MANDATED BENEFIT REVIEW OF
HOUSE BILL 1116 AND SENATE BILL 640
SUBMITTED TO THE 192ND GENERAL COURT:

AN ACT RELATIVE TO PRESERVING FERTILITY

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CHIA.

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1.1 History of the Bill

The Committee on Financial Services referred House Bill (H.B.) 1116 and Senate Bill (S.B.) 640, both entitled "An Act relative to preserving fertility,"[1] to the Center for Health Information and Analysis (CHIA) for review. Massachusetts General Laws (MGL) Chapter 3 §38C requires CHIA to review the medical efficacy of treatments or services included in each mandated benefit bill referred to the agency by a legislative committee, should it become law. CHIA must also estimate each bill's fiscal impact, including changes to premiums and administrative expenses. The language in each bill is the same, and for the remainder of this report, "the bill" will collectively refer to H.B. 1116 and S.B. 640.

This report is not intended to determine whether the bill would constitute a health insurance benefit mandate for purposes of Commonwealth defrayal under the Affordable Care Act (ACA), nor is it intended to assist with Commonwealth defrayal calculations if it is determined to be a health insurance benefit mandate requiring Commonwealth defrayal.

1.2 What Does the Bill Propose?

As submitted in the 192nd General Court of the Commonwealth, to the same extent that benefits are provided for other pregnancy-related procedures, the bill requires coverage for standard fertility preservation services[i] when the enrollee has a diagnosed medical or genetic condition that might directly or indirectly cause[ii] impairment of fertility by affecting reproductive organs[iii,2] or processes. The bill further stipulates that the coverage must include procurement, cryopreservation,[iv] and storage of gametes,[v,3] embryos, or other reproductive tissues. In addition, the benefits "shall not be subject to any greater deductible, coinsurance, copayments, or out-of-pocket limits than any other benefit provided by an insurer."

Upon receiving the bill, CHIA and its consultants submitted an inquiry to the sponsoring legislators and staff to clarify the bill's intent. The sponsors clarified that the bill's intent is to:

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[i] Pursuant to the language in the bill, "standard fertility preservation services" means procedures or treatment to preserve fertility as recommended by a board-certified obstetrician gynecologist, reproductive endocrinologist, or other physician, and this recommendation is made in accordance with current medical practices and professional guidelines published by the American Society for Reproductive Medicine, the American Society of Clinical Oncology, or other reputable professional organizations.

[ii] As set forth in the bill, "may directly or indirectly cause" means that the disease itself, or the necessary treatment, has a likely side effect of infertility as established by the American Society for Reproductive Medicine, the American Society of Clinical Oncology, or other reputable professional organizations.

[iii] Reproductive organs are considered primary or accessory. The primary reproductive organs, or gonads, consist of the ovaries and testes, and are responsible for producing gametes (eggs or sperm). All other organs, ducts, or glands in the reproductive system are considered secondary, or accessory, reproductive organs.

[iv] Cryopreservation is the process of freezing cells and tissues at very low temperatures for future use.

[v] Gametes are an organism's reproductive cells. Female gametes are call ova or egg cells, and male gametes are called sperm.

1. Provide coverage for fertility preservation services for individuals whose fertility might be impaired due to genetic or medical conditions, as well as those facing medical treatments that could lead to infertility.
2. Cover fertility preservation services for all genders without restrictions based on age or diagnosis; the determination of which patient is in need of fertility preservation services is between the patient and their phsician and should be based on guidelines established by the American Society for Reproductive Medicine (ASRM), the American Society of Clinical Oncology (ASCO), or other reputable professional organizations.

1.3 Medical Efficacy of the Bill

Fertility refers to the ability to become pregnant. Fertility-related issues are common, impacting about 9% of men and about 11% of women of reproductive age in the United States.[vi,4,5] Infertility is defined as not being able to get pregnant after one year or longer of unprotected sex or to maintain a pregnancy. Infertility can be related to the woman, the man, or both sexes; in some cases, the cause cannot be identified. [6,7,8] A number of diseases, disorders, and life events might affect fertility.[9] In some cases, the treatments for a disease, such as chemotherapy to treat cancer, might result in infertility. Infertility that results from treatment is referred to as iatrogenic (or medically induced) infertility.[10,11]

Fertility preservation refers to the process of saving or protecting sperm, eggs, or reproductive tissue so that a person can use them to have biological children in the future.[12] There are a number of treatments that can be considered when preserving fertility—such as cryopreservation of sperm, eggs, and embryos—and advances in reproductive technology have made fertility preservation safer and more efficient.[13,14] Cryopreservation techniques have made possible the use of gametes and embryos by means of assisted reproductive technology (ART).[15] Although cryopreservation of semen[vii,16] has remained an established technique for many years and has been utilized routinely for over 40 years, the cryopreservation of mature oocytes[viii,17] was considered experimental by the ASRM until 2013.[18,19]

As a technology that has been demonstrated to be safe and effective, cryopreservation permits storage of gametes for long periods of time. Recent studies indicate egg survival rates after thaw can be upwards of 90%, and the fertilization potential of sperm has been evidenced after long-term storage.[20,21,22] In addition, fertilization success rates with sperm cryopreservation have greatly increased with advances in ART.[23,24] As an established and successful method of fertility preservation, embryo cryopreservation is the preferred choice when feasible.[25]

1.4 Current Coverage

Although the Commonwealth currently requires coverage for infertility pursuant to MGL c.175 §47H, c.176A §8K, c.176B §4J, and c.176G §4I, there is no requirement to provide coverage to preserve fertility. BerryDunn surveyed 10 insurance carriers in the Commonwealth, and six responded. In general, preserving fertility services are covered. All

[vi] Reproductive age is 15 – 44 years for both men and women as referenced by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), based on the National Health Statistics Reports Number 67, August 14, 2013.

[vii] Semen, also called seminal fluid, is fluid emitted from the male reproductive tract that contains sperm cells, which are capable of fertilizing the female's eggs.

[viii] Oocyte is a female germ cell in the process of development. The oocyte is produced in the ovary and gives rise to the ovum (egg).

carriers limit the storage of reproductive tissue to one year with the exception of one carrier that covers two years of storage. All the responding carriers require preserving fertility services to be medically necessary.

1.5 Cost of Implementing the Bill

Requiring coverage for this benefit by fully insured health plans would increase fully insured premiums by as much as 0.006% or $0.04 per member per month (PMPM) on average over the next five years; a more likely increase is approximately 0.003%, equivalent to an average annual expenditure of $455,000 over the period 2022 – 2026.

The impact on premiums is driven by the additional cost of expanding coverage to add individuals not currently meeting medical necessity criteria and removing the time limit that reproductive tissue is stored.

1.6 Plans Affected by the Proposed Benefit Mandate

The bill applies to commercial, fully insured health insurance plans; hospital service corporations; medical service corporations; Health Maintenance Organizations (HMOs); and both fully and self-insured plans operated by the Group Insurance Commission (GIC) for the benefit of public employees. The proposed mandate as drafted affects Medicaid/MassHealth; however, CHIA's analysis does not estimate the potential effect of the mandate on Medicaid expenditures.

1.7 Plans Not Affected by the Proposed Benefit Mandate

Self-insured plans (i.e., where the employer or policyholder retains the risk for medical expenses and uses a third-party administrator or insurer to provide only administrative functions), except for those provided by the GIC, are not subject to state-level health insurance mandates. State mandates do not apply to Medicare and Medicare Advantage plans or other federally funded plans, including TRICARE (covering military personnel and dependents), the Veterans Administration, and the Federal Employees Health Benefit Plan, the benefits for which are determined by or under rules set by the federal government.

2.0 Medical Efficacy Assessment

The bill, as submitted in the 192nd General Court, would require fully insured plans to provide coverage for standard fertility preservation services when the enrollee has a diagnosed medical or genetic condition that might directly or indirectly cause[ix] impairment of fertility by affecting reproductive organs or processes. The coverage includes procurement, cryopreservation, and storage of gametes, embryos, or other reproductive tissues.

MGL Chapter 3 §38C charges the Commonwealth's CHIA with reviewing the medical efficacy of proposed mandated health insurance benefits. Medical efficacy reviews summarize current literature on the effectiveness and use of the mandated treatment or service, and describe the potential impact of a mandated benefit on the quality of patient care and health status of the population.

This report proceeds in the following sections:

2.0 Medical Efficacy

- Section 2.1 describes conditions that can impair fertility.
- Section 2.1.1 describes iatrogenic infertility.
- Section 2.1.2 describes genetic causes of infertility.
- Section 2.2 provides the incidence and prevalence of conditions and treatments that can disrupt fertility and lead to infertilty.
- Section 2.3 details medically necessary treatment to preserve fertility.
- Section 2.4 describes treatment efficacy to preserve fertility.

