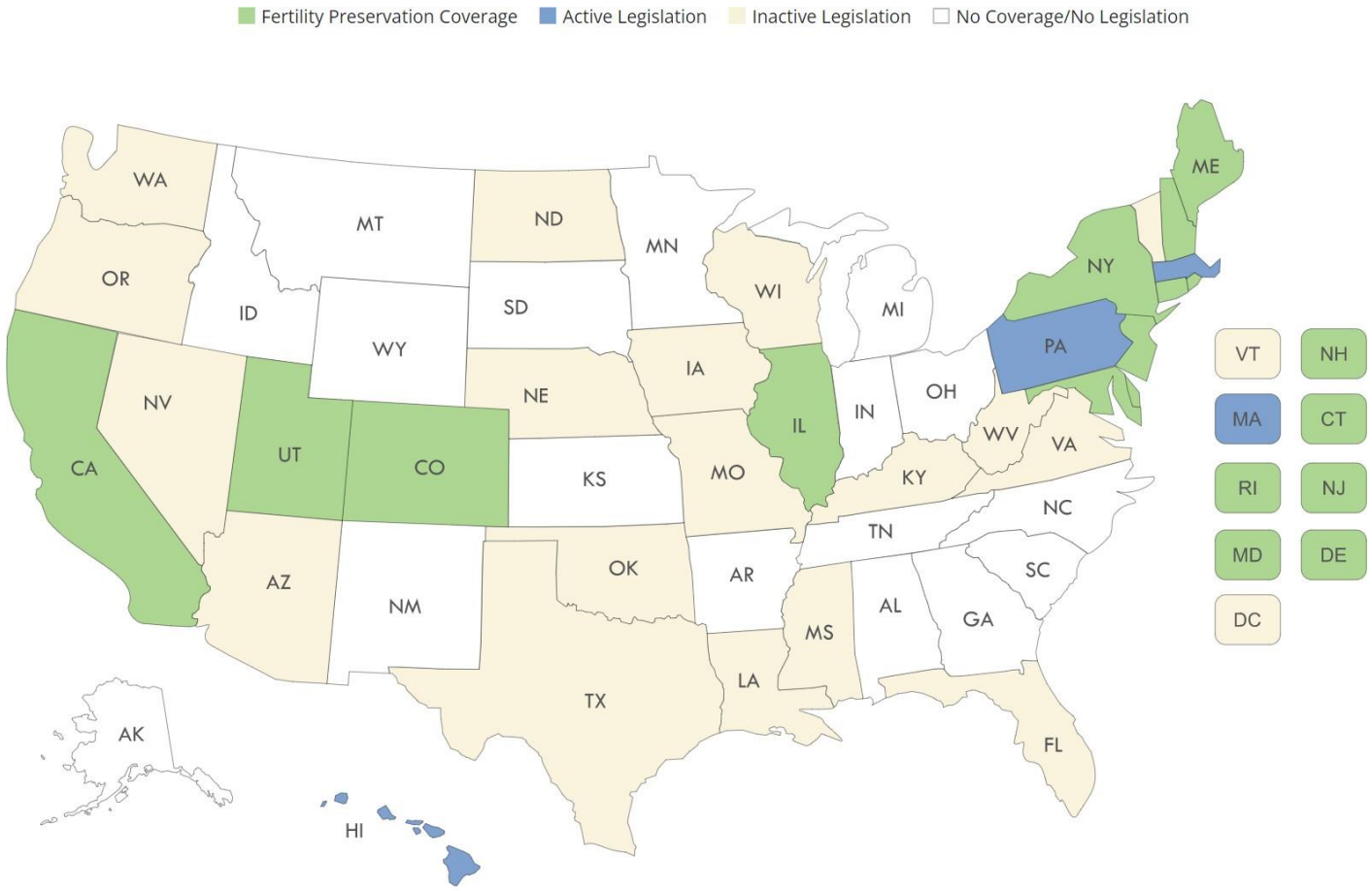
33 States + DC Introduced Bills

11 States Have Enacted FP Coverage:

California	Maryland
Connecticut	New Hampshire*
Colorado*	New Jersey
Delaware*	New York*
Illinois**	Rhode Island
	Utah**

