California Health Benefits Review Program

Analysis of California Assembly Bill 2024
Breast Imaging

A Report to the 2021–2022 California State Legislature

April 14, 2022

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Key Findings

Analysis of California Assembly Bill 2024
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 Assembly Bill 2024 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 AB 2024.

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%). AB 2024 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.

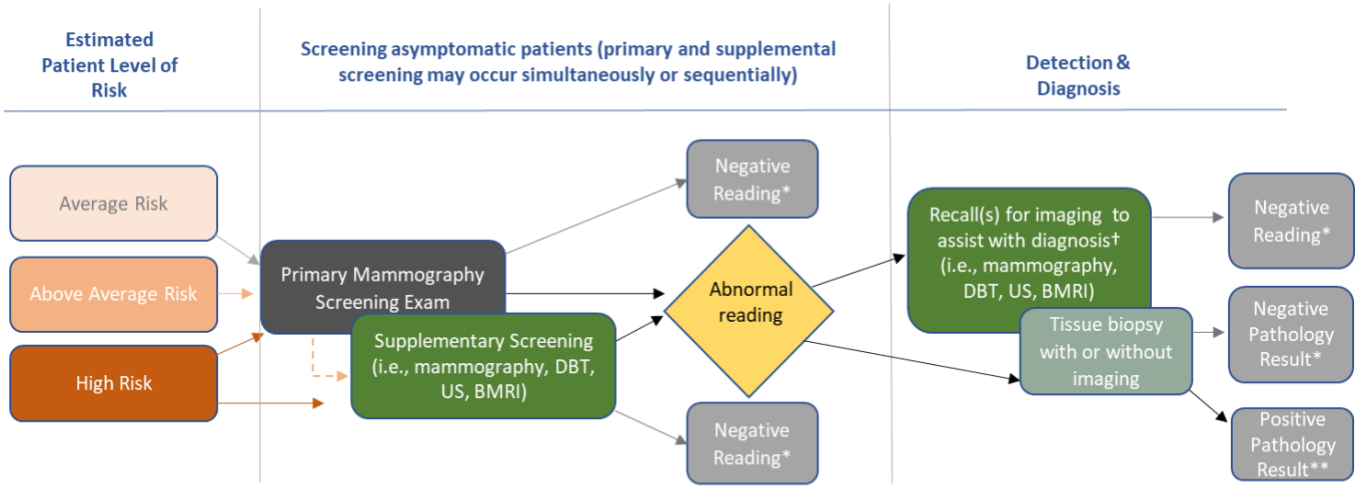
Primary and supplemental screening guidelines are generally organized according to lifetime risk of breast cancer. Guidelines generally recommend primary screening mammography for women beginning at age 40 years (with provider consultation) or age 50 and continuing through age 74.There is less consensus 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 AB 2024. *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.

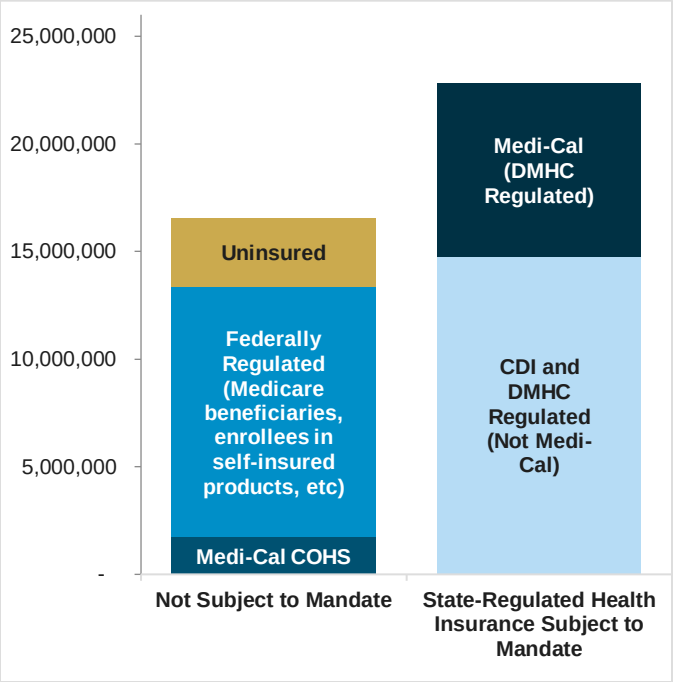
Key: BMRI = beast magnetic resonance imaging; DBT = digital breast tomosynthesis; MRI = magnetic resonance imaging; US = ultrasound.

BILL SUMMARY

AB 2024 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). AB 2024, 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, AB 2024 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, AB 2024 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, AB 2024 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, AB 2024 would create a cost-sharing prohibition for all medically necessary breast imaging when used for diagnostic purposes.

Figure B. Health Insurance in CA and AB 2024



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, AB 2024 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 AB 2024 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.

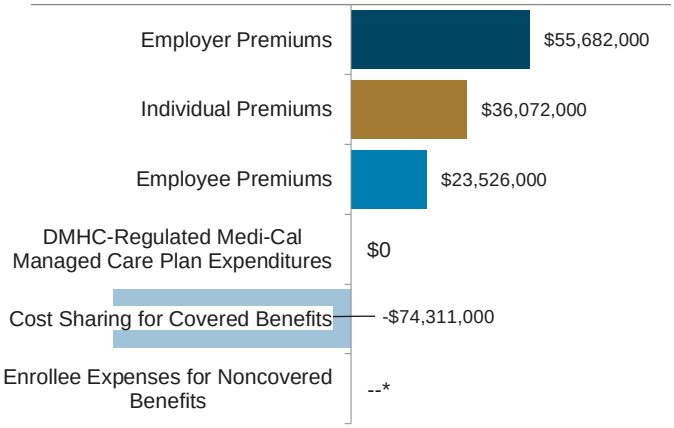
[3] *Limited evidence* indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.

[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

AB 2024 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 AB 2024



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 AB 2024 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 AB 2024 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 AB 2024.

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 AB 2024.

Public Health

AB 2024 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 AB 2024 would not require coverage for a new benefit, the bill appears not to exceed the definition of essential health benefits (EHBs) in California.

A Report to the California State Legislature

Analysis of California Assembly Bill 2024
Breast Imaging

April 14, 2022

California Health Benefits Review Program
MC 3116; Berkeley, CA 94720-3116
www.chbrp.org

Suggested Citation: *California Health Benefits Review Program (CHBRP). (2022). Analysis of California Assembly Bill 2024 Breast Imaging. Berkeley, CA.*

The California Health Benefits Review Program (CHBRP) was established in 2002. As per its authorizing statute, CHBRP provides the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit-related legislation. The state funds CHBRP through an annual assessment on health plans and insurers in California.

An analytic staff based at the University of California, Berkeley, supports a task force of faculty and research staff from multiple University of California campuses to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact. Content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications, are available at www.chbrp.org.

TABLE OF CONTENTS

Policy Context 1
Relevant Populations 1
Analytic Approach and Key Assumptions 1
Interaction With Existing State and Federal Requirements 2
Cost Sharing 4
Background on Breast Imaging 6
Breast Cancer in California 6
Screening, Supplemental, and Diagnostic Breast Imaging 8
Breast Cancer Screening and Supplemental Screening Guidelines & Recommended Populations 9
Disparities and Social Determinants of Health in Breast Cancer and Imaging Tests 10
Medical Effectiveness 12
Research Approach and Methods 14
Outcomes Assessed 14
Study Findings 15
Effectiveness of Diagnostic Imaging Techniques by Usage 15
Benefit Coverage, Utilization, and Cost Impacts 19
Baseline and Postmandate Benefit Coverage 20
Baseline and Postmandate Utilization 20
Baseline and Postmandate Per-Unit Cost 21
Baseline and Postmandate Expenditures 21
Other Considerations for Policymakers 23
Long-Term Impacts 30
Appendix A Text of Bill Analyzed A-1
Appendix B Literature Review Specifications B-1
Appendix C Cost Impact Analysis: Data Sources, Caveats, and Assumptions C-1

References
California Health Benefits Review Program Committees and Staff
Acknowledgments

LIST OF TABLES AND FIGURES

Table 1. AB 2024 on Benefit Coverage, Utilization, and Cost, 2023 x
Table 2. Types of Breast Imaging 12
Table 3. Cost Sharing, at Baseline, for Supplemental/Diagnostic Breast Imaging and Related Biopsies 20
Table 4. Baseline Average Annual Enrollee Out-of-Pocket Expenses for Enrollees With Cost Sharing by Market Segment 22
Table 5. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2023 24
Table 6. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2023 26

Figure 1. Overview of the Intersection of Cost-Sharing Methods Used in Health Insurance 5
Figure 2. Overview of Breast Cancer Screening and Diagnostic Pathways Based on Estimated Patient Level of Risk 9

Table 1. AB 2024 on Benefit Coverage, Utilization, and Cost, 2023

	Baseline (2023)	Postmandate Year 1 (2023)	Increase/ Decrease	Change Post-mandate
Benefit coverage				
Enrollees with health insurance subject to state-level benefit mandates (a)	22,810,000	22,810,000	0	0.00%
Enrollees with health insurance subject to AB 2024	22,810,000	22,810,000	0	0.00%
Total percentage of enrollees with coverage fully compliant with AB 2024	35%	100%	65%	183.92%
Utilization and cost				
Number of enrollees utilizing any **supplemental/diagnostic** breast imaging (f) and any related biopsy	942,908	981,133	38,226	4.05%
Utilization (f)				
All supplemental/diagnostic breast imaging	2,248,656	2,339,817	91,161	4.05%
Mammography	551,678	585,985	34,307	6.22%
Breast MRI	4,522	4,831	309	6.84%
Breast ultrasound	690,961	739,392	48,431	7.01%
Digital breast tomosynthesis (DBT)	1,001,494	1,009,608	8,114	0.81%
Related biopsies	78,139	83,615	5,477	7.01%
Per-unit cost (f)				
Mammography	$205.92	$205.92	—	0.00%
Breast MRI	$2,838.66	$2,838.66	—	0.00%
Breast ultrasound	$162.02	$162.02	—	0.00%
Digital breast tomosynthesis (DBT)	$80.64	$80.64	—	0.00%
Related biopsies	$786.93	$786.93	—	0.00%
Average cost sharing per service for services subject to cost sharing (f)(h)				
Mammography	$143.98	—	-$143.98	−100.00%
Breast MRI	$342.60	—	-$342.60	−100.00%
Breast ultrasound	$113.15	—	-$113.15	−100.00%
Digital breast tomosynthesis	$51.08	—	-$51.08	−100.00%
Related biopsies	$185.88	$185.88	—	0.00%
Expenditures				
Premium (expenditures) by payer				
Private employers for group insurance	$52,967,575,000	$53,019,140,000	$51,565,000	0.0974%
CalPERS HMO employer expenditures (b) (c)	$5,895,476,000	$5,900,862,000	$5,386,000	0.0914%
Medi-Cal Managed Care Plan expenditures	$25,989,411,000	$25,989,411,000	$0	0.0000%
Enrollee premiums (expenditures)				
Enrollees for individually purchased insurance	$24,029,788,000	$24,066,328,000	$36,540,000	0.1521%
Individually purchased – outside exchange	$6,324,312,000	$6,335,165,000	$10,853,000	0.1716%
Individually purchased – Covered California	$17,705,476,000	$17,731,163,000	$25,687,000	0.1451%

Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (c)	$24,504,936,000	$24,528,995,000	$24,059,000	0.0982%
Enrollee out-of-pocket expenses				
Cost sharing for covered benefits (deductibles, copayments, etc.) (g)	$15,807,011,000	$15,733,203,000	−$73,808,000	−0.4669%
Expenses for noncovered benefits (d) (e)	—	—	—	—
Total expenditures	$149,194,197,000	$149,237,939,000	$43,742,000	0.0293%

Source: California Health Benefits Review Program, 2022.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.[6]

(b) Approximately 51.7% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Enrollee premium expenditures include contributions by employees to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care.

