

COVERAGE FOR MEDICALLY INDICATED FERTILITY PRESERVATION

I. BACKGROUND

The Issue: Cancer treatments can cause infertility or sterility.

In the United States, approximately 160,000 individuals between ages 0-45 are diagnosed with cancer each year.ⁱ The therapies needed to treat the cancer can cause infertility. Patients with other conditions requiring similar therapies (e.g., sickle cell anemia, lupus, and thalassemia, etc.) are also at risk.ⁱⁱ Because this infertility arises as a side effect of a medical treatment, it is known as *iatrogenic* infertility.

Chemotherapy, radiation, and surgery, while used to kill cancer cells, can cause collateral damage to other healthy cells, including reproductive cells known as gametes (eggs and sperm). These treatments can also negatively impact reproductive organs and endocrine functioning. Because it is caused by the treatments rather than the cancer itself, iatrogenic infertility is a risk for patients with virtually any type of cancer.

The extent of the reproductive damage can range from a transient cessation in menstrual cycling or sperm production to permanent, irreversible sterility. An individual patient's outcome is difficult to predict, however, because several factors influence the result. These include the type and dose of chemotherapy received, and the location and amount of radiation, but also individual factors such as a patient's age and their underlying fertility, which often is not known. Complicating matters is the possibility of shifts in planned treatment that can occur depending on patient response to treatment.

Due to advances in oncologic care, young cancer patients face good odds; more than 80% will survive.ⁱⁱⁱ This positive trend has led to a shift in focus from cancer as a universally fatal disease to one that is often curable. As a result, more holistic approaches to cancer treatment that encompass both the long-term physical effects of treatment as well as the patient's quality of life have emerged.

Research has shown that, among young adult cancer patients, future fertility ranks high among their concerns. Patients with unresolved infertility from cancer treatment have higher levels of depression and anxiety and report decreased quality of life;^{iv,v} and some patients even opt for less efficacious cancer treatment due to their interest in having biological children.^{vi}

The Solution: Fertility preservation is possible for at-risk patients.

There are now medical interventions that can mitigate the reproductive damage caused by cancer treatments. The most effective way to protect a patient's chance for biological parenthood is to protect their gametes by removing them from the body and freezing and storing them for future use. This process is called fertility preservation.^{vii}

In addition to advances in cancer treatment, the last few decades have seen significant progress in reproductive medicine. Infertility treatments like in vitro fertilization (IVF) were developed more than 40 years ago. While these treatments were intended to assist those unable to conceive on their own, they have given rise to newer techniques like egg and tissue freezing that make fertility preservation a viable option for cancer patients.

The Options: Effective clinical procedures for fertility preservation exist.

For men, sperm banking is the optimal choice for fertility preservation. It is a long-standing, effective, non-invasive, and relatively inexpensive option for post-pubertal men. For those with low sperm counts or those who are unable to produce a specimen, advanced techniques for sperm collection may still allow them to store sperm.

For women, egg (oocyte) or embryo freezing are the preferred technique. The process involves a series of shots to stimulate and mature multiple eggs, ultrasounds and blood work to monitor the maturation process, and collection of the eggs. The eggs can then either be frozen and stored or fertilized with sperm (from a partner or donor) to create embryos, which are then frozen. This process takes about two weeks. For those unable to undergo an ovarian stimulation cycle, either due to acute illness and/or imminency of cancer treatment, ovarian tissue freezing can be considered. This involves the surgical removal of an ovary (or part of an ovary), the preparation of the ovarian tissue, and then the freezing and storage of that tissue.

For pre-pubertal patients, gonadal tissue freezing (ovarian or testicular tissue) is the only option; however, for boys, this procedure is still considered experimental.

The Standard of Care: Leading medical societies recommend fertility preservation for at-risk patients.

Fertility preservation is an option supported by long-standing clinical guidelines and policies from all of the relevant medical societies, including (but not limited to) the American Society of Clinical Oncology (ASCO), the American Society for Reproductive Medicine (ASRM), and the American Medical Association (AMA).^{viii} While practice guidelines are not prescriptive, they do reflect consensus recommendations about what is appropriate clinical care in a given circumstance. Inherent in these guidelines is the understanding that the administration of lifesaving but potentially sterilizing treatments creates an ethical obligation to ameliorate that excess harm. The guidelines establish the framework of that duty: to notify patients of the risks of reproductive damage, to present the options to address it, and to refer them for the appropriate procedures.