**Also mandated IVF coverage*

*** Medicaid*



Updated 6/15/2022

Successful Legislation Fertility Preservation 2017-2021

STATE	YEAR	BILL	STRUCTURE	GROUPS COVERED	LIVES	LIMITATIONS	COVERAGE SPECIFICS
CT	2017	HB7124	Changed definition of Infertility	Individual and group plans	651,134	Cycle limits; religious exemption	Changed statutory definition of "infertility" to "medically necessary"
RI	2017	S 0821A & H 6170A	Amended IVF mandate. Added FP coverage	Individual and group plans	241,582	Age limits (25-40); unclear whether applies to FP	Standard FP services if necessary medical treatment may cause iatrogenic infertility
MD	2018	SB271 & HB908	Amended IVF Mandate. Added FP coverage	Large groups only	926,446	No embryos; religious exemption	Standard FP services if necessary medical treatment may cause iatrogenic infertility
DE	2018	SB139	New mandate for Infertility including IVF+FP	No state employees or Medicaid	120,438	6 cycles; religious exemption; retrieve by 45	Coverage for specific treatments, inc. IVF & sperm, egg/embryo cryo. No exper. treatments
IL	2018	HB2617	New FP coverage not linked to infertility mandate	Broad coverage inclu. state employees and Medicaid	5,303,325	ACA mandate clause re: exceeding EHB	Standard FP services if necessary medical treatment may cause iatrogenic infertility
NY	2019	S719/A2817* *budget*	Amend Infertility mandate to include IVF. Add FP coverage	IVF: Large groups only FP: Ind., all group plans	4,700,000	3 cycles of IVF; FP TBD	Coverage added through State Budget process. IVF + FP coverage.
NH	2019	SB 279	New mandate for Infertility including IVF+FP	All "health carriers" (insurers, HMOs, etc.)	208,515	Limits can't be "arbitrary"	Standard FP services for eggs, embryos, sperm, and "material." Storage through policy term.
CA	2019	SB 600	Clarifies existing coverage for FP	All managed care plans; HMOs, some PPOs	16,900,000	TBD – Regs pending	Codifies regulator's view that medically-necessary FP is a "basic healthcare service"
NJ	2020	S2133	FP coverage	All group plans 50+; state & school employees	1,179,000	No storage	Standard FP services if necessary medical treatment may cause iatrogenic infertility
CO	2020	HB20-1158	Infertility diagnosis and treatment, incl. IVF + FP	All individual and group health plans	1,196,000	3 cycles of IVF; ACA clause; religious exemption	IF dx & treatment; FP for "condition" or medical treatment creating a risk of infertility
UT	2021	HB 192	Directed Medicaid to create waiver for FP coverage	Medicaid	405,590	Cancer only	Standard FP services when needed cancer treatment causes substantial risk of infertility

Rationales for Coverage

1. Fertility Preservation is *Medically Necessary*
2. Treatments are *Standard of Care*
3. Promotes Better Medical Outcomes
4. Low Cost & Potential Cost Offsets
5. Ethical Bases for Coverage

1. Fertility Preservation is *Medically Necessary*

"In the United States, the concept of "medical necessity" continues to serve as the primary gatekeeper for the utilization of health care services. [It is used] to distinguish not only necessary from unnecessary care but also medical from cosmetic, experimental, elective . . .[to] ensur[e] that patients receive treatment that is appropriate and medically indicated while also controlling costs. At the same time, the concept's meaning remains elusive."

- Daniel Skinner, *Medical Necessity, 2019*

"Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) **in accordance with generally accepted standards** of medical practice; (b) **clinically appropriate** in terms of type, frequency, extent, site, and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider."

Examples:

Reference ID	Type	Determination
MN17-26920	Medical Necessity	Overturned Decision of Health Plan
Determination Year	**Severity**	**Days to Review/Adopt**
2017	Expedited	43 / 86
Age Range/Gender	**Diagnosis Category/Subcategory**	**Treatment Category/Subcategory**
21-30 / Female	Cancer / Leukemia	Ob-Gyn Proc / Other