(d) Includes only expenses paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that will be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

(e) For covered benefits, such expenses would be eliminated, although enrollees with newly compliant benefit coverage might pay some expenses if benefit coverage is denied (through utilization management review). 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.

(f) Figures for Utilization, Average Unit Cost and Average Cost Sharing exclude primary screening (mammography) and include diagnostic imaging and supplemental breast imaging for high-risk women.

(g) The net decrease in cost sharing includes, as well as a decrease in cost sharing for breast imaging, an increase in cost sharing for the increase in related biopsies related to increased utilization of breast imaging.

(h) The presence of a deductible not yet met for the plan/policy year could result in the enrollee paying the full unit cost.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HMO = Health Maintenance Organizations.

[6] For more detail, see CHBRP's *Estimates of Sources of Health Insurance in California for 2023*, a resource available at http://chbrp.org/other_publications/index.php.

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[7] conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 2024, Breast Imaging.

AB 2024 would amend California's current benefit mandate for coverage of mammography. AB 2024, 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,
    - AB 2024 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, AB 2024 would interact with a federal law. For women 40-74, the federal Preventive Services mandate, through reference to the recommendations of the Health Resources and Services Administration (HRSA, 2022), already prohibits cost sharing for primary screening mammography.[8] For this group, AB 2024 would expand and existing 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,
    - AB 2024 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,
    - AB 2024 would create a new cost-sharing prohibition for all medically necessary breast imaging when used for diagnostic purposes.

The full text of AB 2024 can be found in Appendix A.

A further discussion of cost sharing appears at the end of this section.

Relevant Populations

If enacted, AB 2024 would apply to the health insurance of approximately 22.8 million enrollees (53% of all Californians). This represents 100% of Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law, which includes health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would apply to the health insurance of all enrollees in DMHC-regulated plans and CDI-regulated policies.

Analytic Approach and Key Assumptions

As noted above, a federal mandate already prohibits cost sharing for primary screening mammography for women aged 40-74 years. As primary screening mammography is only recommended for this group, AB 2024 is expected to have no impact on the use of breast imaging for primary screening. Therefore, this report is focused on supplemental and diagnostic use of breast imaging.

[7] CHBRP's authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.
[8] More information is available in CHBRP's Resource: *Federal Preventive Services Mandates and California Mandates*, available at www.chbrp.org/other_publications/index.php.

Interaction With Existing State and Federal Requirements

Health benefit mandates may interact and align with the following state and federal mandates or provisions.

California Policy Landscape

California law and regulations

As noted, AB 2024 would amend the current benefit mandate for coverage of mammography. For the text of the current mandate, along with AB 2024's proposed amendments, see Appendix A.

Similar requirements in other states

CHBRP is aware of laws in several other states that prohibit cost sharing for some or all breast cancer–related digital imaging.

- Colorado C.R.S. 10-16-104(4)
    - Requires coverage for routine or diagnostic screening by low-dose mammography
    - Prohibits cost sharing if the imaging modality is recommended by the enrollee's provider and is within appropriate use guidelines
- Indiana I.C. Section 5-10-8-7.2
    - Requires self-insurance programs and health maintenance organizations (HMOs) providing coverage for public employees to provide breast cancer diagnostic, outpatient treatment, and rehabilitative services
    - Prohibits coverage from being subject to dollar limits, deductibles, or coinsurance provisions less favorable than those applied to general physical illness
- Michigan M.C.L. Sections 333.21054a, 500.3506d, 500.3616, 550.1416
    - Requires coverage for breast cancer diagnostic services, outpatient treatment services, and rehabilitative services
    - Prohibits dollar limits, deductibles, and coinsurance provisions from being less favorable than those for general physical illness

CHBRP is also aware of bills under consideration in several states that would have similar impacts, if passed into law.

- Arkansas 2021 Regular Session: SB 290
    - Limits cost sharing for diagnostic examinations for breast cancer, including breast MRIs, from being less favorable than cost sharing for screening examinations
- Connecticut 2022 Regular Session: SB 358
    - Requires coverage of diagnostic and screening mammograms, ultrasounds, and breast MRIs for enrollees that meet certain requirements
    - Prohibits cost sharing
- Florida 2022 Regular Session: HB 917 / SB 1052
    - Prohibits cost sharing for diagnostic mammograms, breast MRI scans, or breast ultrasounds when ordered by an enrollee's provider
- Georgia 2021-22 Regular Session: SB 487
    - Limits cost-sharing requirements for diagnostic and supplemental breast screening examinations from being less favorable than the cost-sharing requirements applicable to screening mammography for breast cancer
- Iowa 2021-22 Regular Session: SF 2164

    - Requires coverage for diagnostic breast cancer examinations
    - Limits cost sharing from exceeding that required for screening mammograms
- Kansas 2021-22 Regular Session: SB 471 / HB 2562
    - Limits cost-sharing requirements for diagnostic breast examinations and supplemental breast screening examinations from being less favorable than such requirements for screening mammography examinations for breast cancer
- Massachusetts 2021-22 Regular Session: HB 1100 / HB 1175
    - Prohibits cost sharing for benefits related to the diagnosis and treatment of breast cancer, including diagnostic mammograms, diagnostic breast ultrasounds, or breast MRIs
- Missouri 2022 Regular Session: HB 2760 / SB 1166
    - Limits plans that cover diagnostic examinations for breast cancer from imposing cost-sharing requirements that are less favorable than the cost-sharing requirements for low-dose mammography screening
- North Carolina 2021-22 Regular Session: H 703
    - Limits cost-sharing requirements applicable to diagnostic examinations for breast cancer from being less favorable than the requirements applicable to screening examinations for breast cancer
- Oklahoma 2021-22 Regular Session: HB 3504
    - Requires coverage for a low-dose mammography screening and a diagnostic examination for the presence of occult breast cancer
    - Prohibits coverage from being subject to the policy deductible, copayments, and coinsurance limits of the plan
- Virginia 2022 Regular Session: HB 1243
    - Requires that plans providing coverage for screening mammograms also provide coverage for diagnostic mammograms that is no less favorable than the coverage for screening mammograms
    - Prohibits cost sharing

Federal Policy Landscape

Affordable Care Act

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how AB 2024 may interact with requirements of the ACA as presently exist in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[9,10]

[9] The ACA requires nongrandfathered small-group and individual market health insurance – including, but not limited to, QHPs sold in Covered California – to cover 10 specified categories of EHBs. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.
[10] Although many provisions of the ACA have been codified in California law, the ACA was established by the federal government, and therefore, CHBRP generally discusses the ACA as a federal law.

Essential Health Benefits

In California, nongrandfathered[11] individual and small-group health insurance is generally required to cover EHBs.[12] In 2023, approximately 12.1% of all Californians will be enrolled in a plan or policy that must cover EHBs. [13] As AB 2024 would not require coverage for a new benefit, the bill appears not to exceed the definition of EHBs in California.

Federally Selected Preventive Services

The ACA requires that nongrandfathered group and individual health insurance plans and policies cover certain preventive services without cost sharing when delivered by in-network providers and as soon as 12 months after a recommendation appears in any of the following:[14]

- The United States Preventive Services Task Force (USPSTF) A and B recommendations;
- The Health Resources and Services Administration (HRSA)-supported health plan coverage guidelines for women's preventive services;
- The HRSA-supported comprehensive guidelines for infants, children, and adolescents, which include:
    - The Bright Futures Recommendations for Pediatric Preventive Health Care; and
    - The recommendations of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; and
- The Advisory Committee on Immunization Practices (ACIP) recommendations that have been adopted by the Director of the Centers for Disease Control and Prevention (CDC).

As previously noted, through reference to the HRSA recommendations (HRSA, 2022), the federal Preventive Services mandate prohibits cost sharing for primary screening mammography for women aged 40-74 years. However, the federal Preventive Services mandate is silent regarding cost sharing for other breast imaging.

Cost Sharing

Below is an overview of the cost-sharing structures that may be applicable for health covered benefits.

Cost Sharing

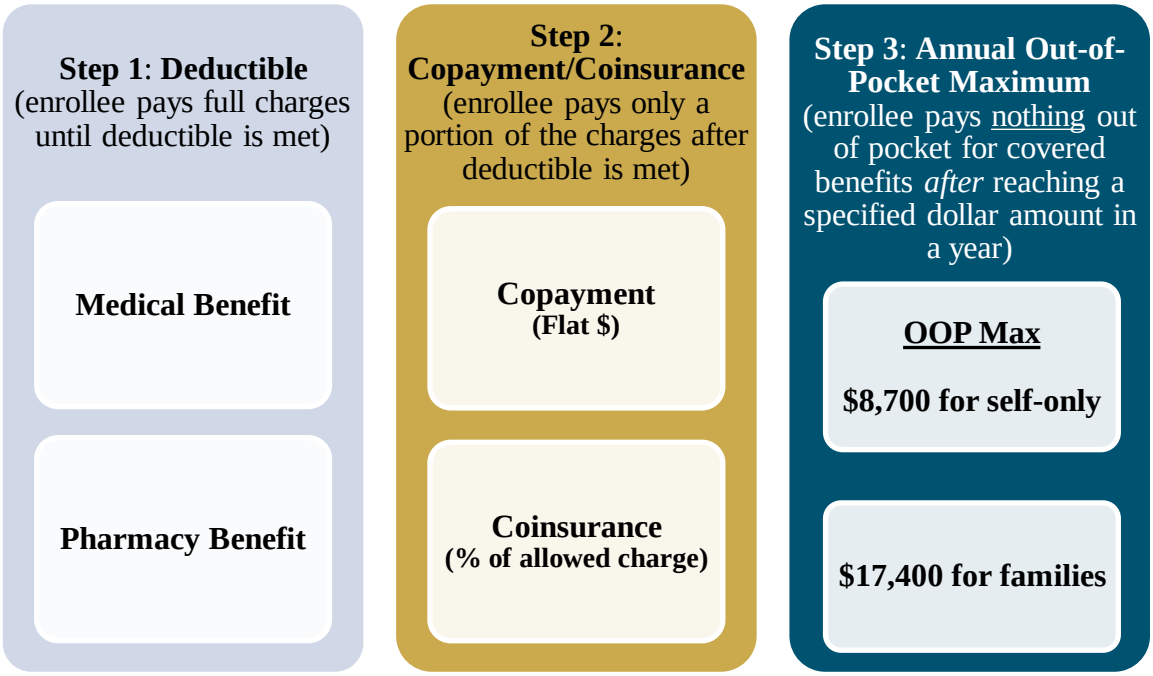
Payment for use of covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Common cost-sharing mechanisms include copayments, coinsurance, and/or deductibles (but do not include premium expenses[15]). There are a variety of cost-sharing mechanisms that can be applicable to covered benefits (**Error! Reference source not found.**). Some health insurance benefit designs incorporate higher enrollee cost sharing in order to lower