2.1 Conditions and Treatments That Can Impair Fertility

Reproductive capacity might be seriously affected by age, different conditions—including genetic syndromes—and medical treatments, especially those with gonadal[x,26] toxicity, often referred to as gonadotoxic.[xi,27,28] Although fertility preservation is most frequently associated with young oncology patients treated with chemotherapy, radiotherapy, or surgery, a number of other medical conditions can impair fertility.[29] In women, other benign pathologies account for 8% – 13% of the indications for fertility preservation.[30] The benign pathologies, or non-oncological conditions, that might result in infertility include chromosomal abnormalities, autoimmune diseases, and conditions caused by environmental factors. In addition, individuals with a genetic disposition for hereditary cancers might choose prophylactic surgeries that impact fertility; as a result, they might choose to consider whether fertility preservation services are indicated.[31]

[ix] As set forth in the bill, "may directly or indirectly cause" means that the disease itself, or the necessary treatment, has a likely side effect of infertility as established by the American Society for Reproductive Medicine, the American Society of Clinical Oncology, or other reputable professional organizations.

[x] Gonads are the primary reproductive glands that produce gametes. In males, the gonads are called testes; in females, the gonads are called ovaries.

[xi] Gonadotoxic treatments are toxic (or similarly deleterious) to the gonads (ovaries or testes).

Getting pregnant involves the sequence of steps set forth below, and infertility might result from a problem with any or several of the steps, with either the man or woman or both the man and woman contributing to inability to conceive:[32,33,34]

- An egg is released from a woman's ovaries.
- A man's sperm must join with the egg, or "fertilize" the egg.
- The fertilized egg must travel through the fallopian tube toward the uterus.
- The fertilized egg must then attach to the inside of the uterus (implantation).

In women, infertility is most commonly caused by the failure to ovulate—the monthly release of an egg from the ovaries—and can have several causes, such as polycystic ovary syndrome (PCOS),[xii] premature ovarian insufficiency (POI),[xiii] diminished ovarian reserve (DOR),[xiv] lifestyle and environmental factors, medical treatments, endocrine disorders, and age.[35,36,37,38,39] Other causes of infertility in women include scarring from surgery, endometriosis, adenomyosis, pelvic inflammatory disease (PID), uterine fibroid, autoimmune disorders, infections, and structural problems of the reproductive system. [40,41,42,43,44]

In men, genetic disorders, autoimmune or malignant disease, and their treatments might negatively affect spermatogenesis.[xv,45,46] Some of the more common issues impacting the formation of sperm include: chromosome defects, diabetes, hyperprolactinemia, injury to the testicles, insensitivity to hormones called androgens, swelling of the testicles from infections, Klinefelter syndrome, thyroid problems, cryptorchidism, varicocele,[xvi] age, lifestyle and environmental factors, and medical treatments.[47]

2.1.1 Iatrogenic Infertility

Iatrogenic (or medically induced) infertility is most often the result of chemotherapy and/or radiation for cancer, as well as treatments for sickle-cell anemia, lupus, and other autoimmune diseases.[48,49] Some treatments for malignancy, medical disorders, or gender affirmation can permanently impair reproductive function.[50] Referred to as gonadotoxic because of their damage to the gonads, these treatments include chemotherapy, radiation, and surgical resection (for treatment of disease or gender affirmation surgery).[51]

Cancer treatments often include surgery, chemotherapy, and/or radiation, and can affect fertility by impacting several biologic systems.[52] Because rapidly dividing cells are the target of chemotherapy and radiation therapy, these treatments not only act on the cancer cells, but also on cells involved in reproduction. [53,54] Although chemotherapy and radiation therapy affect male and female reproductive cells differently, they both affect future fertility.

[xii] PCOS is one of the most common causes of female infertility. PCOS results in the ovaries, and in some cases the adrenal glands, producing more androgens than normal, which interfere with the development of ovarian follicles and the release of eggs during ovulation.

[xiii] POI, previously referred to as premature ovarian failure (POF), occurs when a woman's ovaries stop working before the age of 40 years, affecting about 1% of women. POI can be a result of genetic aberrations; autoimmune ovarian damage; chemotherapy; radiation therapy; or environmental factors, such as viral infection or toxins.

[xiv] DOR is a condition in which the ovary loses its normal reproductive potential.

[xv] Spermatogenesis is the biological process of producing sperm cells within the testes.

[xvi] Varicocele is the most common cause of oligospermia, or low sperm count.

Chemotherapy and radiation therapy impact the germ cells[xvii,55] during spermatogenesis in males; and in females, the number of oocytes is diminished.[56,57] Non-oncological systemic diseases, such as hematological and autoimmune conditions, often require chemotherapy or radiation therapy.[58] As a result, individuals receiving these treatments, although not for cancer, might also have their fertility impaired.

2.1.2 Genetic Causes of Infertility

Advances in molecular biology have resulted in the identification of genetic causes for reproductive disorders in both men and women.[59] In women, several chromosomal and genetic abnormalities are associated with POI. These abnormalities primarily impact the X chromosome, such as Turner's syndrome, trisomy X, fragile X. [60,61] In men, genetic causes of infertility include Klinefelter's syndrome, cystic fibrosis, and Kallman's syndrome.[62] The common characteristic of Klinefelter's syndrome and Turner's syndrome is the gonadal dysgenesis,[xviii] which is the main cause of male or female infertility.[63]

Genetic mutations are also associated with certain cancers and syndromes, such as Lynch syndrome; and although these mutations do not directly cause infertility, an individual might undergo preventative treatments causing infertility, such as prophylactic surgery to remove ovaries.[64,65] Some types of cancer are more likely to be hereditary. Common cancers linked to inherited mutations are breast cancer in both women and men; colorectal cancer; endometrial cancer; fallopian tube, ovarian, and primary peritoneal cancer; gastric cancer; melanoma cancer; pancreatic cancer; and prostate cancer. [66]

Hereditary cancer syndromes arise from a mutation, inherited from either parent, resulting in an elevated risk of cancer development.[67] For example, the presence of the BReast CAncer (BRCA) 2 mutation has been associated with an increased risk of prostate cancer, melanoma cancer, and pancreatic cancer; and more than 90% of hereditary cases of breast cancer and ovarian cancer are thought to result from BRCA 1 and BRCA 2 mutations.[68] As a result, women who have a family history of breast cancer and/or ovarian cancer might decide to have genetic testing to determine if they have the BRCA 1 or BRCA 2 genetic mutations. Women with an increased risk of ovarian, fallopian tube, or primary peritoneal cancers might then choose a salpingo-oophorectomy (RRSO) to decrease their risk of developing a future cancer.[69] Although the procedure has a risk-reducing benefit of 96% for ovarian cancer, the surgery results in infertility.[70]

2.2 Incidence and Prevalence of Conditions and Treatments That Can Disrupt Fertility and Lead to Infertility

Infertility affects both men and women; and fertility issues increase with age, beginning in the early 30s for women and in the mid-to-late 40s for men.[71] A cross-sectional population survey study found one in eight women and one in 10 men experienced infertility.[72] Further, studies suggest that after one year of having unprotected sex, 12% – 15% of couples are unable to conceive; the sources of the problem are as follows:[73,74]

- In one-third of infertile couples, the problem is with the man.
- In one-third of infertile couples, the problem cannot be identified or is with both the man and the woman.

[xvii] A germ cell is a reproductive cell, either the sperm cell or an egg cell.

[xviii] Dysgenesis is the defective development of the gonads.

- In one-third of infertile couples, the problem is with the woman.

Individuals seek fertility preservation for a number of reasons, such as wanting to delay parenthood; planning to undergo cancer treatment; having a medical condition that affects fertility; or planning to undergo gender-affirming surgery.[75] The bill would not cover fertility preservation services in the first instance, absent a medical or genetic condition directly or indirectly causing fertility impairment.

There are more than 270,000 survivors of pediatric cancer, and more than one million survivors of young adult cancer, in the United States today.[76] The same lifesaving treatments that have increased cancer survival rates can also cause immediate or premature infertility in cancer survivors.[77,78] While one cannot precisely predict the chance of infertility, some treatments for cancer induce infertility rates of 80%or more; and research estimates that up to 90% of cancer patients in their reproductive years will become infertile from treatment.[79,80,81] Because infertility is an unfortunate inevitability for many cancer patients, reproductive-age females and males with a newly diagnosed cancer are the primary consumers of fertility preservation services.[82,83]

Collectively, individuals with non-oncological medical and genetic conditions—as well as those pursuing gender affirmation surgery or genetic testing to identify future cancer risk—represent a small portion of individuals seeking fertility preservation. The incidence and prevalence rates of medical and genetic conditions affecting fertility, other than cancer, are relatively low.[84,85,86] For example, systemic lupus erythematosus, an autoimmune disease, affects approximately one – 10 per 100,000,[87] while the genetic conditions of Klinefelter's syndrome affect one in 600 men, and Turner's syndrome affects one in 2,500 women.[88] A relatively small percentage of transgender patients pursue fertility preservation, although this might be due to a number of factors, including cost.[89] Deciding to have genetic testing to understand inherited cancer risk, and ultimately choosing fertility preservation services, is complicated;[90] and there are no studies available to determine the number of individuals who have genetic testing to determine cancer risk and choose to pursue fertility preservation.

