Key Findings

Analysis of California Senate Bill 974
Breast Imaging

Summary to the 2021–2022 California State Legislature, April 14, 2022

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

AT A GLANCE

The version of California Senate Bill 974 analyzed by CHBRP would require coverage for breast imaging and would prohibit some cost sharing. In 2023, of the 22.8 million Californians enrolled in state-regulated health insurance, 100% would have insurance subject to SB 974.

Benefit Coverage: Although cost sharing is not always applied for breast imaging, at baseline, 35% of enrollees have fully compliant benefit coverage. Postmandate, all100% would. The mandate, which would impact cost sharing, but not require new benefit coverage, would not be likely to exceed essential health benefits (EHBs).

Medical Effectiveness: Mammography for primary screening has been widely recognized as effective for more than 25 years. There is a preponderance of evidence that digital breast tomosynthesis (DBT) and breast magnetic resonance imaging (MRI) are effective for increased detection of breast cancer when used in a supplemental role. There is limited evidence that ultrasound is effective for the increased detection of breast cancer when used in a supplemental role. There is clear and convincing evidence that DBT and MRI are effective (sensitivity and specificity) for the diagnosis of breast cancer. The evidence is inconclusive regarding the risks and harms associated with supplementary screening imaging for breast cancer.

Cost and Health Impacts[1]: In 2023, total net annual expenditures would increase by $43,742,000 (0.0293%). SB 974 would result in 38,226 more enrollees using (or using additional) breast imaging. These would be produce many negative results (no cancer detected), some false-positive readings, and a small number of early cancer detections. Measurable impacts at population-level morbidity and mortality are unlikely, though some persons could experience improved outcomes after early detection and some could experience more adverse events after false-positive results.

CONTEXT

The various types of breast imaging are generally used for the purposes described below.

- **Primary screening** exams are conducted for a people at risk for breast cancer, but who are asymptomatic. For primary screening, mammography is the generally used type of breast imaging.
- **Supplemental screening** exams are conducted for people who have been determined to be at high risk for breast cancer, but who are asymptomatic. Supplemental screening may occur intermittently between or in conjunction with primary screening mammography.
- **Diagnostic** exams are conducted for people with symptoms of disease or abnormal results on clinical exams or screening tests. Please note, although clinical terminology often refers to imaging used for this purpose as “diagnostic,” breast cancer is actually diagnosed based on examination of breast tissue by a pathologist, usually after a biopsy.

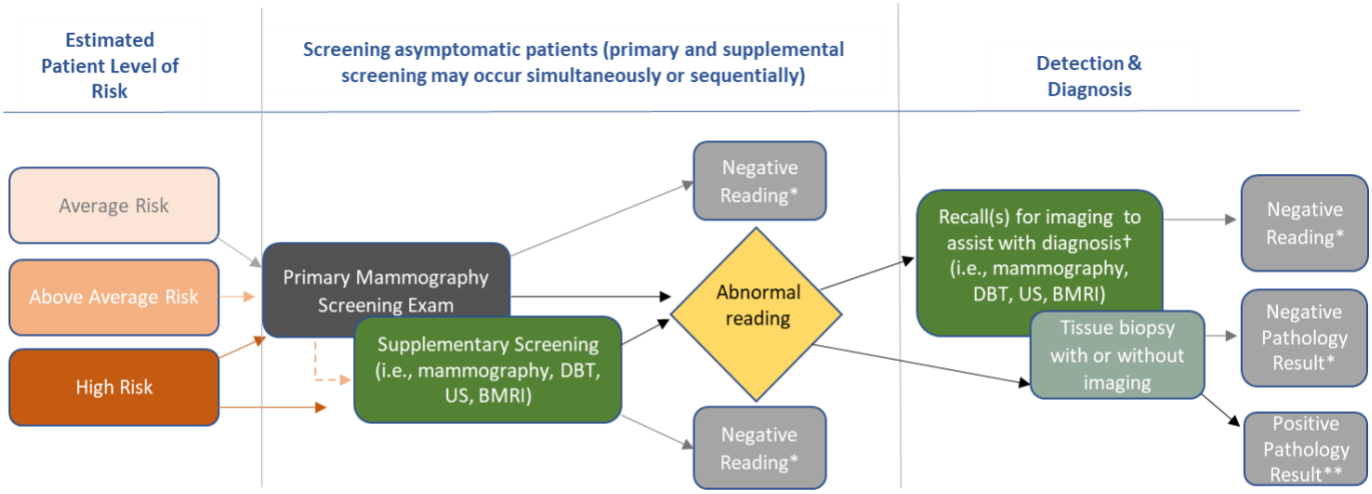
Primary and supplemental screening guidelines are generally organized according to lifetime risk of breast cancer. Guidelines generally recommend primary screening mammography for women beginning at age 40 years (with provider consultation) or age 50 and continuing through age 74.There is less consensus on supplemental screening. Most guidelines recommend supplemental screening for women at highest risk, but guidelines differ as to which category of risk, as well as to the frequency of and which types of breast imaging that should be used. Guidelines generally recommend against supplemental screening for people with dense breast tissue.

