California Health Benefits Review Program

Analysis of California Senate Bill 172
Fertility Preservation

A Report to the 2017-2018 California State Legislature  April 13, 2017
Key Findings:
Analysis of California Senate Bill 172
Fertility Preservation
Summary to the 2017-2018 California State Legislature, April 13, 2017.

CONTEXT
Iatrogenic infertility is medically induced infertility caused by a medical intervention that treats a primary disease or condition.\(^1\) If a patient anticipates a treatment that could increase the risk of iatrogenic infertility, the patient and their provider may pursue fertility preservation services prior to the treatment. The National Cancer Institute defines fertility preservation as a type of procedure used to maintain an individual’s ability to have children.

BILL SUMMARY
As introduced (January 23, 2017), Senate Bill (SB) 172 would require that individual or group health care service plans or policies shall include coverage for standard fertility preservation services when a necessary medical treatment may cause iatrogenic infertility. As amended (March 7, 2017), the bill would require coverage for evaluation and treatment of iatrogenic infertility including, but not limited to, standard fertility preservation services. The cost section of this report estimates impacts of both the introduced and amended language. However, the rest of the report reflects only the language as introduced.

Key Assumption and Focus on Cancer-Related Iatrogenic Infertility
Iatrogenic infertility is most commonly caused by cancer treatments including radiation, chemotherapy (gonadotoxic treatments), and surgical removal of reproductive organs. Autoimmune conditions such as systemic lupus erythematosus, rheumatoid arthritis, or Crohn’s disease sometimes require gonadotoxic or surgical treatments. However, exposure doses to

\(^1\) Refer to CHBRP’s full report for full citations and references.
potentially iatrogenic treatments are lower for autoimmune conditions than for cancer. Also, gonadotoxic treatments are often first-line therapy for patients with cancer, but not for patients with autoimmune diseases. Individuals with who are transgender may also experience gonadotoxic treatments.

For this analysis, CHBRP focuses on iatrogenic infertility attributable to cancer treatments due to the higher prevalence of cancer (and concordant volume of literature), which outweighs that of the aforementioned conditions.

**IMPECTS**

**Benefit Coverage, Utilization, and Cost**

For full impacts for both the language as introduced and the amended bill language, see the full Benefit Coverage, Utilization and Cost section.

To determine the baseline utilization, CHBRP analyzed incidence rates from the most recent CDC data available of the top 10 cancers using treatments that put patients at risk of iatrogenic infertility. These incidence rates represent the population with newly diagnosed cancers, the population CHBRP assumed would potentially seek fertility preservation services prior to gonadotoxic treatment. Utilization was estimated only for females aged 12 to 44 and males aged 12 to 49, as those are the appropriate ages in which the risk of iatrogenic infertility could occur.

At baseline, 85% of enrollees with health insurance that would be subject to SB 172 have coverage that is mandate compliant for fertility preservation coverage (13.7 million), with at least one fertility preservation service included for enrollees (for each gender). CHBRP assumes that benefit coverage for fertility services among enrollees in DMHC-regulated plans or CDI-regulated policies would increase to 100%.

**Utilization**

At baseline, CHBRP estimates that 85% of enrollees with health insurance subject to SB 172 have coverage for fertility preservation at baseline with 7,589 cancer patients at risk of iatrogenic infertility. The number of cancer patients remains the same postmandate; however, the number using fertility preservation services would increase from 1,452 enrollees to 1,887 enrollees postmandate in the first year postmandate. These additional 435 cancer patients using fertility preservation (219 males and 216 females) are comprised of the previously uncovered enrollees using services (121 males and 65 females) as well as an assumed 10% increase in service use among previously covered enrollees due to new provider and public awareness of fertility preservation coverage.

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**Figure 1. Health Insurance in CA and SB 172**

*Such as enrollees in Medi-Cal, Medicare or self-insured products
Source: California Health Benefit Review Program, 2017

**Benefit Coverage**

CHBRP considered benefit coverage to be mandate compliant if enrollees were covered for at least one fertility preservation service (see Appendix C for a complete list of services included in the model). Benefit coverage that only included a fertility preservation service for either men or women (but not both) was not considered to be fully mandate compliant.
Expenditures

Figure 2. Expenditure Impacts of SB 172 (Language As Introduced)
Expenditures by Category Postmandate, SB 172
Net Change: $2,197,000

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Employer Premiums</td>
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<td>Individual Premiums</td>
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<td>Enrollee Out-of-Pocket Expenses for Covered Benefits</td>
<td>$127,000</td>
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<tr>
<td>Enrollee Expenses for Non-Covered Benefits</td>
<td>-$956,000</td>
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SB 172 as introduced would increase total net annual expenditures by $2,197,000 or 0.0015% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a $3,153,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a $956,000 decrease in enrollee expenses for covered and/or noncovered benefits.

Under the amended language, SB 172 would increase total net annual expenditures by $6,001,000 or 0.041% for enrollees with DMHC-regulated plans and CDI-regulated policies. For a corresponding figure of the amended language’s expenditures impacts by category, see the Benefit Coverage, Utilization and Cost Impacts section.

Medi-Cal

SB 172 would have no projected impact on Medi-Cal as the bill does not apply to Medi-Cal. Among publicly funded DMHC-regulated health plans, there would be no impact for Medi-Cal managed care plans.

CalPERS

CalPERS managed care plans are estimated to have a $0.0068 increase in premiums under the bill language as introduced, and a $0.0300 increase in premiums under the amended language.  