2.3 Treatment to Preserve Fertility

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.[91] Fertility preservation is fundamentally an issue for individuals of reproductive age (both male and female) as well as prepubescent boys and girls whose future fertility might be compromised.[92] Individuals who are about to receive treatment for cancer or an autoimmune disease, or who have certain diseases or disorders that affect fertility, might benefit from fertility preservation.[93] Because treatments such as radiation therapy or chemotherapy might cause infertility, fertility preservation should be performed before the medical treatment is initiated.[94,95] Appendix A identifies fertility preservation strategies by type of cancer treatment for both males and females, such as performing fertility-sparing surgery; shielding against radiation; and cryopreserving sperm, oocytes, and embryos.[96]

It is important to note that before considering fertility preservation treatments, a patient must consider the individualized risk that the cancer treatment poses to future fertility. In the case of breast cancer, factors such as the recommended 2-year period of observation after completion of chemotherapy—during which pregnancy should not be attempted—and the delays related to the use of adjuvant hormonal therapies should be considered.[97] Careful coordination of the fertility preservation treatments might be required to allow for timely delivery of cancer treatment.[98]

The ASRM encourages clinicians to inform patients about fertility preservation options prior to undergoing treatment likely to cause iatrogenic infertility.[99] Fertility preservation represents an essential part in the management of young patients who are at risk of premature gonadal failure.[100]

Safeguarding mature spermatozoa is currently the best method of fertility preservation in adult men and boys producing sperm in the ejaculate, and with advances in ART, it allows for maintaining the hope of genetic fatherhood even after long-term storage of a semen sample.[101] Fertility-preserving options for males include:[102,103]

- Sperm cryopreservation[xix]
- Gonadal shielding[xx]
- Testicular transposition
- Testicular tissue freezing

For young women, the risk of premature ovarian failure due to treatment, or to a disease itself, can be fairly high.[104] Preserving fertility options for females include:[105,106]

- Embryo cryopreservation[xxi]
- Oocyte cryopreservation[xxii]
- Gonadal shielding
- Ovarian tissue freezing and reimplantation
- Ovarian suppression[xxiii]
- Ovarian transposition[xxiv]
- Ovarian cystectomy[xxv]
- Uterine suspension[xxvi]
- Radical trachelectomy[xxvii]

[xix] Sperm cryopreservation. In this process, a male provides samples of his semen that are then frozen for future use.

[xx] Gonadal shielding. Steps are taken, such as aiming rays at a small area or covering the pelvic area with a lead shield, to protect the ovaries or testes from radiation.

[xxi] Embryo cryopreservation. A health care provider removes eggs from the ovaries. The eggs are then fertilized with sperm in a lab in a process called in vitro fertilization. The resulting embryos are frozen and stored for future use.

[xxii] Oocyte cryopreservation. In this process, a healthcare provider removes eggs, and the unfertilized eggs are frozen and stored for future use.

[xxiii] Ovarian suppression is the use of medications to temporarily stop ovarian function.

[xxiv] Ovarian transposition is the movement of the ovaries, and sometimes the fallopian tubes, from the area that will receive radiation to an area that will not receive radiation.

[xxv] Ovarian cystectomy is a laparoscopic surgery to remove cysts from the ovaries.

[xxvi] Uterine suspension moves the uterus out of the radiation field.

[xxvii] Radical trachelectomy is the removal of the cervix.

Some of the options for fertility preservation—such as sperm, oocyte, and embryo cryopreservation—are available only to males and females who have gone through puberty and have mature sperm and eggs, while gonadal shielding and ovarian transposition can be used to preserve fertility in children who have not yet gone through puberty.[107]

2.4 Effectiveness of Fertility Preservation Treatment

The goal of fertility preservation is to save or protect sperm, eggs, or reproductive tissues so that a person can use them to have children in the future; and for young patients, fertility preservation is a major concern if their reproductive potential could be impaired by a disease or the result of treatment.[108,109] Several oncological and non-oncological diseases or conditions that affect current or future fertility, either due to the disease itself or to gonadotoxic treatment, need an adequate fertility preservation approach because biological parenthood is possible with appropriate pretreatment and planning.[110,111,112] As such, patients facing treatments likely to impair reproductive function deserve prompt counseling and rapid referral to an appropriate program.[113]

The methods of cryopreservation of gametes and embryos have been demonstrated to be safe and effective.[114] Success rates of semen cryopreservation have greatly increased with advances in ART procedures, such as intra-cytoplasmic sperm injection resulting in pregnancy rates up to 57%.[115] Multiple studies have demonstrated that the length of oocyte storage has no effect on pregnancy rate outcomes.[116,117] However, a large study using data collected from outside of egg donation programs found that the age at which a woman's eggs are cryopreserved impacts potential success, with those women who froze at or before the age of 35 having a 53.9% likelihood of a live birth per embryo transfer, while those freezing at or above the age of 36 had a 22.9% chance.[118]

In 1996, the first case of embryo cryopreservation for fertility preservation took place with the application of an In Vitro Fertilization (IVF) cycle prior to chemotherapy in a woman diagnosed with breast cancer; since then, embryo cryopreservation has become the most established technique for fertility preservation.[119] As a well-established technology, cryopreservation of embryos also has a high pregnancy success rates.[120]

For cancer patients, impaired fertility significantly impacts quality of life in survivorship and is associated with a deterioration in mental health.[121] Health professionals, as well as patients and their parents, consider fertility preservation an important option for young cancer patients, although for the patients themselves, the perceived relevance seems to depend on factors such as the stage of life at cancer diagnosis.[122]

Male fertility preservation has been steadily increasing over the past two decades. As such, when timing and logistics are appropriate, sperm cryopreservation is considered the gold standard for fertility preservation, given the highly effective use of cryopreserved sperm.[123,124] Although testicular tissue and spermatogonial stem cell autotransplantation are considered experimental, they represent a promising alternative for pre-pubertal patients.[125] For women, oocyte and embryo cryopreservation provide effective and established modalities for fertility preservation options; furthermore, ovarian tissue preservation is no longer considered experimental and can be used in prepubertal patients when there is no time for ovarian stimulation.[126,127]

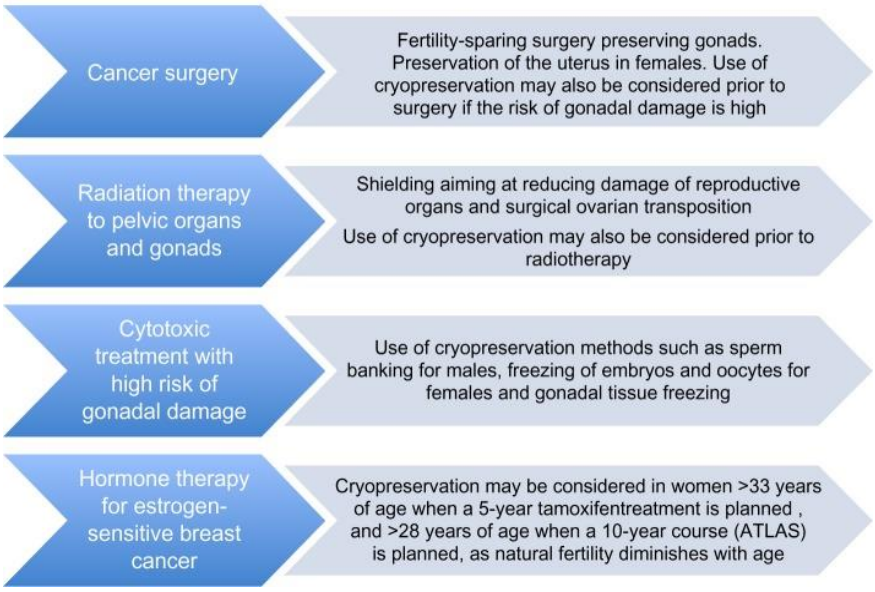
Eleven states (California, Colorado, Connecticut, Delaware, Illinois, Maryland, New Hampshire, New Jersey, New York, Rhode Island, and Utah) have enacted laws requiring certain insurers in the state to subsidize the costs

associated with fertility preservation. [128,129,130] These laws require the inclusion of ovarian stimulating medications, egg and sperm retrieval procedures, and initial freezing. [131,132,133]

Appendix A

Fertility Preservation Strategies

Depending on the Type of Cancer Treatment in Males and Females[134]



Endnotes

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AN ACT RELATIVE TO PRESERVING FERTILITY

COST REPORT

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1.0 Executive Summary

Massachusetts House Bill (H.B.) 1116 and Senate Bill (S.B.) 640, as submitted in the 192nd General Court of the Commonwealth of Massachusetts (Commonwealth), require fully insured plans to cover the cost of standard fertility preservation services[i] when the enrollee has a diagnosed medical or genetic condition that may directly or indirectly cause[ii] impairment of fertility by affecting reproductive organs or processes. The bills require coverage to be provided to the same extent that benefits are provided for other pregnancy-related procedures and include procurement, cryopreservation, and storage of gametes, embryos, or other reproductive tissues. In addition, the benefits "shall not be subject to any greater deductible, coinsurance, copayments, or out-of-pocket limits than any other benefit provided by an insurer."[1] The language in each bill is the same, and for the remainder of the report, "the bill" will collectively refer to H.B. 1116 and S.B. 640.

After referral of the bill to the Massachusetts Center for Health Information and Analysis (CHIA) for review, CHIA and its consultants confirmed the following assumptions regarding the bill's intent:

1. The bill provides coverage for fertility preservation services for individuals whose fertility might be impaired due to genetic or medical conditions, as well as those facing medical treatments that could lead to infertility.
2. Fertility preservation coverage is intended for all genders without restrictions based on age or diagnosis. The determination of which patient is in need of fertility preservation services is between the patient and their physician and should be based on guidelines established by the American Society for Reproductive Medicine (ASRM), the American Society of Clinical Oncology (ASCO), or other reputable professional organizations.