Findings

Nature of Statutory Criteria/Case Summary: An enrollee has requested reimbursement for fertility preservation (ovarian stimulation, oocyte retrieval, oocyte fertilization, and storage of oocytes and/or embryos) who has been diagnosed with acute myeloid leukemia. Findings: The physician reviewer found that egg retrieval and freezing (cryopreservation) is now a recognized option for women who have cancer and who are undergoing treatment that can render them infertile in the future by being toxic to their ovaries/eggs. This option allows these patients to have children in the future. Technically, they are not infertile when undergoing the procedure, as the goal is to protect their gametes from the effect of the chemotherapy. This procedure is a treatment that is appropriate to discuss and offer to such patients. As noted by researchers, "prior to initiating potentially gonadotoxic therapy, physicians should discuss the risk of treatment-induced infertility and possible interventions to preserve fertility. Whenever possible, all patients with newly diagnosed cancer should meet with a reproductive endocrine and infertility specialist if fertility is a concern, preferably before treatment." This treatment is supported by the American Society of Reproductive Medicine. For patients such as this, when chemotherapy is anticipated to damage or destroy the eggs, such a treatment is medically necessary. The American College of Obstetricians and Gynecologists also supports this treatment, noting "oocyte cryopreservation, with appropriate counseling, is recommended for patients facing infertility due to chemotherapy or other gonadotoxic therapies." Other researchers noted that discussion of fertility preservation and appropriate referral for treatment of reproductive age (and younger) cancer patients should be a routine part of cancer care, noting that "sperm and embryo cryopreservation and oocyte cryopreservation are considered standard practice." Final Result: The reviewer determined that the services at issue were medically necessary for treatment of the patient's medical condition. Therefore, the Health Plan's denial should be overturned. Credentials/Qualifications: The reviewer is board certified in obstetrics and gynecology and is actively practicing. The reviewer is an expert in the treatment of the enrollee's medical condition and knowledgeable about the proposed treatment through recent or current actual clinical experience treating those with the same or a similar medical condition.

"The reviewer determined that the services at issue were <u>medically necessary</u> for treatment of the patient's medical condition. Therefore, the Health Plan's denial should be <u>overturned</u>."

asrm
American Society for Reproductive Medicine

Patient Management and Clinical Recommendations During the Coronavirus (COVID-19) Pandemic As of March 17, 2020

ASRM recommends adherence to the following:

- Suspend initiation of new treatment cycles, including ovulation induction, intrauterine insemination (IUIs), in vitro fertilization (IVF), and non-urgent gamete cryopreservation.
- Continue care in cases that are urgent. For the purposes of this document, "urgent" refers to all treatment that is time-sensitive, such as impending gonadotoxic therapy or extirpative reproductive surgery.
- While age and diminished ovarian reserve are time-sensitive, at present these should not be included in the definition of urgent care.