Number of Uninsured in California

CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 172.

Medical Effectiveness

CHBRP summarized the effectiveness of specific fertility preservation services. Eight of these services are considered standard of care and would be covered under SB 172: embryo cryopreservation, oocyte (egg) cryopreservation, sperm cryopreservation, ovarian transposition (oophoropexy), ovarian shielding during radiation therapy, testicular shielding during radiation therapy, and conservative surgical approaches for gynecologic cancers (conservative ovarian cancer surgery and radical trachelectomy [surgical removal of the uterine cervix]).

Nonexperimental Fertility Preservation for Females

Fertility preservation options in females depend on many factors such as patient age, type of cancer diagnosis, prescribed cancer treatment, the length of time the patient can wait before starting cancer treatment, and whether the cancer has metastasized to the patient’s ovaries. Personal factors such as if the patient has a partner, cultural background, and religious beliefs can also influence fertility preservation decisions.

The review found limited evidence that embryo cryopreservation and oocyte (egg) cryopreservation (freezing) are effective methods of fertility preservation measured by three different outcomes: successful thawing of embryos or oocytes; successful implantation of embryos or oocytes; and resulting live births.

The following services are typically performed in conjunction with or as a part of cancer treatment. CHBRP...
Key Findings: Analysis of California Senate Bill 172

found limited evidence that ovarian transposition (surgery to move ovaries out of the field of radiation) is effective in maintaining ovarian function among women undergoing radiation as part of their cancer treatment. There is insufficient evidence that ovarian shielding (decreasing radiation to ovaries) during radiation therapy is an effective method of fertility preservation. A grade of insufficient evidence indicates that there is not enough evidence available to know whether or not a treatment is effective — it does not indicate that a treatment is not effective.

There is limited evidence that trachelectomy (surgical removal of the uterine cervix) and conservative ovarian surgery are effective surgeries in preserving fertility preservation measured by pregnancy rates and live births. There is a preponderance of evidence that trachelectomy and conservative ovarian surgery have no apparent increase in cancer recurrence or mortality for specific cases.

Nonexperimental Fertility Preservation for Males

For males, sperm cryopreservation is the most established technique for maintaining fertility. The review found that there is limited evidence that sperm cryopreservation is an effective method of fertility preservation as measured by pregnancy rates and live births. There is insufficient evidence that testicular shielding is an effective method of fertility preservation in males. A grade of insufficient evidence indicates that there is not enough evidence available to know whether or not a treatment is effective — it does not indicate that a treatment is not effective.

The summary of the literature on fertility preservation described in this report was graded as being of “limited evidence.” A grade of limited evidence indicates that the studies had limited generalizability to the population of interest because they were not limited to cancer patients and/or the studies had a flaw in research design or implementation due to being observational in nature.

Public Health

Quality of Life

Loss of fertility can negatively impact the quality of life for cancer survivors of reproductive age, including unresolved grief, depression, and anxiety. A systematic review was identified regarding the psychosocial and quality of life effects on female cancer patients undergoing fertility preservation. It concluded that those who received counseling and services (for those who chose fertility preservation) experienced reduced regret and dissatisfaction about fertility outcomes.

Based on this and other literature, CHBRP finds that SB 172 would likely improve the quality of life by reducing regret about fertility outcomes, dissatisfaction, and distress for the additional estimated 435 enrollees newly using fertility preservation services in the first year postmandate.

Barriers to Access

SB 172 could potentially increase the rate of physician referrals for fertility counseling and preservation by providing coverage for such services and reducing out-of-pocket costs for patients experiencing iatrogenic infertility. Broader insurance coverage might also remove cost as a provider-perceived barrier.

Impact on Disparities by Sex

In California, females have twice the rate of cancers with treatments causing iatrogenic infertility as males; furthermore, females pay 12 times more for uncovered fertility preservation services than males. Postmandate, SB 172 would decrease the gender disparity by reducing the female financial burden of fertility preservation services. However, CHBRP estimates that some females would still face greater out-of-pocket expense burdens than males, postmandate, due to differences in costs of sex-specific preservation methods.

Long-term Impacts

Utilization and Cost Impacts

Postmandate, CHBRP estimates that SB 172 would increase utilization of fertility preservation services among enrollees with cancer by an additional 435 people during the first year. This estimate is based on an annual incidence rate of the top 10 cancers, and will likely remain constant per annum over the long term as long as the incidence rates also remain constant.

In the long term, these fertility preservation services will lead to some increased utilization of infertility services to achieve pregnancy among the affected enrollees. Research indicates that the percentage of people using
their frozen embryos, oocytes, or sperm is in a range of less than 5% of those who use fertility preservation.

**Essential Health Benefits and the Affordable Care Act**

It is unclear whether SB 172 (bill language as introduced) would exceed EHBs. In some cases, fertility preservation services may be considered a medically necessary component of a service that falls within the EHBs such as chemotherapy treatment for cancer. Also, fertility preservation services for iatrogenic infertility occur before a patient experiences infertility. Thus, fertility preservation is distinct from infertility treatment, which is not included in the state’s benchmark plan.

However, the amended bill language could be interpreted to exceed the EHBs, because the amended language requires coverage of the “evaluation and treatment of iatrogenic infertility.” The treatment of iatrogenic infertility could be interpreted to include a larger range of services beyond fertility preservation services, including infertility treatment. Infertility treatment is a coverage exclusion in the state’s EHB benchmark plan. Therefore, the amended bill language could be interpreted to exceed the EHBs.