The Challenge: Patient access to fertility preservation services

Even though fertility preservation options are now viewed as an integral part of cancer care for age-eligible patients, barriers to access remain. Cost is generally cited as the most significant obstacle to fertility preservation.^{ix} Costs can range from several hundred dollars for men to sperm bank, to approximately \$15,000 for women for egg banking.^x Without insurance coverage, for many patients these treatments are simply unaffordable.



The out-of-pocket costs are exacerbated by the short window of opportunity that cancer patients have before starting potentially sterilizing cancer treatment. Because cancer is not foreseeable, diagnosis usually occurs suddenly, and, because it is often life-threatening, treatment typically begins quickly. This leaves little time for patients to secure thousands of dollars that may be needed for fertility treatments. These young patients may not have substantial savings, and they are facing the high costs of cancer itself – potential loss of employment and other uncovered medical costs that can contribute to “financial toxicity” and crippling debt for many.

Further, oncology providers are often reluctant to propose fertility preservation options with patients whom they perceive cannot afford them. Health insurance coverage would legitimize these services and facilitate both discussion and access.

The Answer: Insurance coverage to improve access to services.

Insurance coverage gives at-risk patients the means to protect their ability to have biological children in the future. There are several rationales supporting this coverage:

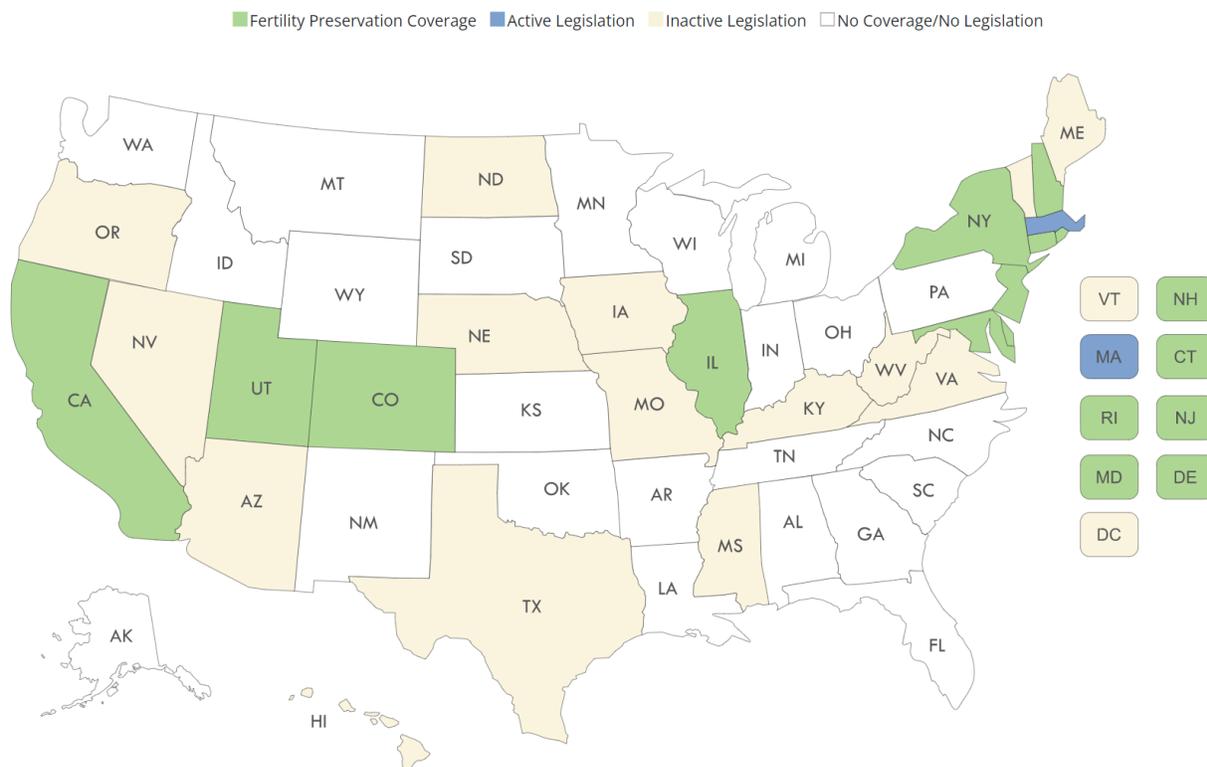
- Medical Necessity. Fertility preservation for iatrogenic infertility is not “elective” or “experimental,” but rather a needed intervention to prevent potential sterility. Patients cannot rationally defer or forego life-saving treatments to spare their fertility. Notably, many insurers have internal clinical guidelines that acknowledge medical advances and identify egg freezing as “medically necessary” for fertility preservation purposes, yet they have not altered their position on coverage to reflect this.
- Address direct side effect of cancer treatment. Remedies for other side effects of treatment, such as breast reconstruction, chemo-induced anemia, wigs, prostheses, etc., typically are covered by insurance.
- Insignificant financial impact on insurers and consumers. While the costs faced by an individual patient are high, the cost of implementing coverage across a population of insureds is very low since this affects a limited number of policyholders each year. Independent analyses in states where coverage has been considered have shown projected costs to be exceedingly low – typically pennies per member per month (PMPM).^{xi}
- Prevent additional harms and associated costs. Infertility causes distress, depression, and anxiety; these have financial and medical consequences and result in overall lower quality of life for survivors. In addition, some patients make sub-optimal treatment decisions (e.g., stopping tamoxifen or choosing less gonadotoxic treatment) to minimize reproductive impact. These decisions may adversely affect both medical outcomes and treatment costs.
- Access disparities. The lack of insurance coverage disproportionately affects women, who face significantly higher preservation costs than men, and those of lower socioeconomic backgrounds who cannot pay out-of-pocket for these procedures.
- Fundamental life activity. Loss of fertility is not merely a medical complication; it permanently affects reproduction and parenthood – fundamental life functions worthy of the highest levels of protection.



