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The Landscape of Coverage for Fertility Preservation in Male Pediatric Patients

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Abstract

Introduction: The Patient Protection and Affordable Care Act(ACA) significantly increased the number of Americans with health insurance and has greatly improved access to health care services. However, states retain considerable jurisdiction over what benefits must be offered. The lack of a federal mandate for fertility preservation coverage results in a patchwork of benefits dependent on state statutes and regulation. Pediatric, adolescent and unmarried patients diagnosed with cancer or autoimmune diseases that impact fertility are often carved out of such coverage.

Methods: This review analyzed legislative and regulatory efforts in 10 states to determine the breadth of fertility preservation coverage in private, employer-based insurance plans and Medicaid, with particular interest in coverage for pediatric and adolescent patients.

Results: Fifteen states require coverage of fertility preservation in private insurance plans; five states only extend this benefit to females. The statutes differ in terms of whom the coverage extends to based on marriage status, diagnosis, length of fertility problems, and the monetary limit of the benefit. Fertility preservation is not a mandatory benefit under federal Medicaid regulation, however states can opt to include it in their state Medicaid plan; no state currently covers fertility preservation as an optional benefit.

Conclusions: Coverage of fertility preservation is extremely limited both in scope of benefits and the number of states that require such a benefit. State governments can expand access to a fertility preservation benefit by removing spousal and expanding diagnostic criteria and by including the benefit in Medicaid plans.

Keywords

Patient Protection and Affordable Care Act; pediatric; fertility preservation; Medicaid; fertility mandate

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Introduction

Since becoming law in 2010, the ACA has significantly impacted health insurance in the United States. The law expands access to coverage, through private insurance plans and public programs and sets standards for a number of benefits.

While the ACA broadened health insurance coverage, it did not abrogate the states' regulatory role. Under the Tenth Amendment, one of the powers reserved to the states is police power, which allows states to protect the general public welfare.[1] This doctrine was a cornerstone of state regulation of private insurance plans, which helps consumers access medical services that might be otherwise unattainable and spread risk of health care costs among many parties.[2] In addition to this imperative to protect the general welfare, state policies that regulate health insurance can protect consumers from fraud and, before the ACA, ensured individuals could obtain contractually-obligated benefits.

Since the creation of Medicare and Medicaid in 1965, there has been a stronger federal role in the provision of health insurance.[3] The federal government administers a number of health programs besides Medicare and Medicaid, including the Federal Employees Health Benefit Program, the Indian Health Service, TRICARE and the State Children's Health Insurance Program. In 2015, the U.S. Census Bureau reported that among insured populations (90.9% of individuals), 37.1% and 67.2% had public and private coverage, respectively.[4] The most common form of insurance is employer-based, which covers 55.7% of the population. Medicaid, a joint federal and state insurance program, covers 19.6% of the population.[5]

Employer-sponsored coverage and Medicaid provide insurance for significant populations and are jointly regulated by the federal government and states. Before the ACA, the federal government had a more principal role in the regulation and administration of Medicaid than it did employer-based coverage; however, employer-based plans must now adhere to ACA provisions as regulated federally, notably essential health benefit coverage and an end to discriminatory practices in the sale of insurance (i.e. pre-existing conditions).[6,7] Under Medicaid, the federal government requires coverage of "mandatory benefits" and states have latitude to offer coverage for additional "optional benefits." This stronger federal regulation of benefits under the ACA, particularly for employer-based plans, has implications for coverage of fertility preservation. This paper assesses current coverage of fertility preservation, its unique impact on childhood and adolescent cancer patients and provides recommendations for state and federal action.

Another facet of fertility preservation is the understanding that chemotherapy is used to treat non-cancerous conditions. The use of gonadotoxic agents to treat, for example, autoimmune diseases, is increasing. While this review highlights male oncofertility, this information has implications for any male patient facing infertility risks secondary to management of a medical condition.

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Materials and Methods

This review is focused current state regulation of male fertility benefits to determine areas for growth in coverage. We identified laws or regulations concerning insurance coverage of fertility preservation using the American Society for Reproductive Medicine (ASRM) compilation of “State Infertility Insurance Laws” and the National Conference of State Legislatures website. These sources guided us to fifteen states with laws or statutes concerning infertility and insurance (Table 1).[8,9] The full text of each statute and/or law was acquired through a search of legislative/regulatory databases for each state. Insurance plans regulated by states included employer-based plans offered in each state and optional benefits offered under Medicaid. Children receive coverage under employer-based plans as dependents; they can receive Medicaid benefits independent of their parent’s insurance so long as they meet requirements for state Medicaid coverage. We examined Medicaid coverage of fertility benefits for the previously mentioned states though the Center for Medicare and Medicaid (CMS) “Medicaid State Plan Amendments” database and each state’s Medicaid agency website.[10]