Massachusetts General Law (MGL) Chapter 3 §38C charges CHIA with, among other duties, reviewing the potential impact of proposed mandated healthcare insurance benefits on the premiums paid by businesses and consumers. CHIA has engaged BerryDunn to provide an actuarial estimate of the effect that enactment of the bill would have on the cost of health insurance in the Commonwealth. The report is required to include the proposed mandate's impact on healthcare costs, including premium and administrative expenses.

This report is not intended to determine whether the bill would constitute a health insurance benefit mandate for purposes of state defrayal under the Affordable Care Act (ACA), nor is it intended to assist with state defrayal calculations if it is determined to be a health insurance benefit mandate requiring state defrayal.

1.1 Current Insurance Coverage

BerryDunn surveyed 10 insurance carriers in the Commonwealth, and six responded. In general, preserving fertility services are covered. All carriers limit the storage of reproductive tissue to one year with the exception of one carrier

[i] Pursuant to the language in the bill, "standard fertility preservation services" means procedures or treatment to preserve fertility as recommended by a board-certified obstetrician gynecologist, reproductive endocrinologist, or other physician, and this recommendation is made in accordance with current medical practices and professional guidelines published by the American Society for Reproductive Medicine, the American Society of Clinical Oncology, or other reputable professional organizations.

[ii] As set forth in the bill, "may directly or indirectly cause" means that the disease itself, or the necessary treatment, has a likely side effect of infertility as established by the American Society for Reproductive Medicine, the American Society of Clinical Oncology, or other reputable professional organizations.

that covers two years of storage. All the responding carriers require preserving fertility services to be medically necessary.

No Commonwealth or federal law requires coverage for preserving fertility.[2] Under the ACA, essential health benefits (EHBs) are defined by state benchmark plans.[3] Although there are no provisions for fertility preservation, the Commonwealth benchmark plan provides coverage for the diagnosis and treatment of infertility.[iii, 4]

1.2 Analysis

BerryDunn estimated the incremental impacts of the requirement that insurers cover standard fertility preservation services when the enrollee has a diagnosed medical or genetic condition that may directly or indirectly cause impairment of fertility by affecting reproductive organs or processes. Required coverage includes procurement, cryopreservation, and storage of gametes, embryos, or other reproductive tissue. Because carriers already voluntarily cover the cost of preserving fertility, the incremental cost of the bill is based on allowing coverage for those with conditions impacting fertility that might not meet the current medical necessity criteria, such as premature ovarian insufficiency and certain chromosomal abnormalities, removing time limits on the storage of reproductive tissue, and the impact that these factors will have on preserving fertility service utilization and the associated cost. The cost per user is estimated using claims data from the Massachusetts all payer claims database (APCD). The number of people anticipated to utilize preserving fertility services and the length of time they will store reproductive tissue is estimated using the APCD, population data, and academic literature. Combining the two components, and accounting for current coverage and carrier retention, results in a baseline estimate of the proposed mandate's incremental effect on premiums, which is projected over the five years following the assumed January 1, 2022, implementation date of the proposed law.

1.3 Summary Results

Table ES-1, on the following page, summarizes the estimated effect of the bill on premiums for fully insured plans over five years. This analysis estimates that the bill, if enacted as drafted for the 192nd General Court, would increase fully insured premiums by as much as 0.006% or $0.04 per member per month (PMPM) on average over the next five years; a more likely increase is approximately 0.003%, equivalent to an average annual expenditure of $455,000 over the period 2022 – 2026.

The impact on premiums is driven by expanding coverage to add individuals not currently meeting medical necessity criteria and removing the time limit that reproductive tissue is stored, the impact on preserving fertility service utilization, and the corresponding cost. Variation between scenarios is attributable to the uncertainty surrounding the average cost of preserving fertility per user per year, the number of new users, and the average time that reproductive tissue is stored. The impact of the bill on any one individual, employer group, or carrier might vary from the overall results, depending on the current level of benefits each receives or provides, and on how those benefits would change under the proposed language.

[iii] Pursuant to MGL c.175 §47H, MGL c.176A §8K, MGL c.176B §4J, and MGL c.176G §4(e), "infertility" shall mean the condition of an individual who is unable to conceive or produce conception during a period of one year if the female is age 35 or younger or during a period of six months if the female is over the age of 35.

Table ES-1: Summary Results

	2022	2023	2024	2025	2026	WEIGHTED AVERAGE	FIVE-YEAR TOTAL
Members (000s)	2,014	2,010	2,007	2,003	2,000		
Medical Expense Low ($000s)	$18	$25	$27	$28	$29	$27	$126
Medical Expense Mid ($000s)	$222	$361	$388	$418	$437	$387	$1,826
Medical Expense High ($000s)	$442	$695	$782	$876	$975	$799	$3,770
Premium Low ($000s)	$21	$30	$31	$33	$34	$31	$148
Premium Mid ($000s)	$261	$424	$456	$491	$513	$455	$2,146
Premium High ($000s)	$520	$816	$919	$1,029	$1,146	$938	$4,430
PMPM Low	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
PMPM Mid	$0.02	$0.02	$0.02	$0.02	$0.02	$0.02	$0.02
PMPM High	$0.03	$0.03	$0.04	$0.04	$0.05	$0.04	$0.04
Estimated Monthly Premium	$590	$617	$645	$674	$704	$646	$646
Premium % Rise Low	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Premium % Rise Mid	0.003%	0.003%	0.003%	0.003%	0.003%	0.003%	0.003%
Premium % Rise High	0.005%	0.005%	0.006%	0.006%	0.007%	0.006%	0.006%

Executive Summary Endnotes

[1] The 192nd General Court of the Commonwealth of Massachusetts. H.B. 1116 and S.B. 640, "An Act relative to preserving fertility." Accessed 19 April 2021: **https://malegislature.gov/Bills/192/H1116** and **https://malegislature.gov/Bills/192/S640**. These bills were submitted in the 191st General Court of the Commonwealth of Massachusetts as H.B. 1004 and S.B. 560, both titled "An Act relative to preserving fertility." Accessed 2 December 2020: **https://malegislature.gov/Bills/191/H1004** and **https://malegislature.gov/Bills/191/S560**.

[2] Weigel G, Ranji U, Long M, et al. Coverage and Use of Fertility Services in the U.S. Women's Health Policy. Kaiser Family Foundation (KFF).15 September 2020. Accessed 3 March 2021: **https://www.kff.org/womens-health-policy/issue-brief/coverage-and-use-of-fertility-services-in-the-u-s/**.

[3] Centers for Medicare & Medicaid Services (CMS), Center for Consumer Information and Insurance Oversight, Information on EHB Benchmark Plans. Accessed 5 October 2020: **https://www.cms.gov/cciio/resources/data-resources/ehb.html**.

[4] CMS. Massachusetts State Required Benefits. Accessed 12 October 2020: **https://downloads.cms.gov/cciio/State%20Required%20Benefits_MA.PDF**.

2.0 Introduction

The Committee on Financial Services referred House Bill (H.B.) 1116 and Senate Bill (S.B.) 640, both entitled, "An Act relative to preserving fertility,"[1] to the Massachusetts Center for Health Information and Analysis (CHIA) for review. Massachusetts General Law (MGL) Chapter 3 §38C requires CHIA to review and evaluate the potential fiscal impact of each mandated benefit bill referred to the agency by a legislative committee. The report is required to include the effects on healthcare costs, including premium and administrative expenses, of the proposed mandate. House Bill (H.B.) 1116 and Senate Bill (S.B.) 640 are identical and will therefore be collectively referred to as the "bill" for the remainder of the report.

Assessing the impact of the proposed mandate on premiums entails analyzing its incremental effect on spending by insurance plans. This, in turn, requires comparing spending under the provisions of the bill to spending under current statutes and current benefit plans for the relevant services.

This report is not intended to determine whether the bill would constitute a health insurance benefit mandate for purposes of state defrayal under the ACA, nor is it intended to assist with state defrayal calculations if it is determined to be a health insurance benefit mandate requiring state defrayal.

Section 3.0 of this analysis outlines the provisions and interpretations of the bill. Section 4.0 summarizes the methodology used for the estimate. Section 5.0 discusses important considerations in translating the bill's language into estimates of its incremental impact on healthcare costs and steps through the calculations. Section 6.0 discusses results.

2.1 Background

The bill, as submitted in the 192nd General Court of the Commonwealth, requires to the same extent that benefits are provided for other pregnancy-related procedures, coverage for standard fertility preservation services[iv] when the enrollee has a diagnosed medical or genetic condition that may directly or indirectly cause[v] impairment of fertility by affecting reproductive organs or processes. The coverage shall include procurement, cryopreservation, and storage of gametes, embryos, or other reproductive tissues. Further, the "benefits set forth in this proposed mandate shall not be subject to any greater deductible, coinsurance, copayments, or out-of-pocket limits than any other benefits provided by an insurer."[2]

After referral of the bill to CHIA for review, CHIA and its consultants confirmed the following assumptions regarding the bill's intent:

1. The bill provides coverage for fertility preservation services for individuals whose fertility might be impaired

[iv] Pursuant to the language in the bill, "standard fertility preservation services" means procedures or treatment to preserve fertility as recommended by a board-certified obstetrician gynecologist, reproductive endocrinologist, or other physician, and this recommendation is made of in accordance with current medical practices and professional guidelines published by the American Society for Reproductive Medicine, the American Society of Clinical Oncology, or other reputable professional organizations.