[11] A grandfathered health plan is "a group health plan that was created – or an individual health insurance policy that was purchased – on or before March 23, 2010. Plans or policies may lose their 'grandfathered' status if they make certain significant changes that reduce benefits or increase costs to consumers." Available at: www.healthcare.gov/glossary/grandfathered-health-plan.
[12] For more detail, see CHBRP's issue brief, *California State Benefit Mandates and the Affordable Care Act's Essential Health Benefits*, available at https://chbrp.org/other_publications/index.php.
[13] See CHBRP's resource, *Estimates of Sources of Health Insurance in California* and CHBRP's issue brief *California State Benefit Mandates and the Affordable Care Act's Essential Health Benefits: An Update and Overview of New Federal Regulations*, both available at https://chbrp.org/other_publications/index.php.
[14] More information is available in CHBRP's Resource: *Federal Preventive Services Mandates and California Mandates*, available at www.chbrp.org/other_publications/index.php.
[15] Premiums are paid by most enrollees, regardless of their use any tests, treatments, or services. Some enrollees may not pay premiums because their employers cover the full premium, they receive premium subsidies through the Covered California, or they receive benefits through Medi-Cal.

premiums. Reductions in allowed copayments, coinsurance, and/or deductibles can shift the cost to premium expenses or to higher cost sharing for other covered benefits.[16]

Annual out-of-pocket maximums for covered benefits limit annual enrollee cost-sharing (medical and pharmacy benefits). After an enrollee has reached this limit through payment of coinsurance, copayments, and/or deductibles, insurance pays 100% of the covered services. The enrollee remains responsible for the full cost of any tests, treatments, or services that are not covered benefits.

Figure 1. Overview of the Intersection of Cost-Sharing Methods Used in Health Insurance



Source: California Health Benefits Review Program, 2022; CMS, 2021.

Note: Steps 1 and 2 are not mutually exclusive. Under certain circumstances (i.e., preventive screenings or therapies), enrollees may pay coinsurance or copayments prior to their deductible being met; also copayments and coinsurance may be applied against the deductible in some circumstances. The figure assumes that the enrollee is in a plan with a deductible. If no deductible, then enrollee pays a coinsurance and/or a copayment beginning with the first dollar spent (Step 2).

The annual out-of-pocket maximums listed in Step 3 increase each year according to methods detailed in CMS' Notice of Benefit and Payment Parameters (CMS, 2021).

Key: OOP Max = annual out-of-pocket maximum.

Allowed Cost Amounts for Medical Services

Insurers usually negotiate how much they will pay for the costs of covered health care services with health care providers and suppliers (Center on Budget and Policy Priorities, 2018). These negotiated amounts are known as the "allowed cost amount." Health care providers, including hospitals and physicians, participating in a plan's network agree to accept these payment amounts when an enrollee covered by the plan uses covered services. The cost-sharing charges the enrollee owes (for example, a 20% coinsurance rate) are based on this allowed cost amount. If an enrollee uses a service that is not covered or sees a provider that is not within the insurer's network, the overall charge, including an enrollee's cost sharing, could be higher than the allowed amount.

[16] Plans and policies sold within Covered California are required by federal law to meet specified actuarial values. The actuarial value is required to fall within specified ranges and dictates the average percent of health care costs a plan or policy covers. If a required reduction in cost sharing impacts the actuarial value, some number of these plans or policies might have to alter other cost-sharing components of the plan and/or premiums in order to keep the overall benefit design within the required actuarial value limits.

BACKGROUND ON BREAST IMAGING

Breast cancer is the most common non-skin cancer diagnosis and the second leading cause of cancer deaths (after lung cancer) for females in California. AB 2024 would require coverage of and prohibit cost-sharing for supplemental and diagnostic breast imaging used to screen for and diagnose breast cancer. This section presents contextual information about the incidence of disease and related mortality, risk factors for breast cancer, descriptions of screening and diagnostic imaging, and disparities in access to and uptake of imaging.

Breast Cancer in California

Breast Cancer Incidence and Mortality Rates

California average

Breast cancer occurs predominantly in females. The annual breast cancer incidence rate in California is 122/100,000 or about 32,000 new cases diagnosed annually (ACS, 2022a). The American Cancer Society estimates an average breast cancer death rate of 19/100,000 or about 4,700 breast cancer deaths annually in California (ACS, 2022a). Breast cancer does occur in males, but at a much lower rate with about 170 cases diagnosed and 40 deaths annually in California (ACS, 2017).

Rate differences by race and ethnicity

Differences in breast cancer incidence and mortality by race and ethnicity persist. Although the most recent data (2012-2016) for age-adjusted incidence of breast cancer remains highest among California's non-Hispanic White (NHW) women (140/100,000), followed by non-Hispanic Black (NHB) women (129/100,000), non-Hispanic Asian and Pacific Islander (NHA/PI) women (102/100,000) and Hispanic women (91/100,000), mortality rates remain highest among NHB women (California Cancer Registry, 2019). NHB have a breast cancer mortality rate of 31/100,000, followed by NHW women (21/100,000), and Hispanic women (16/100,000). NHA/PI have the lowest breast cancer mortality rate of 13/100,000 (California Cancer Registry, 2022).

Screening and treatment impact on mortality rates

After decreasing for 20 years, the National Cancer Institute characterizes the breast cancer death rate in the United States and California as stable. In California, 71% of breast cancer is diagnosed in the early stages of localized disease, which carries a 99% 5-year survival rate (ACS, 2017). California reports that 68% of women aged 45 years and older are up to date on recommended mammography (ACS, 2022a).

Breast Cancer Risk

Assessing risk

The lifetime average risk of breast cancer is about 13%, or 1 in 8 females (males have about a 0.13% lifetime risk, or 1 in 800) with risk increasing with age (ACOG, 2017). Several algorithms have been developed to estimate the risk of breast cancer. The best known and most widely accessible is the Breast Cancer Risk Assessment Tool, which can be found online at: www.cancer.gov/bcrisktool/. This tool uses the following personal information to calculate a woman's risk for breast cancer (NCI, 2022):

- Age
- Race/ethnicity
- Ever had a biopsy (how many, atypical hyperplasia)

- Age at onset of menarche
- Age at first live birth
- Family history of breast cancer in a first degree relative

Other factors such as genetic predisposition (i.e., mutations of BRCA1 and BRCA2 genes) and lifestyle factors (i.e., alcohol, physical activity, obesity) also affect risk (American Society of Clinical Oncology, 2020; CDC, 2021b). Additionally, (radiographically) dense breast tissue is also considered an independent risk factor for breast cancer. Dense breast tissue can also obscure breast cancers on mammography, thus reducing detection of cancer by mammography (CDC, 2021c). Women with dense breast tissue experience higher rates of interval cancers occurring between mammography screenings (Ezratty et al., 2020). However, dense breast tissue alone does not put a person into a high-risk category for breast cancer (ACS, 2021a; CDC, 2021c). Those with dense breast tissue are not more likely to die from breast cancer than those with fatty breast tissue.

Assessing breast density is subjective and varies according to each radiologist's interpretation (ACOG, 2017). CHBRP includes this description of density because it can affect the choice of supplemental and diagnostic breast imaging. Density is classified into one of four Breast Imaging Reporting and Data System (BI-RAD) categories on the proportion of fibrous and glandular tissue to fatty tissue present as seen on a mammogram. About 50% of females have low or average density with tissue that is predominantly fatty (categories A and B), and the other 50% have heterogeneously dense or extremely dense tissue throughout the breast (categories C and D). Women receiving notification of dense breast tissue fall into the C and D categories. Breast density, on average, decreases with age (NCI, 2020a).

Levels of risk

Clinicians consider both protective factors and risk factors when assessing a person's 5-year risk (NCI, 2022). Guidelines recommending breast cancer screening differ based on a person's risk category (see below for guideline discussion). Although risk stratification tools are better at estimating risk levels for groups with certain risk factors, and less accurate for estimating risk at an individual level, these tools can help practitioners and patients determine appropriate screening, including supplemental screening, schedules. Based on the results of a risk assessment tool, health care practitioners can estimate the 5-year and lifetime risk of cancer:

- Women with <15% lifetime risk are considered "average risk".
- Women with 15%-20% lifetime risk are considered "above-average risk" for breast cancer.
- Women with >20% lifetime risk are considered "high risk". Those with one or more of the following factors are classified as "high-risk" by the American Cancer Society:

  a) Genetic (BRCA1 or BRCA2 gene mutation; Li-Fraumeni syndrome plus first-degree relatives; Cowden and Bannayan-Riley-Ruvalcaba syndromes plus first-degree relatives). These genetic mutations and syndromes are relative rare. According to the CDC, about 1 in 500 women in the United States has a BRCA1 or BRCA2 gene mutation. About 50 of 100 women with a BRCA1 or BRCA2 gene mutation will get breast cancer by the time they turn 70 years old, compared to only 7 of 100 women in the general US population (CDC, 2021a).

  b) First-degree relative of BRCA carrier (untested).

  c) Clinical history – chest irradiation treatment between age 10 and 30 years (e.g., Hodgkin's disease treatment).

Screening, Supplemental, and Diagnostic Breast Imaging

Uses of Breast Cancer Imaging Exams

- **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.

AB 2024 requires coverage, with no cost sharing, of medically necessary supplemental screening and diagnostic imaging (see guidelines discussion below). Figure 2 provides an overview of the breast cancer screening and diagnostic pathway for women at different levels of risk for breast cancer.