The types of breast imaging used include mammography, breast magnetic resonance imaging (MRI), digital breast tomosynthesis (DBT), and breast ultrasound.

Figure A describes the paths breast cancer screening and diagnosis may take.

[1] Similar cost and health impacts could be expected for the following year, though possible changes in medical science and other aspects of health make stability of impacts less certain as time goes by.

Figure A. Breast Cancer Screening and Diagnostic Pathways Based on Estimated Patient Level of Risk



Notes: **Green** shapes indicate which breast imaging is subject to SB 974. *Average risk* patients are not recommended for supplementary screening; *above average risk* patients may be recommended for supplemental screening (denoted by dotted arrow), such as some women with dense breast tissue. *High risk* patients are commonly recommended for both primary and supplemental screening. †Imaging detects lesions and diagnosis occurs through tissue biopsy and pathology review.
DBT: digital breast tomosynthesis; **US**: Ultrasound; **BMRI**: Breast magnetic resonance imaging.
* cancer not detected; **cancer detected.

Source: California Health Benefits Review Program, 2022.

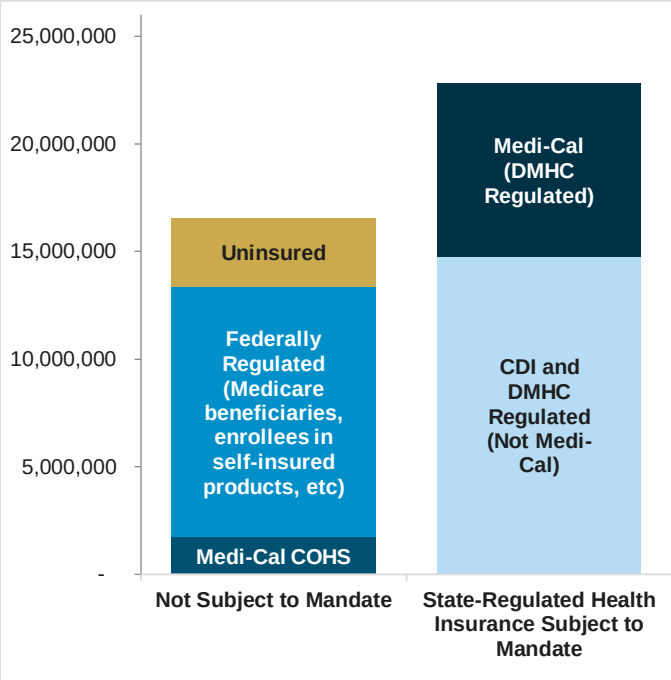
Key: BMRI = beast magnetic resonance imaging; DBT = digital breast tomosynthesis; MRI = magnetic resonance imaging; US = ultrasound.