[v] As set forth in the bill, "may directly or indirectly cause" means that the disease itself, or the necessary treatment, has a likely side effect of infertility as established by the American Society for Reproductive Medicine, the American Society of Clinical Oncology, or other reputable professional organizations.

due to genetic or medical conditions, as well as those facing medical treatments that could lead to infertility.

2. Fertility preservation coverage is intended for all genders without restrictions based on age or diagnosis. The determination of which patient is in need of fertility preservation services is between the patient and their physician and should be based on guidelines established by the American Society for Reproductive Medicine (ASRM), the American Society of Clinical Oncology (ASCO), or other reputable professional organizations.

3.0 Interpretation of the Bill

No Commonwealth or federal law requires coverage for preserving fertility.[3] Under the ACA, essential health benefits (EHBs) are defined by state benchmark plans.[4] Although there are no provisions for fertility preservation, the Commonwealth benchmark plan provides coverage for the diagnosis and treatment of infertility.[vi, 5]

3.1 Plans Affected by the Proposed Mandate

The bill as drafted amends statutes that regulate healthcare carriers in the Commonwealth. The bill amends the following chapters, each of which addresses a particular type of health insurance policy:

- Chapter 32A – Plans Operated by the Group Insurance Commission (GIC) for the Benefit of Public Employees
- Chapter 175 – Commercial Health Insurance Company Plans
- Chapter 176A – Hospital Service Corporation Plans
- Chapter 176B – Medical Service Corporation Plans
- Chapter 176G – Health Maintenance Organization (HMO) Plans

Self-insured plans, except for those managed by the GIC, are not subject to state-level health insurance benefit mandates. State mandates do not apply to Medicare or Medicare Advantage plans, the benefits of which are qualified by Medicare; this analysis excludes members of fully insured commercial plans over 64 years of age and does not address any potential effect on Medicare supplement plans, even to the extent they are regulated by state law.

Self-insured plans, except for those managed by the GIC, are not subject to state-level health insurance benefit mandates. State mandates do not apply to Medicare or Medicare Advantage plans, the benefits of which are qualified by Medicare; this analysis excludes members of fully insured commercial plans over 64 years of age and does not address any potential effect on Medicare supplement plans, even to the extent they are regulated by state law.

[vi] Pursuant to MGL c.175 §47H, MGL c.176A §8K, MGL c.176B §4J, and MGL c.176G §4(e), "infertility" shall mean the condition of an individual who is unable to conceive or produce conception during a period of 1 year if the female is age 35 or younger or during a period of 6 months if the female is over the age of 35.

3.2 Covered Services

BerryDunn surveyed 10 insurance carriers in the Commonwealth, and six responded. Preserving fertility services are covered, and all carriers limit the storage of reproductive tissue to one year with one exception for a carrier that covers two years of storage. Most carriers limit coverage to one cycle of In Vitro Fertilization (IVF) or embryo cryopreservation. The carriers require that the services be medically necessary.

3.3 Existing Laws Affecting the Cost of the Bill

The bill's coverage requirements are not redundant to or in conflict with any existing state or federal coverage requirements.

4.0 Methodology

4.1 Overview

Estimating the impact of the bill on premiums requires assessing the incremental impacts of the requirement that insurers cover standard fertility preservation services when the enrollee has a diagnosed medical or genetic condition that may directly or indirectly cause impairment of fertility by affecting reproductive organs or processes. Required coverage includes procurement, cryopreservation, and storage of gametes, embryos, or other reproductive tissue.

Because carriers already voluntarily cover the cost of preserving fertility services, the incremental cost is based on allowing coverage for those with conditions impacting fertility that might not meet the current medical necessity criteria, such as premature ovarian insufficiency and certain chromosomal abnormalities, removing limits on the storage of reproductive tissue and the impact that these factors will have on utilization and the associated cost. The cost is estimated using claims data from the Massachusetts all payer claims database (APCD) to determine cost per user for preserving fertility services. The number of people anticipated to utilize preserving fertility services and the length of time they will store reproductive tissue is estimated using the APCD, population data, and academic literature. Combining the two components, and accounting for current coverage and carrier retention, results in a baseline estimate of the proposed mandate's incremental effect on premiums, which is projected over the five years following the assumed January 1, 2022, implementation date of the proposed law.

There are two other bills (H.B. 1196 and S.B. 673) that are being considered contemporaneously with H.B. 1116 and S.B. 640. These bills, if enacted, would remove cost-sharing for prenatal, pregnancy, postpartum care, abortion, and abortion-related services. Because the current bill requires coverage to the same extent as benefits provided for other pregnancy-related services, it is BerryDunn's assumption that if both (H.B. 1196 and S.B. 673) and (H.B. 1116 or S.B. 640) were enacted, then the services in H.B. 1116 and S.B. 640 would also be covered with no cost-sharing. This cost impact is beyond the scope of this report.

4.2 Data Sources

The primary data sources used in the analysis are:

- Information about the intended effect of the bill, gathered from the bill's sponsoring legislators and staff to clarify the bill's intent
- Information, including descriptions of current coverage, from responses to a survey of commercial health insurance carriers in the Commonwealth
- The Massachusetts APCD
- Academic literature, published reports, and population data, cited as appropriate
- Discussion with clinical experts and providers

4.3 Steps in the Analysis

BerryDunn performed analytic steps summarized in this section to estimate the impact of the bill on premiums.

1. Estimated the incremental costs to insurers for preserving fertility

To estimate the impact of the cost of preserving fertility, BerryDunn:

A. Used input from a clinical expert and claims data from the APCD to determine the cost per user per year

B. Used publicly available literature to determine the incidence rate of target conditions that might impair fertility in the eligible population

C. Used data from the APCD to determine the uptake rate based on current preserving fertility coverage

D. Used the uptake rate based on current coverage, input from clinical experts, and publicly available literature to determine the incremental uptake rate for fertility preservation procedures based on the removal of limited storage time and other limits

E. Multiplied the number of commercial, fully insured members between the ages of 15 and 45 (inclusive) in the Commonwealth by the portion of eligible adults obtained in Step B, by the incremental uptake rate in Step D to determine the number of new fertility preservation users

F. Multiplied the estimated number of new fertility preservation users in Step E by the corresponding cost per user per year in Step A to determine the incremental cost of preserving fertility services

G. Divided the incremental cost of preserving fertility services by the corresponding membership to calculate a PMPM claims cost

H. Projected PMPM claims cost over the analysis period using an estimated increase in professional services

2. Estimated the impact of removing time limits for storage of reproductive tissue

To estimate the impact of removing time limits for storage of reproductive tissue and to calculate the annual incremental cost, BerryDunn:

A. Used the APCD to determine the annual cost for storing reproductive tissue, and projected the per-user cost forward over the five-year analysis period using an estimated increase in professional services over the period

B. Used academic literature to estimate the average reproductive tissue storage time

C. Used the APCD and carrier surveys to determine the current storage time as a result of limits currently imposed by the carriers

D. Subtracted the currently covered average storage time obtained in Step C from the estimated average full storage time in Step B to calculate the incremental storage time

E. Used the APCD to calculate the number of users storing reproductive tissue over the analysis period

F. Taking into account the average incremental storage time from Step D, multiplied the total number of users each year from Step E by the annual storage cost in Step A to determine the annual incremental cost

G. Divided the annual incremental cost per year obtained in Step F by the corresponding membership to calculate the incremental PMPM cost

3. Calculated the impact of the projected claim costs on insurance premiums

To calculate the impact on health insurance premiums, BerryDunn:

A. Summed the PMPM incremental costs of additional preserving fertility users and the incremental costs from removing storage time limits on reproductive tissue

B. Estimated the fully insured Commonwealth population under age 65, projected for the next five years (2022 – 2026)

C. Multiplied the estimated incremental paid PMPM cost of the mandate by the projected population estimate to calculate the total estimated incremental claims cost of the bill

D. Estimated insurer retention (administrative costs, taxes, and profit) and applied the estimate to the final incremental claims cost calculated in Step C

4.4 Limitations

In general, carriers currently provide coverage for preserving fertility in Massachusetts so the unit cost could be determined from APCD claims. However, all carriers impose limits to the amount of time that reproductive tissue can be stored, and the average length of storage time absent any limits is uncertain. The available literature on the time that people store reproductive tissue is limited and suggests a fairly broad range.

The impact of removing storage limits on uptake rates is uncertain. BerryDunn's literature review indicated that preserving fertility uptake rates are higher for men. However, a review of the APCD shows that uptake rates for men were lower than women in 2018. The literature is limited on the rate of people storing reproductive tissue when there is no cost barrier. Because of the limited literature, BerryDunn included studies from other countries to help predict uptake rates.

BerryDunn projected the costs per user over the analysis period using the long-term average national projection for cost increases to physician services. The actual increase in costs over the projection period is uncertain.