II. EXISTING COVERAGE

State Legislation

Since 2017, eleven states have enacted laws to require health insurers to cover medically necessary fertility preservation services for cancer patients and others at risk of iatrogenic infertility. Because of this effort, more than 31 million Americans now have this health insurance benefit as a part of their state-based plans (based on data from the National Association of Insurance Commissioners (NAIC) and the California Health Benefits Review Program (CHBRP)).



While the intent of these new state laws is the same, each one has important distinctions relating to coverage inclusions, limitations, and exemptions. Some cover a wide range of insurers while others are limited to specific types of plans; some cover anyone at risk for iatrogenic infertility while one (Utah) is limited to cancer patients. Some of the details are listed here:

State	Year	Bill #	Groups Affected	Lives Covered	Description	Limits
Connecticut	2017	HB7124	Individual and group plans	651,134	Changed statutory definition of “infertility” to “medically necessary”	Cycle limits; religious exemption
Rhode Island	2017	S 0821A & H6170A	Individual and group plans	241,582	Standard FP services if necessary medical treatment may cause iatrogenic infertility	Age limits (25-40); unclear whether applies to FP
Maryland	2018	SB271 & HB908	Large groups only	926,446	Standard FP services if necessary medical treatment may cause iatrogenic infertility	No embryos; religious exemption
Delaware	2018	SB139	Commercial plans & state employees; no Medicaid	120,438	Coverage for specific treatments, inc. IVF & sperm, egg/embryo cryo. No exper. treatments	6 cycles; religious exemption; retrieve by 45
Illinois	2018	HB2617	Broad coverage including state employees and Medicaid	5,303,325	Standard FP services if necessary medical treatment may cause iatrogenic infertility	ACA mandate clause re: exceeding EHB
New York	2019	S719 & A2817	Individual, small & large groups only	4,700,000	Coverage added through State Budget process. IVF + FP coverage	3 cycles of IVF; FP TBD
New Hampshire	2019	SB 279	All “health carriers”	208,515	FP for eggs, embryos, sperm, and “material.” Storage through policy term	Limits can’t be “arbitrary”
California	2019	SB 600	All managed care plans; HMOs, some PPOs	16,900,000	Codifies regulator’s view that medically necessary FP is a “basic healthcare service”	TBD – Regs pending
New Jersey	2020	S2133	All group plans 50+; state & school employees	1,179,000	Standard FP services if necessary medical treatment may cause iatrogenic infertility	No storage
Colorado	2020	HB20-1158	Large groups only	1,196,000	FP for “condition” or medical treatment creating a risk of infertility	3 cycles of IVF; ACA clause; religious exemption
Utah	2021	HB 192	Medicaid	405,590	Standard FP services when needed cancer treatment causes substantial risk of infertility	Cancer only

Federal Coverage

While we have seen significant fertility preservation coverage gains at the state level during the past five years, there has also been some limited progress at the federal level during this time period. Whereas state coverage has been achieved through legislation, these federal coverage gains have been realized through the regulatory process.

Department of Defense & TRICARE

TRICARE serves as the health insurance program for active-duty service members and their families, and for National Guard/Reserve members and their families. While the TRICARE website states that the program does not cover fertility preservation for its 9.5 million members, the TRICARE's Supplemental Health Care Program (SHCP) provides coverage through civilian health care for active-duty service members in some narrow circumstances. SHCP is funded separately by the Department of Defense (DoD) and follows different rules than TRICARE.