Results

Pediatric Cancer Survivors and Fertility

Cure rates for cancer in children, adolescents and young adults continue to increase with advances in care. As more oncology patients become long-term survivors, the consequences of their treatment on their quality-of-life have become an important focus of research. It is estimated that 15,780 children and adolescents (<20 years of age) were diagnosed with cancer in 2014; 1,960 are estimated to die of cancer.[11] There were approximately 380,000 survivors of childhood and adolescent cancer in the U.S. in 2010.[12] Between 2004 and 2010, >80% of children and adolescents diagnosed with cancer before age 20 survived over five years.[13] In reaction to improvements in survival for children and adolescents with cancer, there has been a shift among clinicians from a care plan solely focused on survival to considerations of quality-of-life as childhood survivors grow older.[14,15] One noteworthy consideration is efforts to prevent or mitigate therapeutic side effects.

A common and devastating side effect of cancer treatment is infertility. Many chemotherapy and radiation-containing regimens for cancer or before bone marrow transplantation can cause sterility in children and young adults. To address this complex issue, the field of oncofertility has emerged. Oncofertility is the intersection of oncology and reproductive endocrinology, aimed at maximizing the reproductive potential of cancer patients and survivors.[16] A primary goal of fertility preservation is to maintain the capacity for patients to become genetic parents, typically by performing a fertility preservation procedure before starting gonadotoxic treatment. The American Society for Clinical Oncology (ASCO) and the ASRM recommend that providers address the possibility of infertility with males of reproductive age, including boys, and be prepared to refer to appropriate reproductive specialists.[17,18] Fertility preservation is an opportunity for patients to alleviate the sequelae of their treatment and is an opportunity for physicians to abide by their oath to “do no harm.”

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Overview of Fertility Preservation

Fertility preservation refers to cryopreservation of gonadal tissue prior or gametes to the onset of gonadotoxic therapy that has potential to render an individual infertile. As technology has developed, new methods of fertility preservation have become standards of care for subsets of patients. For post-pubescent adolescent and adult patients, interventions might include sperm, embryo or mature oocyte (egg) cryopreservation based on physician recommendation and patient-specific considerations.[19] No fertility preservation procedure is considered standard of care for pre-pubescent male cancer patients. Investigational fertility preservation procedures are currently being studied for boys at a number of institutions under Institutional Review Board(IRB)-approved protocols, including testicular tissue cryopreservation.[20]

Most sexually mature male patients can produce ejaculated specimens sufficient for cryopreservation. Approximately 12% of men, however, are azoospermic or have severe oligospermia or immotile sperm and require alternative sperm retrieval approaches.[21] Penile Vibratory Stimulation (PVS), electroejaculation(EEJ), and epididymal (PESA) or testicular (TESA) sperm retrieval, and microTESE are options if an ejaculated specimen is not possible or adequate. PVS is typically utilized by men with neurogenic anejaculation to help facilitate an ejaculated specimen, but has a role in fertility preservation for male patients who have difficulty producing an ejaculate. The vibrator can be used privately in the office to aid masturbation and facilitate an ejaculate and avoid more invasive sperm retrieval procedures. EEJ is often employed in male patients who are unable to produce an ejaculated specimen because of personal objection to masturbation, sexual dysfunction, or inability to ejaculate because of pain or anxiety. This procedure is performed under anesthesia, and patients should have both the ejaculate which is produced as well as a post-EEJ bladder wash analyzed for the presence of sperm. Aspiration of the epididymis or testis is typically only necessary in cases where EEJ is unavailable or for obstructive azoospermia. Aspiration can be performed in the office under local anesthesia, but sperm yields are often lower than what an ejaculate or EEJ would provide, making this a sub-optimal option. MicroTESE sperm retrieval is only necessary in a select patient population. Males who are candidates for this intensive sperm retrieval procedure have non-obstructive azoospermia (NOA) from testicular failure. There is no role for aspiration or random biopsy for sperm retrieval in men with known NOA because of the likelihood of failure.

Success of these sperm retrieval techniques varies widely based on the etiology of the inadequate ejaculated specimen. Unsurprisingly, young age and known testicular dysfunction secondary to testicular cancer are often the most challenging cases for fertility preservation. Even under those most severe circumstances, however, up to one third of young men will have a successful operative sperm retrieval that does not delay the onset of their chemotherapy.[22] Fertility preservation is clearly a successful endeavor, and patients can significantly benefit from the opportunity to prematurely alleviate the potential long-term damage of their cancer treatment.