2. Treatment is the *standard of care*

ASCO
American Society of Clinical Oncology

AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE

NCCN National Comprehensive Cancer Network®

ACOG
THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

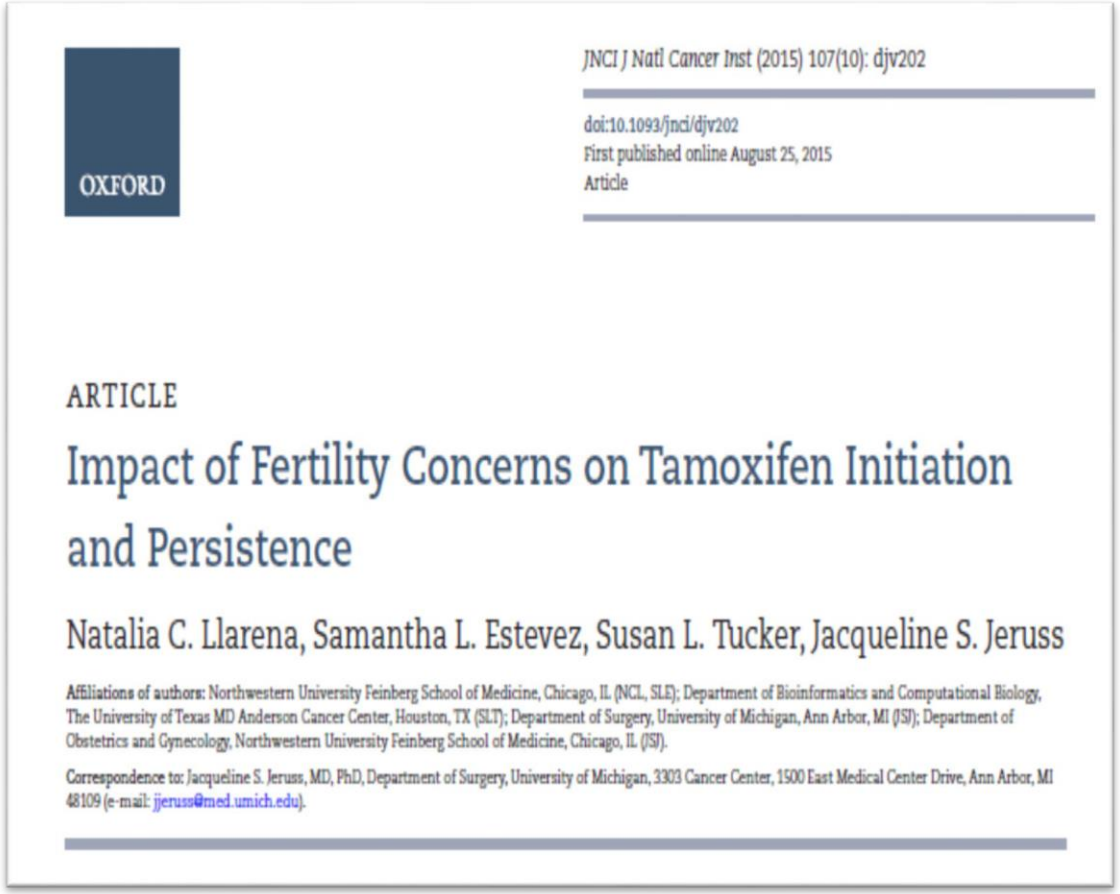
American Academy of Pediatrics

AMA

3. Promotes Better Medical Outcomes

Patient-Provider Discussions	Improved Survivorship	Medical Outcomes
• Sub-par levels of fertility discussions persist • “Wallet biopsy”	• Reduced depression, distress & regret • Report higher Quality of Life	• Some patients don’t follow treatment recommendations due to worries about fertility • Better medical decision-making

- Fertility concerns negatively affected tamoxifen initiation & adherence
- In premenopausal women:
  - 1/2 had concerns
  - 1/3 influenced treatment choices
- Authors recommended FP as way of addressing



OXFORD

JNCI J Natl Cancer Inst (2015) 107(10): djv202

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Article

ARTICLE

Impact of Fertility Concerns on Tamoxifen Initiation and Persistence

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4. Low Relative Costs

Provider Cost (Low)

- Pennies!
- 2017 CHBRP report: ($.01 - $.06 PMPM)
- 2021 MA: ($.04)
- FP costs are miniscule % of total cancer care cost

Patient Cost (High)

- Extremely expensive for an individual patient, esp. females
- Urgency exacerbates costs
- Patients facing additional costs of cancer care

Cost Offsets

- Reduced distress
- High costs incurred if less effective treatment leads to more disease
- Value of future lives/parenthood?

5. Ethics Arguments

- *"Therefore, females are facing costs for preserving fertility that are more than 28–35 times that faced by males."*
- *"[CA Bill] is expected to decrease the gender disparity by reducing females' financial burden of fertility preservation services."*

1. Origin of the harm (iatrogenic) → Does this create a duty to remedy?
2. Quality of the harm → Damage is irreversible
3. Status quo (non-coverage) → Disparate impact
   - Women
   - Lower socio-economic population

- 4. Value of what is at stake → Genetic parenthood
  - Impact beyond the physical
  - Affects patient, but also spouse, extended family
  - Family building as a human right
- 5. LOOKING AHEAD: Equity argument: what about access for other diseases? Spontaneous POI? Natural aging?

Tom W.,
Hodgkin’s lymphoma, diagnosed at age 26
Froze sperm, no coverage

•When I was 26 years-old I was diagnosed with stage IV Hodgkin’s lymphoma. Besides being blindsided by a cancer diagnosis, I was also confronted with a side effect I hadn’t ever thought I’d need to worry about: infertility.

•My medical oncologist informed me that I had a 90%+ chance of losing my fertility due to treatment. I would need to bank my sperm if I wanted to have a family later in life.

•On my own I was able to locate a fertility clinic. I was informed I’d need to pay out-of-pocket, which was another shock to absorb. Even in 2006, my upfront cost was $750 for the collection and first year of storage.

•As the doctors predicted, my fertility never returned. I had four analyses performed, all with the same, certain results: infertile. Each of these tests weren’t covered by insurance, so were also paid out of pocket. Additionally, I continue to pay storage for my banked sperm, which costs more than $300 yearly.

- BABY WHITESIDE WAS BORN IN JUNE!

Thank you!

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