Finally, BerryDunn did not adjust for a potential impact of COVID-19 on the number of preserving fertility users. This projection is based upon pre-COVID-19 data, and starts in 2022. BerryDunn assumed that COVID-19 will not impact utilization in 2022. Fully insured membership declined due to increased unemployment. The impact that COVID-19 will have on unemployment in the 2022 – 2026 projection period is uncertain.

The more detailed, step-by-step description of the estimation process in the next sections addresses these uncertainties further.

5.0 Analysis

This section describes the calculations outlined in the previous section in more detail. The analysis includes development of a best-estimate middle-cost scenario, as well as a low-cost scenario using assumptions that produced a lower estimate and a high-cost scenario using more conservative assumptions that produced a higher-estimated cost impact.

- Section 5.1 describes the steps used to calculate the cost per user of preserving fertility services.
- Section 5.2 describes the steps used to estimate the incremental number of preserving fertility users and the associated cost.
- Section 5.3 describes the steps to calculate the incremental cost to remove time limits on storing reproductive tissue.
- Section 5.4 combines the two incremental costs. Section 5.5 projects the fully insured population ages 0 – 64 in the Commonwealth over the 2022 – 2026 analysis period.
- Section 5.6 calculates the total estimated incremental cost of the bill. Section 5.7 adjusts the projected incremental costs for carrier retention to arrive at an estimate of the bill's effect on premiums for fully insured plans.

5.1 Cost Per User

Estimated the cost per user for preserving fertility services

BerryDunn used a combination of claims data from the APCD and an interview with a Massachusetts clinical expert with specific expertise in fertility to calculate the cost per user per year for preserving fertility services. The average cost per user was calculated from 2016 – 2018 APCD claim data using charge and paid amounts. Charge amounts are the full charges made by the providers. Paid amounts made by the carriers reflect a negotiated allowed contractual payment rate and member cost sharing.

For women, the average charges from providers were between $10,000 and $11,600 per user per year. This is consistent with a cost range provided to BerryDunn by the clinical fertility specialist, who indicated that the annual charges for women would be between $8,000 and $12,000 per year. The average paid cost for women ranged between $7,000 and $8,000 per user per year.

The average paid cost per user per year for men was $800, with a range from $700 to $900 per user per year. The cost per user includes microsurgical epididymal sperm aspiration for sperm retrieval. This is a medically necessary procedure in cases when an obstruction occurs, with a cost per user of approximately $3,400; the average cost per user excluding this procedure was approximately $600. BerryDunn used the average paid cost in the middle scenario and assumed a lower cost per user in the low scenario and a higher cost per user in the high scenarios. The annual per user per year costs are reflected in Table 1.

Table 1: Estimated 2018 Paid Cost per User per Year

	MEN	WOMEN
Low Scenario	$700	$7,000
Mid Scenario	$800	$7,500
High Scenario	$900	$8,000

5.2 Number of Preserving Fertility Users

Estimated the number of incremental preserving fertility users

The bill requires insurers to cover preserving fertility services for those at risk of losing fertility due to genetic or medical conditions. Fertility might be seriously affected by age, different conditions—including genetic syndromes—and medical treatments, especially those with gonadal[vii,6] toxicity, often referred to as gonadotoxic.[viii,7,8] Although fertility preservation is most frequently associated with young oncology patients, a number of other medical conditions can impair fertility.[9] The non-oncological conditions that might result in infertility include chromosomal abnormalities, autoimmune diseases, and conditions caused by environmental factors. In addition, individuals with a genetic disposition for hereditary cancers or undergoing gender affirmation procedures might choose prophylactic or elective surgeries that impact fertility; as a result, they might choose to consider whether fertility preservation services are indicated.[10]

The carriers indicated that they do not limit their coverage to any specific condition, and they do cover individuals undergoing gender affirmation procedures. However, conditions impacting fertility that do not meet the current medical necessity criteria are not covered. According to the clinical expert, the majority of the patients seeking treatment are cancer patients. In order to estimate the number of new users, BerryDunn focused on the number of cancer patients. The high end of the range estimate takes into account preserving fertility users with other conditions.

[vii] Gonads are the primary reproductive glands that produce gametes. In males, the gonads are called testes; in females, the gonads are called ovaries.

[viii] Gonadotoxic treatments are toxic (or similarly deleterious) to the gonads (ovaries or testes).

The Massachusetts fertility expert provided a listing of cancer types that put patients most at risk for loss of fertility. Using a 2011 – 2015 Cancer Incidence and Mortality Report from the Massachusetts Cancer Registry,[11] BerryDunn summed incidence rates for each of the types of cancer that put patients at risk for infertility. BerryDunn then multiplied the total incidence rates by the number of fully insured members in the Commonwealth aged 15 – 44, by gender and by age cohort. BerryDunn estimated that approximately 0.034% of men and 0.068% of women suffer from the targeted cancer sites each year. The at-risk cancer types and their incidence rates by age cohort are presented in Table 2.

Table 2: At Risk Cancer Incidence Rates per 100,000 by Age Cohort

CANCER TYPE	15 -- 19	20 -- 24	25 -- 29	30 -- 34	35 – 39	40 -- 44
Men						
Brain & Other Nervous System	2.8	2.5	4.9	4.1	3.5	4.4
Breast	--	--	--	0.3	0.2	0.6
Breast *in situ*	--	--	--	--	0.1	0.2
Colon / Rectum	0.5	0.8	2.4	5.6	9.5	21.1
Hodgkin Lymphoma	2.7	5.4	5.6	4.9	2.9	3.6
Non-Hodgkin Lymphoma	2.5	4.0	2.9	5.7	9.0	12.2
Prostate	--	--	--	0.1	0.3	8.1
Testis	2.9	11.0	16.2	14.9	14.0	10.7
Women						
Brain & Other Nervous System	2.8	2.4	2.7	3.2	3.8	4.7
Breast	0.1	1.8	10.7	30.4	70.6	141.2
Breast *in situ*	0.2	0.2	1.1	4.9	14.0	65.1
Colon / Rectum	0.7	1.2	2.5	5.0	11.3	20.7
Hodgkin Lymphoma	3.4	6.0	4.3	3.9	2.9	3.0
Non-Hodgkin Lymphoma	1.2	1.8	2.5	3.7	5.9	8.9

Because preserving fertility benefits is relatively new, published literature on uptake rates is limited. According to research by Specchia et al. (2019),[12] of 568 women who received fertility counseling, 43% elected to preserve their fertility. Consistent with what the Massachusetts fertility expert indicated, the majority (60%) of these patients were diagnosed with breast cancer, followed by women with lymphoma (27%), and then women with cancer involving other sites. Patients did not have to pay for these services. In a study of 550 cancer survivors diagnosed between the ages of 15 and 39, 182 or 33% of the survivors took steps to preserve their fertility. Men, survivors who did not have

children, those who received chemotherapy, and those who lived in the Northeast (vs. the South) were more likely to preserve fertility.[13] A 2009 study examining patient attitudes toward fertility preservation found that 75% of survivors who were childless at diagnosis would like future offspring.[14] Based on the incidence rates, the average age of the at-risk population skews older and, as such, many individuals would already have children prior to needing fertility preservation. Given that, 75% is likely well above the maximum preserving fertility uptake rate. A study that reviewed assisted reproductive techniques in long-term cancer survivors found that when offered to preserve fertility, 53% of men and 35% of women elected to preserve.[15]

Using the APCD, BerryDunn calculated the uptake rates based on the current coverage voluntarily provided by the carriers. Relative to the target population, 14% of men and 35% of women elected to preserve their fertility. BerryDunn's literature review indicated that preserving fertility uptake rates are higher for men. However, the review of the APCD shows that in 2018, uptake rates for men were lower. BerryDunn took this discrepancy into account when setting the uptake ranges. Not every person with cancer will elect to undergo fertility preservation services.

In the middle scenario, BerryDunn used the Specchia research indication that 43% of women would preserve fertility if the benefit was fully paid for and assumed that the total uptake would reach 43%. For men, BerryDunn assumed the uptake rate would be 30%, or slightly more than double the APCD uptake rate. In this scenario, new users would be 8% of the targeted population for women and 16% for men. In the low scenario, BerryDunn assumed no additional uptake of preserving fertility users. In the high scenario, BerryDunn assumed the total uptake rate would reach 50% for men and women. In this scenario, new users would be 15% of the targeted population for women and 36% for men.

Based on a Commonwealth population study included in Appendix A, there were approximately 2.031 million commercial fully insured individuals age 64 and younger in 2018. Of these 2.031 million individuals, BerryDunn estimates there were 498,827 men and 522,991 women between the ages of 15 and 44.[ix] BerryDunn multiplied the number of fully insured members, the annual rate of people diagnosed with cancer types that result in a high risk of iatrogenic infertility, and the incremental uptake rate of preserving fertility to estimate the number of incremental users who would preserve fertility. Results are presented in Table 3.

[ix] BerryDunn used the age range of 15 – 44 years based on input from clinical experts.