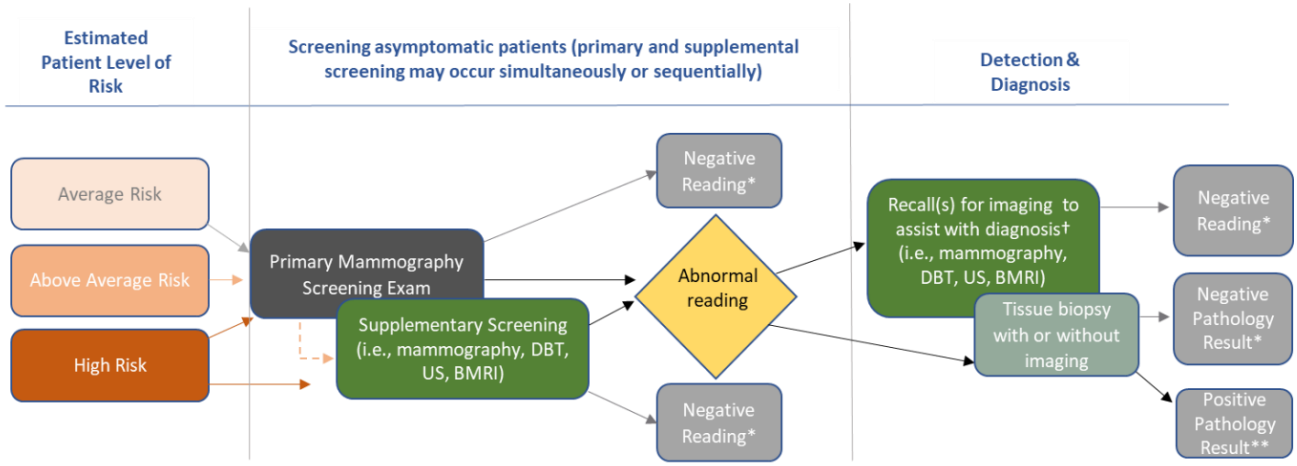
Primary screening mammography is a first step in the detection of breast cancers for women at any risk level. Patients who are considered above average or high risk for cancer may undergo additional imaging, known as supplemental screening, with other types of imaging such as breast MRI, breast ultrasound, or digital breast tomosynthesis (DBT).

Patients with abnormalities upon screening mammography and/or clinical exam may undergo additional imaging for diagnosis and/or they may directly undergo a biopsy of the suspicious area(s) to confirm whether there is a malignancy in the breast tissue.

It should be noted that although clinical terminology refers to imaging exams as "diagnostic," breast cancer is diagnosed based on examination of breast tissue by a pathologist (usually from biopsy). By enabling the detection of certain forms of invasive cancer at an earlier stage of disease, breast imaging exams have the potential to reduce breast cancer morbidity and mortality. However, as discussed in the *Medical Effectiveness* harms section, screening imaging can result in some overdiagnoses (false-positive results or benign cancers) leading, in those cases, to unnecessary interventions (further imaging, biopsies, treatment), as well as potential psychosocial consequences (NCCN, 2021). For those with positive screening and diagnostic results, treatment and prognosis of invasive breast cancers are guided by multiple factors, including biological characteristics of the cancer and the stage of disease, which is determined after excision of a tissue sample or surgery to remove the lump or whole breast.

Note that increases in supplemental screening may identify additional lesions that may or may not be cancerous. Some results will identify cancers that would become invasive, thus resulting in better outcomes due to early diagnosis. Other results may identify cysts or noncancerous lesions leading to interventions that do not result in a cancer diagnosis (Haas et al., 2016; Huang et al., 2021; Killelea et al., 2013). See the *Medical Effectiveness* and *Public Health* sections for discussion of outcomes and harms associated with supplemental screening and diagnostic imaging. Achieving appropriate care is the goal; according to most practice guidelines, supplemental screening, usually with breast MRI, is recommended for those women with a high lifetime risk of breast cancer (>20%) (see screening guideline discussion below).

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 AB 2024. *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.

Breast Cancer Screening and Supplemental Screening Guidelines & Recommended Populations

Primary and supplemental breast cancer screening guidelines are generally organized according to lifetime risk of breast cancer. Major U.S. guideline organizations generally agree on primary screening mammography for women every 12 to 24 months (United States Preventive Services Task Force (USPSTF), the ACS (American Cancer Society), and the American College of Obstetricians and Gynecologists (ACOG) (CDC, 2020). There is less consensus on the supplemental screening guidelines, with most organizations recommending supplemental imaging for women at highest risk, but differing by risk categories, frequency, and imaging characteristics.

- **Average Risk of Breast Cancer (<15% lifetime risk)**: All guidelines recommend annual or biennial breast cancer screening by mammography for women aged 50 years and older at average risk for breast cancer. For women aged 40 and 49 years, the United States Preventive Services Task Force (USPSTF), the ACS (American Cancer Society), and the American College of Obstetricians and Gynecologists (ACOG) recommend screening mammography every 12 to 24 months. The American College of Physicians (ACP) recommends screening mammography only as an opt-in test based on the clinician and patient's decision. (This primary screening mammography step is not the focus of AB 2024, but it is included here because it is the beginning of the breast imaging pathway.) Most major guideline organizations do not recommend supplemental screening with breast ultrasound or MRI for average-risk females (Freer et al., 2022); however, the American College of Radiologists (ACR) finds DBT supplemental screening "usually appropriate" for average-risk females regardless of tissue density; breast MRI and ultrasound "may be appropriate" for those with dense tissue, but otherwise at average risk (ACR, 2021).

- **Above-Average/Intermediate Risk of Breast Cancer (15% to 20% lifetime risk)**: Several national guideline organizations suggest early start of mammography screening with or without shorter (supplemental) screening intervals for women with above-average risk of breast cancer. However, none of the guidelines recommend a specific age to begin screening. For those with intermediate risk of breast cancer, the National Comprehensive Cancer Network (NCCN) recommends supplemental screening on an individual basis depending on clinical risk factors (NCCN, 2021). These guidelines do not recommend for or against supplemental screening with breast ultrasound for this risk category. The ACS recommends that, for those with above-average lifetime risk, a mutual decision should be made between a patient and the clinician regarding annual adjuvant breast MRI. ACR finds DBT supplemental screening "usually appropriate"; breast ultrasound and MRI "may be appropriate" for those with dense breast tissue in this risk category (Freer et al., 2022).

- **High Risk of Breast Cancer (>20% lifetime risk)**: The ACS recommends individualized, shared decision-making on when to initiate mammography screening for those aged 30 years and older at high risk for breast cancer (Freer et al., 2022). CHBRP includes this primary mammography screening recommendation because it falls outside of the recommended screening with $0 cost share per the ACA. A recent review notes that because dense breast tissue is not relevant to those at high risk, supplemental breast ultrasound is unnecessary; however, breast MRI in combination with mammography is recommended (Freer et al., 2022). ACR/Society of Breast Imaging recommend breast ultrasound for those for whom breast MRI is contraindicated. ACR also finds DBT supplemental screening "usually appropriate" for this risk category (ACR, 2021). ACS also recommends an annual adjuvant screening with breast MRI if the woman has a lifetime risk of breast cancer of more than 20% or has a BRCA mutation. The American Society of Breast Disease and NCCN concur with the ACS breast MRI recommendation (Freer et al., 2022).

- **Dense Breast Tissue:** USPSTF, ACS, ACOG, and American Academy of Family Physicians do not recommend adjunctive (supplemental) breast ultrasonography, MRI, DBT, or other types imaging for people with dense breast tissue and negative mammogram results (Freer et al., 2022).

Disparities[17] and Social Determinants of Health[18] in Breast Cancer and Imaging Tests

Per statute, CHBRP includes discussion of disparities and social determinants of health (SDoH) as it relates to breast cancer prevalence, and cost sharing for diagnostic and supplemental breast imaging tests. Disparities are noticeable and preventable differences between groups of people. SDoH include factors outside of the traditional medical care system that influence health status and health outcomes (e.g., income, education, geography, etc.).

Differences in breast cancer incidence and mortality rates by race and ethnicity are influenced by age at diagnosis as well as by a complex interplay between unequal distribution of breast cancer molecular subtypes, genetic and lifestyle factors (both protective and risk factors), screening rates, socioeconomic factors, and treatment (Hill et al., 2019; Newman, 2017).

Some research consensus appears to be building around identifying the largest contributing factor to racial and ethnic cancer outcome disparities. Molecular tumor types differ in progression, treatment

[17] Several competing definitions of "health disparities" exist. CHBRP relies on the following definition: Health disparity is defined as the differences, whether unjust or not, in health status or outcomes within a population. (Wyatt et al., 2016).
[18] CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from: CDC, 2014; Healthy People 2020, 2019).

response, and survival outcome present with different frequencies in different race/ethnicity groups. For example, cancer subtypes with the most favorable outcomes (HR-positive/HER2-negative) are 23% higher in White women than Black women (age-adjusted), and 45% higher in Hispanic and American Indian/Alaska Native women (Gehlert et al., 2021). By contrast, triple-negative breast cancer, an aggressive form of cancer with poorer outcomes, is significantly higher among Black women aged 50 years and younger (21%) than in White women (10%) (Rebner and Pai, 2020). Rebner and Pai report that the prevalence of mutations in the BRCA1/BRCA2 genes, which are associated with the highest risk for breast cancer, also vary by race/ethnicity with highest rates found among Ashkenazi Jewish women and Black women, and lowest rates found among Asian American women (John et al., 2007; Rebner and Pai, 2020).

Black and Hispanic women are more likely to be diagnosed with more advanced cancer stages as compared with White women, further contributing to disparities in breast cancer outcomes. One estimate showed that 23% of breast cancers diagnosed in Black women occur in those younger than guideline recommendations as compared with 16% of White women (Oppong et al., 2021).

The body of literature studying rates of screening and supplemental breast imaging that CHBRP reviewed is inconclusive regarding utilization disparities according to various demographic factors. These studies have acknowledged and unacknowledged limitations such as unknown lifetime risk of study population, patient–physician communication, insurance status, and inconsistent/unclear reporting within the paper.

Several studies reported more breast imaging studies ordered for White women than women of other races, and for women with higher educational attainment than those with high school or less (Ezratty et al., 2020; Killelea et al., 2013; Lee et al., 2021), However, other studies, including those related to patient breast density notification laws or analyzing lifetime risk factor cohorts, found a convergence in supplemental screening rates between White and Black women (Killelea et al., 2013; Lee et al., 2021; Manning et al., 2019). Other studies have noted that Black women report being up-to-date with mammography screening at rates similar to or higher than White women (NCI, 2021).