According to Chapter 17, Section 3, 2.4.2.11.1 of the TRICARE Operations Manual for the Supplemental Health Care Program, TRICARE covers fertility preservation for service members who are classified with a Category II or III illness as a result of their cancer and scheduled to undergo a gonadotoxic treatment for their cancer. Female service members must be age 49 years or younger to freeze their eggs and male service members must be age 61 years or younger to bank their sperm. Service members must also be on active duty for a period greater than 30 days and scheduled to remain on active duty for the duration of the retrieval and freezing process. This coverage took effect on April 21, 2017.

Veterans Health Administration

On June 20, 2017, the Veterans Health Administration (VHA) issued [Directive 1332](#), which created a fertility preservation benefit for the 9 million military veterans enrolled in the Department of Veterans Affairs (VA) healthcare system.^{xii}

While the directive does provide for medically necessary fertility preservation for veterans, the coverage is somewhat limited. The benefit applies to veterans only, not spouses or dependents, and only allows for the freezing of eggs and sperm; currently, the freezing of embryos or ovarian tissue is not permitted. This directive is scheduled for recertification by June 30, 2022, and conversations with VHA staff have indicated that the recertification process is already underway.

Federal Employees Health Benefits (FEHB)

The FEHB program is the largest employer-sponsored group health insurance program in the world, covering almost 9 million people including federal employees and their family members as well as some former spouses and former employees.

On February 17, 2021, the U.S. Office of Personnel Management (OPM) issued a [FEHB Program Carrier Letter](#) to all FEHB health insurance carriers, indicating that they would need to add a fertility preservation benefit to all policies offered to FEHB insureds. According to OPM,



coverage will include standard fertility procedures for men and women as recognized by the American Society for Reproductive Medicine (ASRM) and/or American Society of Clinical Oncology (ASCO), for anyone facing the possibility of iatrogenic infertility from a necessary medical intervention. The benefit will not include the costs of storage. This required coverage will take effect January 1, 2022.

III. OPPORTUNITIES FOR EXTENDING COVERAGE

Adding Federal Coverage

While the trend to enact fertility preservation coverage by several states and some federal programs is certainly laudable, a majority of Americans are left out of this coverage. This includes those who have federally regulated health insurance – either through self-insured companies subject to ERISA or public programs including Medicaid and Medicare.

Employee Retirement Income Security Act

Most private sector health plans are covered under the Employee Retirement Income Security Act (ERISA) which is regulated by the Department of Labor (DOL). According to the American Association of Health Plans (AAHP), 180 million Americans receive their health coverage through employer-based health plans.

The breast cancer advocacy community's successful effort to secure widespread coverage under ERISA for breast reconstruction after a mastectomy through the [Women's Health and Cancer Rights Act of 1998 \(WHCRA\)](#) might offer some lessons for federal fertility preservation. The path to a federal law requiring insurance companies cover breast reconstruction costs after a mastectomy was viable only after sixteen states had already passed their own reconstruction coverage mandates. This "patchwork" of coverage became viewed as inequitable and provided strong foundation for federal coverage.

Requiring employer-funded private health plans to cover fertility preservation would have a major impact on young cancer patients across the country, since so many Americans receive their health insurance coverage through ERISA plans.

Medicaid

Medicaid is the nation's public health insurance program for low-income Americans; it is a federal-state partnership program first established in 1965. According to estimates from the Center for Medicare and Medicaid Services (CMS), over 75 million, or one in five, individuals were enrolled in Medicaid last year. Significantly, over 50% of pediatric cancer patients are on Medicaid. Eligibility for Medicaid is based on income and states have a significant role in determining which specific health services are covered through its state plan.

Illinois and Utah are the only states that have enacted laws requiring fertility preservation coverage for Medicaid patients. The Illinois bill went into effect on January 1, 2019, but, according to providers in Illinois, implementation has been a challenge because most fertility



providers are not enrolled in the state Medicaid system and fertility drugs needed for egg and embryo preservation processes are not approved by Medicaid. The Utah bill was signed into law on March 16, 2021, and the state is in the process of securing a Medicaid waiver from CMS. The Utah law only applies to cancer patients. It will go into effect once the waiver is approved or on January 1, 2023, whichever is later. In addition, as of March 1, 2021, the Washington State Health Care Authority (HCA) has provided fertility preservation coverage to its Medicaid beneficiaries under the age of 21 through the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program pursuant to its interpretation that it is a medically necessary oncology service.