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Cost Estimates

Fertility preservation is expensive because of the cumulative years of storage often required, highly specialized isolation and manipulation of gonadal tissue or embryos that is needed, and the requirement for IVF for patients that remain infertile after treatment. Reprotech, one commercial entity which focuses on long-term storage of reproductive tissue, estimates oocyte freezing costs of $7,000–$10,000, including storage at $275/year and $5,000 for lab and clinical services at thaw.[23] Embryo freezing is estimated to cost $10,000–$13,000. Cryopreservation of ejaculated specimens costs approximately $250 to process each sample and $275/ year for storage. The cost of utilizing aspirated testicular or epididymal tissue for cryopreservation is approximately $2,500 for aspiration, $1100 for sperm identification, and $300 to $500/year for storage. The costs of EEJ and microTESE are even greater as they necessitate the additional costs of general anesthesia and operating room facility fees. These estimates only encapsulate a portion of the financial burden of fertility preservation. An IVF cycle costs $12,000–$15,000.[24] Furthermore, the female partner of male cancer survivors will need to undergo extensive laboratory testing and radiographic imaging prior to IVF, and will assume the risks of ovarian stimulation and egg retrieval to facilitate IVF with the cryopreserved sperm. These IVF costs can often be the reason that utilization of cryopreserved sperm is less than 10%.[25]

Insurance Coverage of Fertility Preservation

The existing literature on insurance coverage of fertility preservation is extremely limited; current publications only discuss the implications of insurance coverage for adults seeking fertility preservation.[26,27,28] The literature also notes an absence of state legislation or administrative statutes specifically requiring coverage of fertility preservation for cancer patients. There are two distinct types of coverage this section will discuss: employer-sponsored insurance and Medicaid coverage.

Forty-seven percent of children receive insurance coverage through the employer-sponsored plan of a parent and/or guardian.[29] Pediatric health benefits are a distinct category under the “Essential Health Benefits” (EHB) statute of the ACA and is exceptionally broad in terms of what benefits must be covered. But similarly to all of the other essential benefits regulated by the ACA, states retain the authority to require additional benefits not provided for in the EHB statute, including coverage of infertility diagnosis and treatment for adults and/or children.

Of the 15 states that regulate private insurance coverage of a fertility benefit, four states only require the coverage of IVF for female patients (Arkansas, Hawaii, Maryland and Texas). As this procedure is not directly related to male infertility diagnosis and treatment, these four states have been excluded from this analysis. In addition, fertility benefit regulations that refer to coverage of a fertility procedure for a “spouse,” “husband,” or “wife” neglects the population of children who could benefit from a more broadly written regulation. The inclusion of these terms in the regulation narrowly restricts who can seek this benefit; it excludes not only children, but any unmarried patient seeking an infertility diagnosis and/or treatment. All of the states with fertility benefit regulation prohibit discrimination on the basis of gender. This allows both genders to receive coverage for the *diagnosis* of infertility;

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however, all of the *treatment* options that are included in the regulations are female-specific procedures. To ensure equity of coverage and adhere to the regulations' nondiscrimination clause, states that cover fertility treatments for females should cover an equal range of treatments for males. One notable exception to this lack of equity in treatment coverage is Massachusetts.

Massachusetts is the only state to include cryopreservation options in its fertility benefit regulation. While it does not require insurers to cover treatment, it grants them permission to cover experimental procedures, surrogacy, reversal of sterilization or egg cryopreservation.[30] Sperm cryopreservation is not specifically mentioned in the statute; however, the regulation could be amended to include its coverage. The Massachusetts regulation is a strong starting point for other states considering this issue. Of the fifteen states with a current regulation regarding fertility benefits, it is the broadest in terms of treatment options. Testicular tissue cryopreservation for boys could also be covered at an insurers' discretion as an experimental procedure.

In addition to those receiving insurance through an employer, Medicaid is a significant source of health insurance in the U.S. This federal-state partnership provides health insurance to one in three children, including half of all low-income children in the U.S.[31] States are required to cover a set of benefits deemed mandatory by the federal government and can choose to cover additional benefits. Medicaid-eligible individuals under age 21 are entitled to expansive coverage under Early and Periodic Screening, Diagnosis and Treatment (EPSDT), which covers any mandatory or optional benefit necessary to "correct or ameliorate" a child or adolescent's physical or mental health.[32] States are able to limit EPSDT services by covering only "medically necessary" services. While each state can define "medically necessary" for treatment coverage, it is expected that states strongly consider the recommendations of the treating physician.[33] However, while the state must consider the recommendation, it is not obligated to agree with it. For example, under a state's "medically necessary" criteria, a physician could recommend fertility preservation for a patient but the state can disagree and refuse coverage. The federally determined mandatory benefits for Medicaid do not include coverage of fertility diagnosis or treatment, nor do any State Plan Amendments (SPA) that outline state-selected optional benefits for coverage.