Socioeconomic factors such as employment status, income, insurance status, education, and urbanicity affect breast cancer incidence, stage at diagnosis, access to breast imaging providers, and treatment (Huang et al., 2021; Lee et al., 2021; Newman, 2017). See the *Public Health* section for more detail.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, AB 2024 would replace the current screening and diagnostic mammography benefit mandate. As well as requiring coverage for screening mammography and other digital imaging, the bill will, in many instances, prohibit cost sharing.

Additional information on modalities for breast cancer imaging is included in the *Background* section. The medical effectiveness review summarizes findings from evidence[19] regarding the effectiveness of the diagnostic imaging techniques specified below. It also reviews any substantial risks or harms associated with these techniques when used in the context of the mandates of this bill. It presents available information from 2012 to present.

The diagnostic imaging techniques included in this section are:

1. Mammography
2. Contrast enhanced mammography (CEM)
3. Digital breast tomosynthesis (DBT)
4. Breast magnetic resonance imaging (MRI)
5. Breast ultrasound

Table 2 summarizes the different types of images commonly used to screen for and help diagnose breast cancer.

Table 2. Types of Breast Imaging

Imaging Type	Description	
Digital Mammography (a)	*Screening or diagnostic* An x-ray machine compresses the breast firmly between two plates; two views of each breast are taken, which are then digitized and stored on a computer (rather than conventional x-ray film). Uses radiation.	

[19] Much of the discussion in this section is focused on reviews of the available literature. However, as noted in the section on Implementing the Hierarchy of Evidence on page 11 of the *Medical Effectiveness Analysis and Research Approach* document (posted at http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php), in the absence of fully applicable to the analysis peer-reviewed literature on well-designed randomized controlled trials (RCTs), CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

Imaging Type	Description	
Digital Breast Tomosynthesis (DBT) (a)	*Screening or diagnostic* DBT is a type of digital mammography that creates 3-D mammography images. Similar to a CT scan, an x-ray machine takes multiple, layered images of the breast from different angles and uses computer software to reconstruct an image. Uses very low-dose x-rays, but, because it is generally performed simultaneously with standard (2-D) mammography, the radiation dose is higher than that of standard mammography. Use of DBT screening increased from13% to 40% between 2015 and 2017; 73% of breast imaging clinics report using DBT. Uses radiation.	
Breast Magnetic Resonance Imaging (MRI) (b)	*Diagnostic* MRI uses radio waves and a powerful magnet linked to a computer to create detailed images of soft tissue, bone, and organs. Uses no radiation.	
Breast Ultrasound (b)	*Diagnostic* High-energy sound waves (ultrasound) bounce off internal tissues to form an image that differentiates tissue (fluid-filled vs. solid masses). Machines may be handheld or automated, which are less widely available (pictured). Ultrasound may also be used to guide diagnostic needle biopsy procedures. Uses no radiation.	

Source: California Health Benefits Review Program, 2022. Images from https://www.itnonline.com/article/study-uncovers-value-mammogram-screening-younger-women (mammography); https://my.clevelandclinic.org/health/diagnostics/8332-mri--breast-cancer (MRI); https://womens-imaging.com/services/breast-ultrasound-and-abus/ (ultrasound).

(a) NCI, 2021(b).

(b) NCI, 2022.

Key: CT = computed tomography.

Research Approach and Methods

Studies of relevant diagnostic imaging techniques were identified through searches of PubMed, Cochrane Library, Web of Science, and Embase. The search was limited to abstracts of studies published in English.

The search was limited to studies published from 2012 to present. CHBRP relied on systematic reviews published in 2016 and 2018 for findings from studies published prior to 2012. Of the 517 articles found in the literature review, 65 were reviewed for potential inclusion in this report on AB 2204, and a total of 24 studies were included in the medical effectiveness review for this report. The other articles were eliminated because they did not focus on specific population, were of poor quality, or did not report findings from clinical research studies. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.[20] Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

Key Questions

1. Are the diagnostic techniques listed above effective for **supplemental screening** for high-risk persons?

2. Are the diagnostic techniques listed above effective for **diagnostic breast exams** [21]?

3. What are the risks involved with the processes listed above?

Outcomes Assessed

The primary outcomes assessed involve the effectiveness of each respective technique with regard to supplemental or adjunctive screening test, confirming diagnoses or otherwise accurately determining the medical status of patients. The specific outcomes will involve the ability to fulfill these roles with regard to detection (e.g., cancer detection rates, sensitivity, and specificity where applicable). The impact of these techniques on long-term mortality rates will not be evaluated because there are multiple factors in addition to detection that come into play after detection and diagnosis that impact these rates.

Additionally, where relevant, the potential risks and harms of each technique will be described. In some cases information regarding effectiveness for screening may be presented where evidence regarding use of a technique for the purposes listed above may be lacking, or if the technique is largely used in combination with another technique.

[20] Grey literature consists of material that is not published commercially or indexed systematically in bibliographic databases. For more information on CHBRP's use of grey literature, visit http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

[21] Supplemental breast examination" means a medically necessary and appropriate examination of the breast, including an examination using breast magnetic resonance imaging or breast ultrasound that is either of the following:
(A) Used to screen for breast cancer when an abnormality is not seen or suspected.
(B) Necessary based on personal or family medical history or additional factors that may increase the individual's risk of breast cancer.

Study Findings

This following section summarizes CHBRP's findings regarding the strength of evidence for the effectiveness of the diagnostic imaging techniques addressed by AB 2204. Each section is accompanied by a corresponding figure. The title of the figure indicates the test, treatment, or service for which evidence is summarized. The statement in the box above the figure presents CHBRP's conclusion regarding the strength of evidence about the effect of a particular test, treatment, or service based on a specific relevant outcome and the number of studies on which CHBRP's conclusion is based. Definitions of CHBRP's grading scale terms is included in the box below, and more information is included in Appendix B.

Terminology

- **Cancer Detection Rate (CDR)** is the number of true-positive results divided by the total number of screenings or exams.
- **Diagnostic Imaging** refers to the use of imaging techniques for the diagnosis of breast cancer after there is indication of potential issues such as lesions or masses found from a physical exam of screening mammogram.
- **Primary Screening** involves testing or examining for signs of cancer before any symptoms appear.
- **Recall Rate** is the number of patients recalled for further testing due to inconclusive or suspicious test results. Some recalled patients have positive findings, and some have negative findings, meaning their recall was unnecessary. The U.S. Agency for Healthcare Research and Quality (AHRQ) sets the desirable recall rate for screening mammography at <10% (Feig, 2007).
- **Sensitivity** is defined as the proportion of breast cancers detected when breast cancer is present, or the true-positive rate. The AHRQ sets the desirable sensitivity rate at greater than 85%.
- **Specificity** is defined as the proportion of negative test results when cancer is absent. If the test specificity is low, the test would have a high false-positive rate that could result in unnecessary interventions. The AHRQ sets the desirable specificity rate at greater than 90%.
- **Supplemental Screening** is extra or additional screening generally recommended for women with above average risk for breast cancer (>15% lifetime risk), but also when asymptomatic. Please see the *Background* section for more details regarding levels of risk.

Effectiveness of Diagnostic Imaging Techniques by Usage

Supplemental Screening for High-Risk Persons

Supplemental screening is additional screening usually for women with above-average risk for breast cancer. Multiple modalities are used in the supplemental screening role. Although mammography is most often utilized in a primary screening role and is considered to be the single most effective screening tool, credited with sharply reducing cancer-related mortality (Siu and USPSTF, 2016), it has been criticized for its moderate sensitivity and specificity (75%), which are often lower than other modalities such as DBT, and also due to its limited ability to distinguish between lesions and overlapping tissue (Chen et al., 2021; Hooshmand et al., 2021).

Digital breast tomosynthesis (DBT)

DBT is often used in conjunction with digital or other 2-D mammography for in the supplemental role for high-risk supplemental purposes (e.g., Hofvind et al., 2018). DBT has been shown to be more effective than traditional 2-D with regard to tissue visualization, resulting in greater confidence in interpretation for the characterization of suspicious findings from initial screening (Houssami and Skaane, 2013; Zuley et

al., 2013). A meta-analysis of studies comparing 2-D mammography and DBT for supplemental screening reviewed 17 studies involving over 1 million patients. They found that DBT improves detection rates and reduces recall (Marinovich et al., 2018).

Breast magnetic resonance imaging (MRI) and ultrasound

A recent systematic review (Zeng et al., 2022) evaluated the effectiveness of supplemental screening using either breast MRI or ultrasound for high-risk women for both cancer detection and interval cancer rate. Five studies including over 142,000 women were included. They found that supplemental imaging using breast MRI or ultrasound both increased cancer detection rates, with breast MRI more effective in this role. The addition of breast MRI yielded a greater increase in CDR as compared with ultrasound, again with a proportional increase in recall rates. Reported sensitivity of breast MRI ranged between 95% and 97% for MRI, and 74% and 77% for ultrasound. Another systematic review (Mann et al., 2019) examined the results of nine studies published after 2012 that examined the use of MRI, digital mammography (DM), and ultrasound, or a combination. MRI used in combination with DM yielded the best results, with sensitivity ranging from 75% to 100%, with an average sensitivity of 89%. Specificity, which has been criticized for breast MRI when used as a screening tool, is good when breast MRI is used as a supplemental technique, yielding 96% specificity as compared to 92% for digital mammography (Benndorf et al., 2010).

Studies regarding the relative effectiveness of ultrasound as compared to DBT or breast MRI provides evidence that ultrasound may be less capable in this role (e.g., Zeng et al., 2022). Additionally, multiple studies have found that after factoring in increased biopsies, false positives, and sometimes marginal sensitivity, the benefits of supplemental screening for high-risk patients may not outweigh the potential harms (Buchberger et al., 2018; Lee et al., 2019; Melnikow et al., 2016; Rebolj et al., 2018).

Summary of findings DBT and breast MRI: There is a preponderance of evidence from 3 studies and 1 systematic reviews, that **DBT** and **breast MRI** are effective for increased detection of breast cancer when used in a supplemental role.

Summary of findings ultrasound: There is limited evidence from 1 systematic review and 4 studies that **Ultrasound** is effective for the increased detection of breast cancer when used in a supplemental role.

Diagnostic Usage

As with supplemental screening, multiple modalities are used in the diagnostic roll, with DBT and MRI representing the most commonly utilized.