Table 3: Estimated 2018 Incremental Users

SCENARIOS	CANCER INCIDENT RATE	PEOPLE AT INFERTILITY RISK	INCREMENTAL UPTAKE %	INCREMENTAL USERS
Men				
Low Scenario	0.0340%	170	0%	0
Mid Scenario	0.0340%	170	16%	27
High Scenario	0.0340%	170	36%	61
Women				
Low Scenario	0.0681%	356	0%	0
Mid Scenario	0.0681%	356	8%	28
High Scenario	0.0681%	356	15%	53
Total				
Low Scenario		526		0
Mid Scenario		526		55
High Scenario		526		114

BerryDunn then multiplied the number of incremental users from Table 3 by the cost per user in Table 1 to estimate the annual incremental cost of additional users. Table 4 presents these results.

Table 4: Estimated Incremental Cost for New Users

	INCREMENTAL USERS	COST PER USER	TOTAL COST
Men			
Low Scenario	0	$700	$0
Mid Scenario	27	$800	$21,600
High Scenario	61	$900	$54,900
Women			
Low Scenario	0	$7,000	$0
Mid Scenario	28	$7,500	$210,000
High Scenario	53	$8,000	$424,000
Total			
Mid Scenario	0		$0
High Scenario	55		$231,600
High Scenario	114		$478,900

BerryDunn divided the total annual, incremental cost for new users by the total corresponding membership in order to calculate the incremental PMPM. The costs per user were projected over the analysis period using the long-term average national projection for cost increases to physician services (4.6%).[16] Results are presented in Table 5.

Table 5: Estimated Incremental PMPM Cost of New Users

	2018	2022	2023	2024	2025	2026
Low Scenario	$0.000	$0.000	$0.000	$0.000	$0.000	$0.000
Mid Scenario	$0.010	$0.011	$0.012	$0.012	$0.013	$0.014
High Scenario	$0.020	$0.023	$0.024	$0.026	$0.027	$0.028

The next section develops the cost of eliminating time limits of storage of reproductive tissue.

5.3 Storage Costs

Estimated total incremental costs to insurers to remove time limits on storing reproductive tissue.

BerryDunn used claims data from the APCD to calculate the cost per user for storing reproductive tissue. The average cost per user was calculated from 2018 APCD claim data using amounts paid. The costs per user were projected over the analysis period using the long-term average national projection for cost increases to physician services (4.6%).[17] The annual per-user storage costs are reflected in Table 6.

Table 6: Estimated 2018 Annual Paid Cost Per User for Storing Reproductive Tissue

SCENARIOS	2018	2022	2023	2024	2025	2026
Men						
Low Scenario	$155	$185	$194	$203	$212	$222
Mid Scenario	$165	$197	$206	$215	$225	$235
High Scenario	$175	$209	$219	$229	$239	$250
Women						
Low Scenario	$135	$161	$169	$177	$185	$193
Mid Scenario	$145	$173	$181	$190	$198	$207
High Scenario	$155	$185	$194	$203	$212	$222

Next, BerryDunn determined the total number of annual users. BerryDunn added the current number of users to the estimated number of new users to get the total number of users under the proposed bill. Results are shown in Table 7.

Table 7: Estimated Total Users

SCENARIOS	CURRENT USERS	NEW USERS	TOTAL USERS
Men			
Low Scenario	24	0	24
Mid Scenario	24	27	51
High Scenario	24	61	85
Women			
Low Scenario	124	0	124
Mid Scenario	124	28	152
High Scenario	124	53	177

Based on available literature, the length of time that men store reproductive tissue varies. A 2014 study found that the average storage time among men being treated for testicular cancer was about two years.[18] Another study, published in 2019, found that the median storage time was eight-and-a-half years.[19] BerryDunn assumed that the average total storage time in the low scenario would be two years, five years in the middle scenario, and eight years in the high scenario.

Literature documenting average storage time for women also suggests a broad range. Research by Druckenmiller et al. (2016) found that the median storage time for cancer-surviving women was about two years.[20] A 2019 paper conversely found that 11 patients (4.5%) returned in order to use their oocytes after an average interval of 3.4 years. However, at the time of publication, 95.7% of the oocytes retrieved were still in storage.[21] Since the beginning of treatment was between January 2001 and March 2019, it is possible that some oocytes might have been stored up to

18 years. BerryDunn assumed that the average total storage time in the low scenario would be two years, five years in the middle scenario, and eight years in the high scenario.

Based on the APCD and the carrier surveys, the current average storage time covered by carriers is one year. BerryDunn subtracted the current average storage time from the projected average storage times to calculate the incremental storage years, which are one, four, and seven years in the low, middle, and high scenarios, respectively. The number of users will increase over time as new users store reproductive tissue. BerryDunn projected the number of users over the analysis period by taking into account the number of new users per year and the average storage time. Results are shown in Table 8.

Table 8: Total Users Per Year Storing Reproductive Tissue

SCENARIOS	2022	2023	2024	2025	2026
Men					
Low Scenario	24	24	24	24	24
Mid Scenario	51	102	153	204	204
High Scenario	85	170	255	340	425
Women					
Low Scenario	124	124	124	124	124
Mid Scenario	152	304	304	304	304
High Scenario	177	354	531	708	885

BerryDunn then multiplied the total number of users each year from Table 8 by the annual storage cost per user in Table 6 to determine the annual incremental cost. Table 9 presents these results.

Table 9: Cost to Remove Storage Limit of Reproductive Tissue

	2022	2023	2024	2025	2026
Men					
Low Scenario	$4,449	$4,652	$4,865	$5,088	$5,321
Mid Scenario	$10,041	$21,000	$32,941	$45,931	$48,032
High Scenario	$17,790	$37,207	$58,364	$81,379	$106,378
Women					
Low Scenario	$20,020	$20,936	$21,894	$22,896	$23,943
Mid Scenario	$26,359	$55,129	$57,651	$60,289	$63,047
High Scenario	$32,811	$68,624	$107,645	$150,093	$196,200
Total					
Low Scenario	$24,469	$25,589	$26,759	$27,983	$29,264
Mid Scenario	$36,399	$76,129	$90,592	$106,219	$111,079
High Scenario	$50,600	$105,831	$166,009	$231,472	$302,577

BerryDunn divided the total annual incremental cost for new users by the total membership in order to calculate the incremental PMPM. Results are located in Table 10.

Table 10: Estimated Incremental PMPM Cost to Remove Storage Limits

	2022	2023	2024	2025	2026
Low Scenario	$0.001	$0.001	$0.001	$0.001	$0.001
Mid Scenario	$0.001	$0.003	$0.004	$0.004	$0.005
High Scenario	$0.002	$0.004	$0.007	$0.010	$0.012

Section 5.4 combines the costs of two incremental components of the proposed bill.

5.4 Combined Incremental Cost

Calculating combined incremental costs to insurers to cover preserving fertility services for new users and removal of storage time limits on reproductive tissue

Adding together the estimated PMPM costs associated with the additional users and removing limits on storing reproductive tissue (from Tables 5 and 10) yields the total PMPM incremental cost, shown in Table 11.

Table 11: Estimated Incremental PMPM Cost of Preserving Fertility Services

	2022	2023	2024	2025	2026
Low Scenario	$0.001	$0.001	$0.001	$0.001	$0.001
Mid Scenario	$0.013	$0.015	$0.016	$0.017	$0.018
High Scenario	$0.025	$0.029	$0.032	$0.036	$0.041

5.5 Projected Fully Insured Population in the Commonwealth

Table 12 presents the projected fully insured population in the Commonwealth (ages 0 – 64) from 2022 through 2026. Appendix A describes the projection methodology and sources of these values.

Table 12: Projected Fully Insured Population in the Commonwealth, Ages 0 – 64

2022	2023	2024	2025	2026
2,014,007	2,010,132	2,006,510	2,003,142	1,999,776

5.6 Total Incremental Medical Expense

Multiplying the total estimated PMPM cost by the projected fully insured membership over the analysis period (2022 – 2026) results in the total cost (medical expense) associated with the proposed requirement, as shown in Table 13. BerryDunn's analysis assumes the bill, if enacted, would be effective on January 1, 2022.[x]

Table 13: Estimated Incremental Cost of Preserving Fertility

	2022	2023	2024	2025	2026
Low Scenario	$17,550	$25,405	$26,520	$27,686	$28,904
Mid Scenario	$222,478	$360,740	$388,371	$417,787	$436,869
High Scenario	$442,348	$694,717	$781,945	$875,603	$975,348

[x] The analysis assumes the mandate would be effective for policies issued and renewed on or after January 1, 2022. Based on an assumed renewal distribution by month, by market segment, and by the Commonwealth market segment composition, 72.1% of the member months exposed in 2022 will have the proposed mandate coverage in effect during calendar year 2022. The annual dollar impact of the mandate in 2022 was estimated using the estimated PMPM and applying it to 72.1% of the member months exposed.

5.7 Carrier Retention and Increase in Premium

Carriers include their retention expense in fully insured premiums. Retention expense includes general administration, commissions, taxes, fees, and contribution to surplus or profit. Assuming an average retention rate of 14.9% based on CHIA's analysis of fully insured premium retention in the Commonwealth,[22] the increase in medical expense was adjusted upward to approximate the total impact on premiums shown in Table 14.