BILL SUMMARY

SB 974 would amend California's current mammography benefit mandate, which applies to the benefit coverage of enrollees in plans and policies regulated by the Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI). SB 974, as well as requiring coverage for breast imaging (including, but not limited to, primary screening mammography) would, as described in the bullets below, establish some cost-sharing prohibitions.

- For women aged 40-74 years, SB 974 would prohibit cost sharing for all medically necessary breast imaging when used for any of the following purposes: (1) diagnostic or (2) primary screening for those not known to be at higher risk, or (3) supplemental screening for those at high risk for breast cancer. For this age group, SB 974 would expand an existing federal prohibition on cost sharing for primary screening mammography to also prohibit cost sharing for supplemental screening and diagnostic breast imaging.
- For others, women and men, at high risk for breast cancer, SB 974 would create a new cost-sharing prohibition for all medically necessary breast imaging when used for either of the following purposes: (1) diagnostic or (2) supplemental screening for those at high risk for breast cancer.
- For others, women and men, not known to be at higher risk, SB 974 would create a cost-sharing prohibition for all medically necessary breast imaging when used for diagnostic purposes.

Figure B. Health Insurance in CA and SB 974



Source: California Health Benefits Review Program, 2022.

Key: CDI = California Department of Insurance; DMHC = Department of Managed Health Care; COHS = County Organized Health System.

ANALYTIC APPROACH

As noted above, a federal mandate already prohibits cost sharing for primary screening mammography for women aged 40-74 years. Because primary screening mammography is only recommended for this group, SB 974 is expected to have no impact on the use of breast imaging for primary screening. Therefore, this report is focused on supplemental screening and diagnostic use of breast imaging.

IMPACTS

Medical Effectiveness

Although primary screening is not the focus of this analysis, it seems appropriate to note that the medical effectiveness of mammography for primary screening has been widely recognized in the United States and abroad for more than 25 years.

There is a *preponderance of evidence*[2] that DBT and breast MRI are effective for increased detection of breast cancer when used in a supplemental role.

There is *limited evidence*[3] that ultrasound is effective for the increased detection of breast cancer when used in a supplemental role.

There is *clear and convincing* evidence[4] that DBT and MRI are effective (sensitivity and specificity) for the diagnosis of breast cancer.

The evidence is *inconclusive*[5] regarding the risks and harms associated with supplementary screening imaging for breast cancer.

Benefit Coverage, Utilization, and Cost

Benefit Coverage

At baseline, 35% of enrollees with health insurance that would be subject to SB 974 have benefit coverage for breast imaging that does not include cost sharing for any breast imaging, including imaging for diagnostic and supplemental screening purposes. These are the Medi-Cal beneficiaries enrolled in California Department of Managed Health Care (DMHC)-regulated plans, who generally have no applicable cost sharing – including no applicable deductibles.

Postmandate, 100% of enrollees in DMHC-regulated plans or CDI-regulated policies would have $0 cost share for medically necessary breast imaging.

Utilization

At baseline, 942,908 enrollees have breast imaging annually. Utilization is unevenly distributed by age and gender, with services mostly utilized among women aged 50-74 years. A significant number of breast imaging services, however, are performed for enrollees who are younger or older than the clinical guidelines would indicate for population-based screening. Postmandate, utilization of breast imaging is estimated to increase by an average of 4.05% for all types of breast imaging, ranging from 0.81% to 7.01% depending on the type.

[2] *Preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

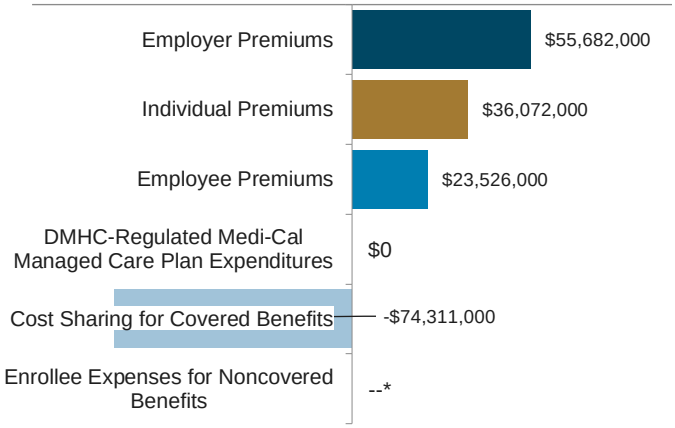
[3] *Limited evidence* indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.