Digital breast tomosynthesis (DBT)

A recent combined systematic review and meta-analysis examined the accuracy of DBT in the diagnostic setting. The authors pooled data from 20 studies (N = 44,513) and reported sensitivity and specificity of

90% (for both), as compared with 76% and 83% for DM alone (Ko et al., 2021). An earlier meta-analysis of studies comparing DBT with digital mammography found similar results. They pooled seven studies involving over 2,000 patients and found DBT had a sensitivity and specificity of 90% and 79%, as compared with 89% and 72%, respectively, for DM (Lei et al., 2014). In another study comparing the diagnostic efficacy of DBT with digital mammography, researchers reported a sensitivity of 100% and specificity of 98% as compared to a sensitivity of 64% and specificity of 78% for traditional (full field) digital mammography (Naeim, 2021). They concluded that DBT offers better characterization of anomalies, including for women with higher than normal breast density. Another study examining the diagnostic properties of DBT versus DM for anomalies (e.g., distortions, masses, asymmetries) have found significantly fewer false positives and more accurate classifications without a reduction in specificity as compared with DM (Zuley et al., 2013). Another study comparing the diagnostic performance of DBT versus traditional 2-D mammography revealed similar results, namely that DBT had significantly better diagnostic efficacy for detecting malignant breast lesions (You et al., 2020).

Breast magnetic resonance imaging (MRI)

Breast MRI is another commonly used imaging technique for the characterization and diagnosis of breast cancer. One study retrospectively examined records from 216 patients who had a previous DM and were referred to a follow-up MRI and DM. They reported a sensitivity of 96% for MRI compared to 75% for DM. However, although it is very sensitive in the diagnostic role, its specificity, while often moderate, often lags behind the sensitivity of other techniques (Radhakrishna et al., 2018). In another retrospective study examining the diagnostic performance of DBT for women with abnormal screening results, it was reported that the addition of DBT to digital mammography following an abnormal screening proved more effective as compared to digital mammography alone (Ohashi et al., 2018). Another study comparing breast MRI to digital mammography as well as ultrasound concluded that breast MRI had the highest performance with regard to sensitivity and specificity for the diagnosis and characterization of suspected breast cancer (Sun et al., 2018). Another study reported similar findings regarding the use of breast MRI to characterize breast lesions. The authors concluded that breast MRI in combination with digital mammography provided the best diagnostic performance as compared to DBT and DM, or DM alone (Tang et al., 2017).

Summary of findings: There is clear and convincing evidence from 2 systematic reviews, 1 meta-analysis, and 7 studies that DBT and MRI are effective (sensitivity and specificity) for the diagnosis of breast cancer.

Risks Associated With Screening Imaging Techniques

There is a large body of evidence arguing that the risks involved with primary screening using digital mammography are small compared to the potential decrease in mortality rates (Hooshmand et al., 2022), the risks associated with and supplementary screening are not as well documented. The risk of screening tests is a false positive test leading to further diagnostic testing and treatment. In 2016, a systematic review of the effects of supplemental screening of women with dense breasts was conducted for the US Preventive Services Task Force (USPSTF) (Melnikow et al., 2016). The USPSTF review included an analysis of potential harms of supplementary screening and concluded that, although no specific studies have explored the harms of supplementary screening, harms are likely to be dependent on the risk of having the condition being screened for. People at higher risk categories have a lower likelihood of a false-positive test compared to people at lower risk of having the disease. People at lower risk are more likely to experience harms associated with screening than people at higher risk for the disease.

Currently, the USPSTF recommendation on breast cancer screening states that: “The evidence on adjunctive screening for breast cancer using breast ultrasound, MRI (magnetic resonance imaging), DBT (digital breast tomosynthesis), or other methods in women identified to have dense breasts on an otherwise negative screening mammogram is insufficient, and the balance of benefits and harms cannot be determined” (Siu and USPSTF, 2016). The 2016 breast cancer screening recommendation from the USPSTF graded that current evidence is insufficient to recommend for or against supplemental screening among women with dense breasts and a negative mammogram.

Summary of findings: The evidence is inconclusive regarding the risks and harms associated with supplementary screening for breast cancer.

Imaging and Procedures Not Covered in This Review

Primary screening

Although the effectiveness of imaging for primary screening is not the focus of this analysis, any narrative would be incomplete without providing a brief summary of the effectiveness of imaging for this purpose. The medical effectiveness of mammography for primary screening has been widely recognized in the United States and abroad for more than 25 years. National guidelines, customary practices of care, and current health care coverage, as mandated by existing California statute, all accept mammography as the standard for the screening of breast cancer. The National Cancer Institute (NCI) reports the sensitivity for mammography screening is approximately 79%, but ranges between 54% and 58% in women aged 40-49 years and 81% to 94% in women aged 65+ years (NCI, 2022). A systematic review published in 2016 provided an update to the 2009 US Preventive Services Task Force findings that recommended biennial mammography screening for women aged 50 to 74 years. Their review and meta-analysis included 26 clinical trials. In agreement with the 2009 findings, they concluded that breast cancer mortality is generally reduced with mammography screening and advanced cancer is reduced with screening for women aged 50 years or older (Nelson, et al., 2016).

Biopsy

As with primary screening, biopsies are not reviewed with regard to medical effectiveness for the purposes of this analysis. However, it is probable that increased access to diagnostic imaging and supplemental screening for high-risk patients may lead to increases in biopsies. Both surgical and core-needle biopsies have been shown to be effective for finding breast cancer, although there is some variability between different biopsy methods. In one recent review of existing literature on biopsies, it was reported that surgical biopsies will find 98% to 99% of breast cancers, guided core-needle biopsy (ultrasound or stereotactic guided) will find 97% to 99%, and freehand biopsies will find about 86% of breast cancers (JME 2016).

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, AB 2024 would prohibit health plans and health policies regulated by the Department of Managed Health Care (DMHC) or the California Department of insurance (CDI) from, in some instances, imposing cost sharing on enrollees for breast imaging, either through copays, coinsurance, or deductibles. The types of breast imaging are detailed in the *Medical Effectiveness* section. For this benefit coverage, cost, and utilization analysis, we differentiate by type of breast imaging, but not by whether the breast imaging service is used for supplemental screening for enrollees at higher risk, or diagnostic purposes.

In addition to commercial enrollees, more than 70% of enrollees associated with the California Public Enrollees' Retirement System (CalPERS) and more than 80% of Medi-Cal beneficiaries are enrolled in DMHC-regulated plans.[22] As noted in the *Policy Context* section, these CalPERS enrollees' benefit coverage would be subject to AB 2024 as would that of these Medi-Cal beneficiaries. However, because cost sharing is generally not applicable for Medi-Cal beneficiaries, AB 2024 would have no impact on these beneficiaries' benefit coverage.

This section reports the potential incremental impacts of AB 2024 on benefit coverage, utilization, and overall cost.

Analytic Approach and Key Assumptions

Nationally, one study of the breast imaging pathway estimated that diagnostic mammography is used for about 88% of initial diagnostic workups with decreasing proportions of women undergoing second, third, and even fourth diagnostic imaging workups, including breast biopsies (Vlahiotis et al., 2018). AB 2024 would remove enrollee out-of-pocket costs associated with imaging services performed during those recall visits. The study found that 71% of breast biopsies result in negative findings while costing an average of $1,938 (excluding ancillary services) (Vlahiotis et al., 2018).

There is limited literature exploring the impact of cost sharing as a barrier to supplemental screening for high-risk women and diagnostic breast imaging among the commercially insured (Wharam et al., 2018). A few studies indicate that cost sharing may be one factor causing delay in additional screening or diagnosis. Other factors include concerns about additional radiation exposure; doubts about benefits for women without dense breast tissue/family history of breast cancer; and anxiety about tests (i.e., claustrophobia preventing a breast MRI) (Chiu et al., 2020; Wharam et al., 2019). Other reasons may include lack of physician referral or prior authorization requirements.

The bulk of the postmandate cost-sharing reductions would occur among women between the ages of 50 and 74 years, who are the main utilizers of breast imaging as per most clinical guidelines and following the United States Preventive Services Task Force (USPSTF) recommendations. Through reference to HRSA recommendations, the Affordable Care Act of 2010 (ACA) prohibits cost sharing for women ages 40-74 for primary screening mammography. However, CHBRP is aware that other enrollees may also need breast imaging for either screening or diagnostic purposes. Additionally, approximately 1.6% of costs is associated with breast imaging utilized by men. This is principally diagnostic use, as neither primary screening nor supplemental screening is recommended for men.[23] Throughout this analysis, this section will refer to "enrollees," which should be interpreted as mainly women aged 50 to 74 years, but also includes other ages and genders.

[22] For more detail, see CHBRP's *Estimates of Sources of Health Insurance in California for 2023*, a resource available at http://chbrp.org/other_publications/index.php.
[23] Some portion of this use may relate to persons assigned female at birth who have transitioned and so are men in their medical records.

CHBRP is aware that many enrollees in the commercial markets may have high deductible health plans.[24] At baseline, deductibles would affect whether some enrollees were responsible for the entire per-unit cost of some or all breast imaging services. The reductions in cost sharing presented in Table 1 represent reductions in average deductible, copay, and coinsurance charges. For further details on the underlying data sources and methods used in this analysis, please see Appendix C.

Baseline and Postmandate Benefit Coverage

Although cost sharing is not always applied for breast imaging (see Table 3), at baseline, 35% of enrollees with health insurance subject to state-level benefit mandates have benefit coverage fully compliant with AB 2024 (see Table 1). These are the Medi-Cal beneficiaries enrolled in DMHC-regulated plans, who generally have no applicable cost sharing – and no deductibles. Postmandate, 100% of enrollees in DMHC-regulated plans or CDI-regulated policies would have $0 cost share for medically necessary breast imaging.

Baseline and Postmandate Utilization

Enrollees who are subject to cost sharing may either delay or decrease their overall utilization of breast imaging (Norris, et al, 2022; Pan, et al., 2022; Tran, et al., 2022; Wharam, et al., 2018, 2019). These enrollees will be more cost conscious when choosing when and where to get breast imaging, even if ordered by a doctor and more likely to delay care if cost sharing is present (Wharam et al, 2018, 2019). Therefore, utilization of enrollees who had cost sharing at baseline would increase postmandate (see Appendix C for full discussion).

At baseline, 942,908 enrollees have some type of breast imaging annually (see Table 1). A total of 2,248,656 instances of breast imaging are conducted annually for these 942,908 enrollees, including 551,678 mammograms, 4,552 breast MRIs, 690,961 breast ultrasounds, and 1,001,494 digital breast tomosynthesis (DBT) (Table 3). CHBRP also finds that 78,139 related biopsies are performed at baseline as a follow-up from breast imaging among the 942,908 enrollees. For the 2,248,656 instances of breast imaging, CHBRP estimates that an average of 28% of all types of breast imaging are performed with enrollees paying some cost sharing (see Table 3).

Table 3. Cost Sharing, at Baseline, for Supplemental/Diagnostic Breast Imaging and Related Biopsies

Test	Baseline Utilization	Percent with Cost Sharing
Mammography	551,678	41.8%
Breast MRI	4,522	45.9%
Breast ultrasound	690,961	47.1%
Digital breast tomosynthesis (DBT)	1,001,494	7.1%
Related breast biopsies	78,139	41.6%

Source: California Health Benefits Review Program, 2022.