Table 14: Estimate of Increase in Carrier Premium Expense

	2022	2023	2024	2025	2026
Low Scenario	$20,621	$29,851	$31,160	$32,531	$33,962
Mid Scenario	$261,412	$423,869	$456,336	$490,899	$513,321
High Scenario	$519,758	$816,291	$918,784	$1,028,832	$1,146,032

6.0 Results

The estimated impact of the proposed requirement on medical expense and premiums is explained in Section 6.1 and summarized on the following page in Table 15. The analysis includes development of a best estimate "mid-level" scenario, as well as a low-level scenario using assumptions that produced a lower estimate, and a high-level scenario using more conservative assumptions that produced a higher estimated impact.

The impact on premiums is driven by the provisions of the bill that require carriers to cover preserving fertility services with no limits on the time reproductive tissue is stored. Variation between scenarios is attributable to the uncertainty surrounding the cost per user for preserving fertility services, the increased adoption rate of preserving fertility services, and the average annual storage time for reproductive tissue.

6.1 Five-Year Estimated Impact

Table 15 presents the projected net impact of the bill on medical expense and premiums for each year over the 2022 – 2026 period using a projection of Commonwealth fully insured membership. The low scenario would result in $31,000 per year on average. It assumes a cost per user of $7,000 per year for women and $700 per year for men, that no additional men or women will adopt a preserving fertility benefit, and an additional one year of reproductive tissue storage for men and women. The high scenario's projected impact is $938,000 and assumes a cost per user of $8,000 per year for women and $900 per year for men, that an additional 36% of men and 15% of women will adopt preserving fertility services, and an additional seven years of reproductive tissue storage time for men and women. The mid scenario would result in average annual costs of $455,000, or an average of 0.003% of premiums. It assumes a cost per user of $7,500 per year for women and $800 per year for men, that an additional 16% of men and 8% of women will adopt preserving fertility services, and an additional four years of reproductive storage for men and women.

The impact of the proposed law on any one individual, employer group, or carrier might vary from the overall results, depending on the current level of benefits each receives or provides and on how benefits would change under the proposed language.

Table 15: Summary Results

	2022	2023	2024	2025	2026	WEIGHTED AVERAGE	FIVE-YEAR TOTAL
Members (000s)	2,014	2,010	2,007	2,003	2,000		
Medical Expense Low ($000s)	$18	$25	$27	$28	$29	$27	$126
Medical Expense Mid ($000s)	$222	$361	$388	$418	$437	$387	$1,826
Medical Expense High ($000s)	$442	$695	$782	$876	$975	$799	$3,770
Premium Low ($000s)	$21	$30	$31	$33	$34	$31	$148
Premium Mid ($000s)	$261	$424	$456	$491	$513	$455	$2,146
Premium High ($000s)	$520	$816	$919	$1,029	$1,146	$938	$4,430
PMPM Low	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
PMPM Mid	$0.02	$0.02	$0.02	$0.02	$0.02	$0.02	$0.02
PMPM High	$0.03	$0.03	$0.04	$0.04	$0.05	$0.04	$0.04
Estimated Monthly Premium	$590	$617	$645	$674	$704	$646	$646
Premium % Rise Low	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
Premium % Rise Mid	0.003%	0.003%	0.003%	0.003%	0.003%	0.003%	0.003%
Premium % Rise High	0.005%	0.005%	0.006%	0.006%	0.007%	0.006%	0.006%

The total projected medical expense and premium dollars are calculated using PMPM results and the projected fully insured membership from 2022 – 2026. Due to the impact of COVID-19 on the economy, there is a great deal of uncertainty around the anticipated level of commercial fully insured membership over the next five years. BerryDunn is conservatively assuming economic recovery by 2022. Please refer to Appendix A for additional discussion on the membership projection.

6.2 Impact on the GIC

Effective July 1, 2018, all GIC plans were converted to self-insured funding. BerryDunn assumes that the proposed legislative change would apply to self-insured plans operated for state and local employees, with an effective date for all GIC policies on July 1, 2022.

GIC benefit offerings are similar to most other commercial plans in the Commonwealth. Responses to carrier surveys for this study confirmed that coverage is similar for preserving fertility services, as well. Therefore, BerryDunn assumed that the estimated incremental PMPM of the proposed legislative language on GIC medical expense will not differ from that calculated for the other fully insured plans in the Commonwealth.

To estimate the medical expense separately for the GIC, the PMPM medical expense for the general fully insured population was applied to the GIC membership starting in July 2022.

Table 16 breaks out the GIC self-insured membership, as well as the corresponding incremental medical expense. Finally, the proposed legislative requirement is assumed to require the GIC to implement the provisions on July 1, 2022; therefore, the results in 2022 are approximately one-half of an annual value.

Table 16: GIC Summary Results

	2022	2023	2024	2025	2026	WEIGHTED AVERAGE	FIVE-YEAR TOTAL
GIC Self-Insured							
Members (000s)	313	312	312	311	311		
Medical Expense Low ($000s)	$2	$4	$4	$4	$4	$4	$19
Medical Expense Mid ($000s)	$24	$56	$60	$65	$68	$61	$273
Medical Expense High ($000s)	$48	$108	$122	$136	$151	$126	$565

Endnotes

[1] The 192nd General Court of the Commonwealth of Massachusetts. H.B. 1116 and S.B. 640, "An Act relative to preserving fertility." Accessed 19 April 2021: **https://malegislature.gov/Bills/192/H1116** and **https://malegislature.gov/Bills/192/S640**. These bills were submitted in the 191st General Court of the Commonwealth of Massachusetts as H.B. 1004 and S.B. 560, both titled "An Act relative to preserving fertility." Accessed 2 December 2020: **https://malegislature.gov/Bills/191/H1004** and **https://malegislature.gov/Bills/191/S560**.

[2] Op. cit. The 192nd General Court of the Commonwealth of Massachusetts, House Bills 1116 and Senate Bill 640, "An Act relative to preserving fertility."

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Appendix A: Membership Affected by the Proposed Language

Membership potentially affected by proposed mandated change criteria includes Commonwealth residents with fully insured, employer-sponsored health insurance issued by a Commonwealth-licensed company (including through the GIC); nonresidents with fully insured, employer-sponsored insurance issued in the Commonwealth; Commonwealth residents with individual (direct) health insurance coverage; and lives covered by GIC self-insured coverage.

Please note these are unprecedented economic circumstances due to COVID-19, which makes the estimation of membership extremely challenging. The membership projections are used to determine the total dollar impact of the proposed mandate in question; however, variations in the membership forecast will not affect the general magnitude of the dollar estimates. As such, given the uncertainty, BerryDunn took a simplified approach to the membership projections as described below. These membership projections are not intended to be used for any other purpose than producing the total dollar range in this study. Further, to assess how recent volatility in commercial enrollment levels might affect these cost estimates, please note that the PMPM and percentage of premium estimates are unaffected because they are per-person estimates, and the total dollar estimates will vary by the same percentage as any percentage change in enrollment levels.

The 2018 Massachusetts APCD formed the base for the projections. The Massachusetts APCD provided fully insured membership by insurance carrier. The Massachusetts APCD was also used to estimate the number of nonresidents covered by a Commonwealth policy. These are typically cases in which a nonresident works for a Commonwealth employer that offers employer-sponsored coverage. Adjustments were made to the data for membership not in the Massachusetts APCD, based on published membership reports available from CHIA and the Massachusetts Department of Insurance (DOI).

CHIA publishes monthly enrollment summaries in addition to its biannual enrollment trends report and supporting databook (enrollment-trends-March-2020-databook[1] and Monthly Enrollment Summary – August 2020[2]), which provides enrollment data for Commonwealth residents by insurance carrier for most carriers. (Some small carriers are excluded.) CHIA uses supplemental information beyond the data in the Massachusetts APCD to develop its enrollment trends report. The supplemental data was used to adjust the resident totals from the Massachusetts APCD. In 2020, commercial, fully insured membership is 2.9% less than in 2019 with a shift to both uninsured and MassHealth coverage. The impact of COVID-19 on fully insured employers over the five-year projected period is uncertain. BerryDunn took a high-level conservative approach and assumed that membership would revert to 2019 levels by January 1, 2022.

The DOI published reports titled Quarterly Report of HMO Membership in Closed Network Health Plans as of December 31, 2018[3] and Massachusetts Division of Insurance Annual Report Membership in MEDICAL Insured Preferred Provider Plans by County as of December 31, 2018.[4] These reports provide fully insured covered members for licensed Commonwealth insurers where the member's primary residence is in the Commonwealth. The DOI reporting includes all insurance carriers and was used to supplement the Massachusetts APCD membership for small carriers not in the Massachusetts APCD.

The distribution of members by age and gender was estimated using Massachusetts APCD population distribution

ratios and was checked for reasonableness and validated against U.S. Census Bureau data.[5] Membership was projected from 2019 – 2026 using Massachusetts Department of Transportation population growth rate estimates by age and gender.[6]

Projections for the GIC self-insured lives were developed using the GIC base data for 2018 and 2019, that BerryDunn received directly from the GIC, as well as the same projected growth rates from the Census Bureau that were used for the Commonwealth population. Breakdowns of the GIC self-insured lives by gender and age were based on the Census Bureau distributions.

Appendix A Endnotes

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[3] Massachusetts Department of Insurance. HMO Group Membership and HMO Individual Membership Accessed 12 November 2020: **https://www.mass.gov/doc/group-members/download**; https://www.mass.gov/doc/individual-members/download.

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