Discussion

While insurance coverage of fertility preservation can significantly impact adults of reproductive age, it can also drastically alter the lives of pediatric and adolescent patients facing potential infertility. The most effective strategy for widespread coverage of an infertility benefit would be a federal directive requiring its inclusion in all insurance plans, public and private.

While the financial implications of such a directive are currently unknown, the premise of health insurance is to share risk to lower cost. The ACA has restricted how private insurers can adjust premiums; they can be altered based on age, geographic location, tobacco use, individual vs. family enrollment and plan category.[34] A possible strategy would be for insurers to include an infertility benefit in one or two plan categories (i.e. platinum and

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gold). These plans have higher premiums than lower level plans due to their more extensive benefit coverage. However, it is currently unlikely that the federal government will mandate the inclusion of additional benefits in insurance plans as the current presidential administration and Congress work towards altering or repealing the ACA. The most appropriate place for current movement on this issue is at the state level, which has consistently been a hub of innovation for healthcare coverage.

We have identified two courses of action that can be taken to improve access to infertility diagnosis and treatment services for males of all ages. First, states can statutorily require all insurers that provide private, employer-based coverage to include a gender-neutral infertility diagnosis and treatment benefit in all or some plans. To ensure that pre- and post-pubescent males can benefit from this coverage, states should: (1) require coverage of sperm donation and banking for post-pubescent males; and (2) allow insurers to cover experimental procedures, such as testicular tissue cryopreservation, at their discretion. Second, state Medicaid agencies can include sperm donation and banking as part of the “medically necessary” criteria for a male facing infertility as a result of treatment of a medical condition. Conversely, states can include such a benefit as an optional Medicaid service for adults and children.

Conclusion

There are significant impediments in private and public insurance programs that limit the coverage of fertility preservation for children. Aside from the handful of states that address the issue of fertility preservation in insurance regulation, there is no specific attention paid to children or patients of any age who are facing possible infertility due to a medical diagnosis. At this political juncture, the state level is the most appropriate setting in which to address this issue.

Glossary

ACA	Affordable Care Act
ART	assisted reproductive technology
IVF	in vitro fertilization
EHB	essential health benefits
HHS	Department of Health and Human Services

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Table 1:

Summary of fertility benefit in states with laws related to infertility coverage

State	Covered Treatment	Restriction of Use	Law/Code
California	Diagnosis, diagnostic testing, medication, surgery, gamete intrafallopian transfer	Exempts IVF	Cal. Health & Safety Code §1374.55, Cal. Insurance Code §10119.6
Connecticut	Diagnosis of infertility; treatment of iinfertility including intrauterine insemination, embryo transfer, GIFT, ZIFT, low tubal embryo transfer		Conn. Gen. Stat. §38a-509, §38a-536
Illinois	embryo transfer, artificial insemination, GIFT, ZIFT, intracytoplasmic sperm injection	1 yr. history of infertility or inability to carry pregnancy to term	Ill. Rev. Stat. ch. 215, §5/356m
Louisiana	Diagnosis and treatment of correctable medical condition	Exceptions include coverage of fertility drugs; IVF, ART, tubal ligation removal and vasectomy	La. Rev. Stat. Ann. §22:1036
Massachusetts	Artificial insemination, GIFT, sperm/egg/ inseminated egg retrieval (donor); ICSI, ZIFT; insurers can choose to cover experimental procedures	1-yr. history of infertility	Mass. Gen. Laws Ann. Ch. 175, §47H, ch. 176A, §8, ch. 176B, §4J, ch. 176G, §4; 211 Code of Mass. Reg. 37.00
Montana	Infertility services as part of basic preventative health care services	No definition of infertility or scope of services	Mont. Code. Ann. §33-22-1521, §33-31-102(2)(v)
New Jersey	Diagnosis, medication, surgery, embryo transfer, artificial insemination, GIFT, ZIFT, ICSI	2-yr. history of infertility (under age 35) or 1-yr. history of infertility (over age 35)	N.J. State. Ann §17:48A-7w, §17:48E-35.22, §17B:27-461x
New York	Diagnosis and treatment of infertility	Between 21 and 44 yrs of age, excludes IVF, GIFT, ZIFT, experimental procedures	N.Y. Insurance Law §3216(13), §3221(6), §4303
Ohio	Basic preventative health services including infertility	No definition of services but must be medically necessary; does not cover experimental procedures	Ohio Rev. Code Ann. §1751.01(A)(7)
West Virginia	Medically necessary infertility services	No definition of services	W. Va. Code §33-25A-2

** This table does not include Arkansas, Hawaii, Maryland, Rhode Island, Texas. These four states have a fertility benefit that only requires coverage of female infertility diagnosis or treatment.