[24] See CHBRP's resource, *Estimates, Deductibles in State-Regulated Health Insurance*, available at https://chbrp.org/other_publications/index.php.

Postmandate, utilization of breast imaging would increase by an average of 4.05% (91,161) for all types, among an additional of 38,226 enrollees (see Table 1). CHBRP projects the largest increase in the number of breast ultrasounds performed postmandate (48,431), followed by mammograms (34.307), DBT (8,114), and breast MRI (309). This additional breast imaging would also lead to an increase of 5,477 in related biopsies.

Baseline and Postmandate Per-Unit Cost

At baseline, CHBRP estimates that on average, mammography per-unit costs $205.92 per breast imaging, which is lower than the average per-unit cost of a breast MRI, at $2,838.66 (see Table 1). Breast ultrasound and DBT have lower per-unit costs, at $162.02 and $80.64, respectively. Related biopsies have a per-unit cost of $786.93 at baseline. These average per-unit costs will not change postmandate.

Baseline and Postmandate Expenditures

Table 5 and Table 6 present baseline and postmandate expenditures by market segment for DMHC-regulated plans and CDI-regulated policies. The tables present per member per month (PMPM) premiums, enrollee expenses for both covered and noncovered benefits, and total expenditures (premiums as well as enrollee expenses).

AB 2024 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, which includes a $1,018,000 increase in cost sharing for the additional biopsies that will be performed.

Premiums

Changes in premiums as a result of AB 2024 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 5, and Table 6), with health insurance that would be subject to AB 2024.

Among DMHC-regulated plans, CHBRP estimates that postmandate, premiums will increase by $0.5343 PMPM for large-group plans. Among small-group and individual DMHC plans, premiums will increase by an estimated $0.6719 PMPM and $1.0437 PMPM, respectively. Among CDI-regulated policies, CHBRP estimates that postmandate, premiums will increase by $0.6114 PMPM for large-group policies. Among small-group and individual CDI policies, premiums will increase by an estimated $0.9243 PMPM and $0.9364 PMPM, respectively.

Among enrollees in publicly funded DMHC-regulated plans, impacts would vary. For CalPERS enrollees in DMHC-regulated plans, the elimination of cost sharing for breast imaging, postmandate, will increase utilization, and so premiums are expected to increase by $0.2236 PMPM. For Medi-Cal beneficiaries in DMHC-regulated plans – because these enrollees have no cost sharing at baseline, and utilization is not expected to change postmandate – no impact would occur.

Enrollee Expenses

AB 2024–related changes in cost sharing for covered benefits (deductibles, copays, etc.) and out-of-pocket expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 5, and Table 6) with health insurance that would be subject to AB 2024 who are expected to use the relevant breast imaging during the year after enactment.

Although benefit coverage is broad, it is possible that some enrollees incurred expenses related to breast imaging for which coverage was denied, but CHBRP cannot estimate the frequency with which such situations occur and so cannot offer a calculation of impact.

Among DMHC-regulated plans, CHBRP estimates that postmandate, enrollee expenses for covered benefits will decrease by $0.3226 PMPM for large-group plans. Among small-group and individual DMHC plans, enrollee expenses will decrease by an estimated $0.4054 PMPM and $0.7050 PMPM, respectively. Among CDI-regulated policies, CHBRP estimates that postmandate, enrollee expenses for covered benefits will decrease by $0.3904 PMPM for large-group policies. Among small-group and individual CDI policies, enrollee expenses will decrease by an estimated $0.6066 PMPM and $0.6162 PMPM, respectively.

Among publicly funded DMHC-regulated health plans, as previously noted, enrollee expenses are not expected to change for Medi-Cal beneficiaries in DMHC-regulated plans, because these enrollees have no cost sharing at baseline. For CalPERS enrollees in DMHC-regulated plans, however, the elimination of cost sharing for breast imaging, postmandate, will decrease enrollee expenses by $0.3896 PMPM.

Average enrollee expenses per user

AB 2024 will affect cost sharing for breast imaging services. At baseline, current out-of-pocket costs among enrollees with cost sharing for breast imaging varies among market segments, with enrollees in the individual market having the highest average cost sharing. Cost sharing is an average of $104.40 for enrollees in large-group DMHC-regulated plans or CDI-regulated policies, $128.49 for enrollees in small-group plans or policies, and $122.68 for CalPERS HMO enrollees. Enrollees in individual plans or policies have the largest average out-of-pocket expenses for breast imaging, at $212.70 (see Table 4).

Table 4. Baseline Average Annual Enrollee Out-of-Pocket Expenses for Enrollees With Cost Sharing by Market Segment

	Large Group	Small Group	Individual	CalPERS HMO	Medi-Cal HMO*
Baseline annual enrollee out-of-pocket expenses for breast imaging	$104.40	$128.49	$212.70	$122.68	$0.00

Source: California Health Benefits Review Program, 2022.

* Benefit coverage for Medi-Cal beneficiaries does not generally include any cost sharing.

Key: CalPERS = California Public Employees' Retirement System; HMO = Health Maintenance Organizations.

The variation in the reduction of out-of-pocket expenses by market segment is likely due to the different penetration levels of high deductible health plans (HDHP) in the different types of markets. According to CHBRP's report on deductibles in California's health insurance markets (CHBRP, 2022), 27% of enrollees in small-group plans or policies and 47% of enrollees in individual plans or policies have an HDHP. Enrollees in HDHP plans or policies typically have higher cost sharing than enrollees in non-HDHP plans or policies. On average by type of breast imaging, enrollees with cost sharing pay $143.98 out-of-pocket for a mammogram, $342,60 for breast MRI, $113.15 for a breast ultrasound, and $51.08 for DBT (see Table 1).

The presence of a deductible not yet met for the year[25] could result in the enrollee paying the full unit cost, but hitting the annual out-of-pocket maximum[26] would result in the enrollee having no further cost sharing.

[25] For estimates of enrollees in plans and policies with deductibles, see CHBRP's resource, *Deductibles in State-Regulated Health Insurance*, available at https://chbrp.org/other_publications/index.php.

[26] For most enrollees in most plans and policies regulated by DMHC or CDI, applicable copays and coinsurance is limited to $250, or $500 for enrollees in the "bronze plans" available from Covered California, the state's ACA

Postmandate, all enrollees in commercial/CalPERS enrollees would have no cost sharing for covered breast imaging. However, existing cost sharing of an average of $185.88 for related biopsies would still be applicable postmandate (Table 1).

Potential Cost Offsets or Savings in the First 12 Months After Enactment

CHBRP estimates that no measurable cost offsets or savings are expected in year one postmandate, although earlier detection from the greater number of breast imaging and related biopsies could potentially lead to less costly treatment for some persons.

Postmandate Administrative Expenses and Other Expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies will remain proportional to the increase in premiums. CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost portion of premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums.

Other Considerations for Policymakers

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, related considerations for policymakers are discussed below.

Postmandate Changes in the Number of Uninsured Persons

Because the change in average premiums does not exceed 1% for any market segment (see Table 1, Table 4, and Table 5), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 2024.

Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of AB 2024.

How Lack of Benefit Coverage Results in Cost Shifts to Other Payers

Because enrollees in Medi-Cal already have breast imaging coverage without cost sharing, there is no expected cost shifting to occur from public programs into the privately insured market nor would these public programs incur a cost as a result of AB 2024. CHBRP is also aware that the publicly funded Every Woman Counts program can assist women to access breast imaging with free services if eligible; however, CHBRP is unable to quantify how many enrollees in DMHC-regulated plans or CDI-regulated policies who may use these services (CA DHCS, 2020).

marketplace (H&SC 1342.73; IC 10123.1932). Cost sharing could be higher for an enrollee in a plan or policy that includes a deductible.

Table 5. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2023

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs (b)*	*MCMC (Under 65) (c)(f)*	*MCMC (65+) (c)(f)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts	8,317,000	2,125,000	2,758,000	881,000	7,158,000	876,000	485,000	44,000	166,000	22,810,000
Total enrollees in plans/policies subject to state mandates (d)	8,317,000	2,125,000	2,758,000	881,000	7,158,000	876,000	485,000	44,000	166,000	22,810,000
Total enrollees in plans/policies subject to AB 2024										
Premiums	$407.24	$369.14	$0.00	$557.65	$238.69	$521.94	$465.60	$379.33	$0.00	$84,852,462,000
Average portion of premium paid by employer	$166.59	$204.69	$691.58	$113.48	$0.00	$0.00	$228.48	$246.41	$572.88	$48,534,724,000
Average portion of premium paid by employee	**$573.83**	**$573.83**	**$691.58**	**$671.13**	**$238.69**	**$521.94**	**$694.08**	**$625.74**	**$572.88**	**$133,387,186,000**
Total premium										
Enrollee expenses	$48.46	$124.44	$175.87	$58.77	$0.00	$0.00	$146.18	$200.65	$200.15	$15,807,011,000
Cost sharing for covered benefits (deductibles, copays, etc.)	$48.46	$124.44	$175.87	$58.77	$0.00	$0.00	$146.18	$200.65	$200.15	$15,807,011,000
Expenses for noncovered benefits (e)	--	--	$0.00	--	--	--	--	--	--	--
Total expenditures	**$622.29**	**$698.27**	**$867.45**	**$729.89**	**$238.69**	**$521.94**	**$840.26**	**$826.39**	**$773.02**	**$149,194,197,000**

Source: California Health Benefits Review Program, 2022.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Approximately 51.7% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance. 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.

(f) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

Table 6. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2023

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs (b)*	*MCMC (Under 65) (c)(f)*	*MCMC (65+) (c)(f)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,317,000	2,125,000	2,758,000	881,000	7,158,000	876,000	485,000	44,000	166,000	22,810,000
Total enrollees in plans/policies subject to AB 2024	8,317,000	2,125,000	2,758,000	881,000	7,158,000	876,000	485,000	44,000	166,000	22,810,000
Premiums										
Average portion of premium paid by employer	$0.3792	$0.4322	$0.0000	$0.5095	$0.0000	$0.0000	$0.4122	$0.5603	$0.0000	$56,952,000
Average portion of premium paid by employee	$0.1551	$0.2397	$1.0477	$0.1037	$0.0000	$0.0000	$0.2023	$0.3640	$0.9364	$60,599,000
Total premium	$0.5343	$0.6719	$1.0477	$0.6132	$0.0000	$0.0000	$0.6144	$0.9243	$0.9364	**$117,550,000**
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	-$0.3226	-$0.4054	-$0.7050	-$0.3896	$0.0000	$0.0000	-$0.3904	-$0.6066	-$0.6162	-$73,808,000
Expenses for noncovered benefits (e)	--	--	--	--	--	--	--	--	--	--
Total expenditures	$0.2117	$0.2665	$0.3427	$0.2236	$0.0000	$0.0000	$0.2240	$0.3176	$0.3202	**$43,742,000**
Postmandate percent change										
Percent change insured premiums	0.0931%	0.1171%	0.1515%	0.0914%	0.0000%	0.0000%	0.0885%	0.1477%	0.1635%	0.0881%
Percent change total expenditures	0.0340%	0.0382%	0.0395%	0.0306%	0.0000%	0.0000%	0.0267%	0.0384%	0.0414%	0.0293%

Source: California Health Benefits Review Program, 2022.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Approximately 51.7% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance. 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.