IV. ESSENTIAL ASPECTS OF FERTILITY PRESERVATION COVERAGE

A diagnosis of cancer should not foreclose the possibility of future parenthood. In order to protect the option of biological parenthood for all young cancer survivors, broader health insurance coverage for fertility preservation is needed.

Coverage Goal

Every health insurance plan regulated by the federal government that provides hospital, medical, or surgical coverage should include coverage for medically necessary expenses for standard fertility preservation services when a necessary medical treatment may directly or indirectly cause iatrogenic infertility to a covered person.

Key Definitions

- “Iatrogenic Infertility” means an impairment of fertility caused directly or indirectly by surgery, chemotherapy, radiation, or other medical treatment.
- “Standard Fertility Preservation Services” means procedures to preserve fertility that are consistent with established medical practices or professional guidelines published by the American Society of Clinical Oncology or the American Society for Reproductive Medicine.
- “Medical Treatment That May Directly or Indirectly Cause Iatrogenic Infertility” means medical treatment with a potential side effect of impaired fertility as established by the American Society of Clinical Oncology or the American Society of Reproductive Medicine.

Key Principles

All patients have the right to be fully informed about the possible effects of their medical treatment on their reproductive system and their ability to have children in the future. They also deserve to be told of their options for preserving and protecting their ability to have genetic offspring and/or become a parent in the future, and to be referred to a fertility specialist for a thorough consultation.

Fertility preservation options are only true options if patients can access them. Without insurance coverage for medically necessary fertility preservation treatments, many patients



simply cannot afford sperm, egg, embryo, or tissue banking, especially in the midst of urgent, distressing, and often, costly, cancer treatment.

In furtherance of these principles, *ideal* fertility preservation coverage should:

- Apply to all insurance plans regulated by the federal government.
- Include anyone who is at risk for iatrogenic infertility due to needed treatment for any disease or medical condition.
- Not discriminate based on any health conditions such as present or future disability, quality of life, or predicted length of life; or personal characteristics including, age, gender, sexual orientation, gender identity, or marital status.
- Allow the oncologist, reproductive endocrinologist, or other appropriate treating physician to determine the medical necessity of fertility procedures for patient.
- Cover expenses for standard fertility preservation services as defined by the American Society for Reproductive Medicine and recognized by the American Society of Clinical Oncology.
- Include expenses for evaluations, laboratory assessments, medications and treatments associated with cryopreservation procedures.
- Cover costs for storage of reproductive materials until the patient is able to use them or no longer needs them. At a minimum, storage should be for at least one year and/or until the patient completes active cancer treatment. For pediatric patients, storage of reproductive tissues until age 18, at a minimum, should be included.
- Allow medical personnel to determine the number of procedures and/or cycles necessary to optimize an individual's likelihood of success.
- Not include religious exemptions which would unduly burden patient access.
- Not permit insurer-driven criteria concerning selection of clinics, physicians, or facilities.



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- ^{viii} Oktay, K., Harvey, B.E., Partridge, A. et al. Fertility Preservation in Patients With Cancer: ASCO Clinical Practice Guideline Update. *J Clin Oncology*. 2018. doi:10.1200/JCO.2018.78.1914; American Society of Reproductive Medicine. Fertility preservation and reproduction in patients facing gonadotoxic therapies: a committee opinion. *Fertil Steril*. 2013;100(5):1224-1231; Association AM. Oncofertility and Fertility Preservation Treatment. <http://www.ama-assn.org/ama/pub/news/news/2013/2013-06-17-new-ama-policies-annual-meeting.page>. Published 2013.
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- ^x FertilityIQ. The Costs of Egg Freezing. <https://www.fertilityiq.com/egg-freezing/the-costs-of-egg-freezing>. Published 2017. Accessed July 14, 2018
- ^{xi} California’s estimate: \$.01 PMPM; Massachusetts’s estimate: \$.04 PMPM. See California Health Benefits Review Program (CHBRP) Analysis of Assembly Bill 912: Health Care Coverage: Fertility Preservation, A Report to the 2013–2014 California Legislature, April 25, 2013; [MBR-Preserving-Fertility.pdf \(chiamass.gov\)](#) Accessed October 12, 2021.
- ^{xii} Directive 1332 states: *Gamete cryopreservation (sperm or oocytes) is allowable when it is determined by appropriate health care professionals that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice (e.g., for oncofertility with cryopreservation of gametes to preserve fertility prior to cancer treatment which would ordinarily render the patient permanently sterile).*