[5] *Inconclusive evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

Expenditures

SB 974 would increase total net annual expenditures by $43,742,000, or 0.0293%, for commercial/CalPERS enrollees in DMHC-regulated plans and CDI-regulated policies. This is due to a $117,550,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a decrease of $73,808,000 in enrollee expenses for covered and/or noncovered benefits.

Figure C. Expenditure Impacts of SB 974



Source: California Health Benefits Review Program, 2022.

Notes: *Although benefit coverage is broad, some enrollees may have self-paid for some services. CHBRP is unable to quantify, but such expenses would be eliminated postmandate.

Cost Sharing

At baseline, for three of the types of breast imaging used for supplemental/diagnostic purposes (mammography, breast MRI, and breast ultrasound) cost sharing is present for less than half of the services, 42%, 46% and 47%, respectively. For the fourth (DBT), cost sharing is present for 7% of services.

Postmandate, all supplemental/diagnostic breast imaging would be provided without cost sharing. So SB 974 would result in an additional 38,226 enrollees to become new users of or to make additional use of supplemental/diagnostic breast imaging. As a group, these enrollees would and would see the $74 million reduction in cost sharing noted in Figure C.

The average per supplemental/diagnostic breast imaging service cost sharing that SB 974 would prohibit (for enrollees for whom cost sharing had been applicable) would be between $104.40 (for an enrollee in a large-group market plan or policy) and $212.70 (for an enrollee in an individual market plan or policy). For enrollees in plans and polices with applicable deductibles, especially those enrolled in high deductible plans and polices, the reduction in total out-of-pocket spending could be greater. Depending on the enrollee's spend towards the deductible in that plan/policy year, the enrollee could have been, at baseline, responsible for the full unit cost of the breast imaging test.

Medi-Cal

No impact would be expected on the premiums paid to enroll Medi-Cal beneficiaries in DMHC-regulated plans, as their coverage generally includes no cost sharing and so is compliant with SB 974.

CalPERS

Aggregate premiums for CalPERS would increase by $5,386,000 (0.09%)

Covered California – Individually Purchased

Aggregate premiums for all persons purchasing individual market plans and policies through Covered California would increase by $25,687,000 (0.14%).

Number of Uninsured in California

Because the change in average premiums does not exceed 1% for any market segment, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 974.

Public Health

SB 974 would produce an unknown impact on breast cancer morbidity and mortality.

An additional 38,226 enrollees would obtain an additional 91,161 breast imaging tests. Results would vary. Many would yield negative results (no cancer detected).Some would yield false-positive results that would require unnecessary recall treatment (biopsy) and costs A smaller number would yield earlier cancer detection.

The marginal impact of the earlier cancer detection is unknown, as is the marginal impact of the additional adverse events stemming from false-positives (i.e., physical pain, anxiety, added biopsy expense, and overtreatment). Measurable impacts at the population level are unlikely, though some persons could experience improved outcomes and some could experience more adverse events.

Long-Term Impacts

Assuming that current technology remains in place, utilization of breast imaging in years following the first year postmandate will be relatively stable. As in the first postmandate year, CHBRP does not anticipate long-term population-level measurable change in the annual number of cancer treatments since the additional imaging results in earlier, but not additional, diagnoses. On the person level, some persons might receive less intensive cancer treatments because cancers were identified at an earlier stage than otherwise would have occurred. However, others might experience adverse impacts due to unnecessary treatment related to false-positive imaging results.

Essential Health Benefits and the Affordable Care Act

As SB 974 would not require coverage for a new benefit, the bill appears not to exceed the definition of essential health benefits (EHBs) in California.