(f) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, AB 2024 would mandate coverage with $0 cost sharing for medically necessary supplemental screening, diagnostic breast imaging as well as primary screening for breast cancer. This public health analysis estimates the short-term and long-term impact of AB 2024 on breast cancer diagnosis, potential harms from false-positive screening, and enrollee financial burden.

Estimated Public Health Outcomes

Although the *Medical Effectiveness* section cites evidence that medically necessary breast imaging modalities used in supplemental screening and/or diagnostic imaging are mostly effective in identifying suspicious lesions and utilization of breast imaging would increase, the short- and long-term public health impact of AB 2024 on breast cancer morbidity or mortality is unknown. Ultimately, the differences in outcomes of breast cancers diagnosed earlier than what would have been discovered at regularly scheduled primary mammography screening are unknown. Postmandate, following the removal of cost-sharing requirements, CHBRP estimates an additional 38,226 enrollees (4% increase) would obtain an additional 91,161 supplemental and/or diagnostic breast images. These are the enrollees for whom CHBRP assumes cost-sharing is a barrier to care, and would change their behavior to seek supplemental and diagnostic breast imaging once cost sharing was eliminated. Most of the 38,226 new imaging users would have negative readings from supplemental screenings. Those with positive readings indicating suspicious anomalies could progress to diagnostic imaging, which would further divide the group into 2 subgroups: a false-positive group (benign findings) or a group diagnosed with breast cancer. In this analysis of AB 2024, CHBRP estimates about 5,477 extra biopsies would occur from those new supplemental screenings or diagnostic images. Based on national data, between 70% and 80% of breast biopsies would result in negative findings (AHRQ, 2019; Vlahiotis et al., 2018). If this assumption is true, this could result in approximately 1,370 breast cancer cases (0.75 x 5,477) being diagnosed earlier due to the removal of breast imaging cost sharing. However, the morbidity and mortality outcomes of these earlier diagnoses as compared with later diagnoses are unknown.

Earlier cancer diagnosis could lead to earlier treatment, which may or may not improve outcomes. For example, an aggressive cancer, such as triple-negative breast cancer, caught earlier may yield better outcomes. Triple-negative breast cancer, comprising 10-15% of breast cancer cases, is an aggressive, difficult-to-treat cancer that is more prevalent in women under age 40, who are black, or have a mutation in BRCA1 gene (ACS, 2022b). Those individuals with triple-negative typology could benefit from earlier, treatments which might reduce the chance of breast cancer recurrence. By contrast, slow-growing cancers, including small hormone sensitive tumors would be diagnosed eventually, receive similar treatment, and result in a similar health outcomes. More ductal carcinoma *in situ* (DCIS) would also be diagnosed with additional imaging. DCIS is non-invasive cancer that may or may not become invasive; it comprises about 20% of new cancer diagnoses. Despite increasing incidence of DCIS and subsequent treatment over the last 20 years, its identification and treatment has not been found to reduce advance stage cancer incidence or reduce mortality rates (ACS, 2021b; van der Borden et al., 2019). Studies following DCIS outcomes over 15-25 years reported that between 25%-50% of DCIS progresses to invasive stages (Co, 2020). Thus, some enrollees could be “overtreated” by incurring unnecessary treatment and cost for cancers that would not have become invasive. Clinical research is still being conducted to better predict which DCIS lesions progress to invasive breast cancer (van der Borden et al., 2019).

Postmandate, AB 2024 would produce an unknown impact on short- and long-term public health outcomes of breast cancer morbidity and mortality. Although CHBRP projects an additional 38,226 enrollees would obtain an additional 91,161 breast images, resulting in 5,477 more biopsies, the marginal impact of the proportion of earlier-identified cancers is unknown. For those enrollees with earlier diagnosed aggressive/advanced stage cancers, which would have otherwise been delayed, AB 2024 could lead to earlier treatment, and, on an individual level, affect survival odds.

CHBRP also concludes that AB 2024 would have an unknown impact on disparities in health outcomes by race, ethnicity, income, or age, or on premature death and societal economic losses.

Potential Adverse Effects of Supplemental Screening and Diagnostic Imaging

Some breast cancers identified through the additional imaging would be overdiagnosed and overtreated with adverse effects resulting from unnecessary treatments (Nelson et al., 2016). Examples of adverse effects, such as higher recall and biopsy rates (ultrasound or magnetic resonance imaging Au: As per journal style, MRI has been changed to CMR when referring to imaging the heart. Please confirm that this has been done correctly throughout.] of women with dense breasts) and additional radiation exposure (digital breast tomosynthesis [DBT]) when compared with digital mammography alone, can result in greater out-of-pocket expenses, psychological stress/anxiety, and physical pain. Although primary screening can produce false-positive results, national public health and clinician organizations agree that the benefits of primary screening outweigh those harms in terms reduced mortality. However, there is inconclusive evidence about whether benefits from supplemental imaging results outweigh the harms. The USPSTF states that "the balance of benefits and harms cannot be determined" due to insufficient evidence adjunctive screening for breast cancer using breast ultrasound, MRI, and DBT for women with dense breasts (Siu and USPSTF, 2016). The clinical guidelines described in the *Background* section recognize that people in higher risk categories have a lower likelihood of a false-positive test and therefore have lower potential for harms. Thus, their recommendations for supplemental screening focus on higher risk categories.

CHBRP assumes that some of the additional 5,477 biopsies performed postmandate would result in false-positive findings; however, the impact AB 2024 on adverse effects stemming from false positives (i.e., physical pain, anxiety, added biopsy expense, and overtreatment) is unknown.

Potential Enrollee Financial Impacts

AB 2024 would remove enrollee cost-sharing obligations for medically necessary supplemental screening and diagnostic imaging. Although 96% of enrollees' breast imaging-seeking behavior would remain the same regardless of the removal of the cost-sharing provision, *all* enrollees using breast imaging would receive an aggregated, net savings of about $74 million in out-of-pocket costs. This is inclusive of an additional $1 million in out-of-pocket expenditures by enrollees undergoing new biopsies.

As noted in the *Cost and Utilization* section, CHBRP estimates the average enrollee cost-share would decrease the most for enrollees in individual plans ($203) and, small-group plans ($119) followed by CalPERs plans ($113) and large-group plans ($95).

However, these are averages, and the reduction in cost sharing for those in high deductible health plans is likely to be much greater. To the extent that cost sharing is a barrier for the portion of 38,266 new users who are ultimately diagnosed with breast cancer, especially those enrollees with high deductible health plans (~27% of enrollees with small-group insurance and ~47% of enrollees with individual insurance), AB 2024 could expedite breast cancer diagnosis and treatment by removing that cost barrier.

Postmandate, AB 2024 would remove a cost barrier for an additional 38,226 enrollees who would become new users of breast imaging services and would net about $74 million in out-of-pocket savings for *all* enrollees using breast imaging (including an increase of an additional $1 million in biopsy costs for new users only). Those enrollees with high deductible health plans and policies (~27% of those in small group and ~47% of those in individual insurance) would see greater-than-average out-of-pocket savings than their counterparts with other insurance.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of AB 2024, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

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 because 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.

APPENDIX A TEXT OF BILL ANALYZED

On February 16, 2022, the California Assembly Committee on Health requested that CHBRP analyze AB 2024. On Thursday, March 10, 2022, the Committee asked CHBRP to analyze proposed amendments (which became public on March 16 and are below). As the amendments required no substantive change to the analytic approach already underway, CHBRP was able to do so and still complete its analysis within the given 60 days.

AMENDED IN ASSEMBLY MARCH 16, 2022

ASSEMBLY BILL **NO. 2024**

Introduced by Assembly Member Friedman

February 14, 2022

An act to ~~repeal and add~~ *amend* Section 1367.65 of the Health and Safety Code, and to ~~repeal and add~~ *amend* Section 10123.81 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 2024, as amended, Friedman. Health care coverage: diagnostic imaging.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care, and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan contract issued, amended, delivered, or renewed on or after January 1, 2000, or an individual or group policy of disability insurance or self-insured employee welfare benefit plan to provide coverage for mammography for screening or diagnostic purposes upon referral by specified professionals.

This bill would require a health care service plan contract *or health insurance policy* issued, amended, or renewed on or after January 1, 2023, to provide coverage for medically necessary diagnostic or supplemental breast examinations, as defined, ~~without a~~ *for screening or diagnostic purposes upon* referral by specified professionals. The bill would ~~require the cost-sharing imposed for a diagnostic or supplemental breast examination to be the same as the cost-sharing imposed for mammography under~~ *prohibit* a health care service plan contract *or health insurance policy* issued, amended, or renewed on or after January 1, ~~2023.~~ *2023, from imposing cost sharing for medically necessary or supplemental breast examinations.*

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

DIGEST KEY

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

---

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. *It is the intent of the Legislature to ensure that health care service plan contracts and health insurance policies provide coverage for both initial screening and diagnostic breast examinations and supplemental breast examinations deemed medically necessary and upon referral by a health care provider, without cost-sharing requirements.*

SEC. 2. *Section 1367.65 of the Health and Safety Code is amended to read:*

1367.65. (a) On or after January 1, 2000, each health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed shall be deemed to provide coverage for mammography for screening or diagnostic purposes upon referral by a participating nurse practitioner, participating certified nurse-midwife, participating physician assistant, or participating physician, providing care to the patient and operating within the scope of practice provided under existing law.

~~(b)This section does not prevent application of copayment or deductible provisions in a plan, nor shall this section be construed to require that a plan be extended to cover any other procedures under an individual or a group health care service plan contract. This section does not authorize a plan enrollee to receive the services required to be covered by this section if those services are furnished by a nonparticipating provider, unless the plan enrollee is referred to that provider by a participating physician, nurse practitioner, or certified nurse-midwife providing care.~~

(b) A health care service plan contract issued, amended, or renewed on or after January 1, 2023, shall provide coverage for medically necessary diagnostic or supplemental breast examination for screening or diagnostic purposes upon the referral of a participating nurse practitioner, participating certified nurse-midwife, participating physician assistant, or participating physician, providing care to the patient and operating within the scope of practice provided under existing law.

(c) A health care service plan contract issued, amended, or renewed on or after January 1, 2023, shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement for medically necessary diagnostic or supplemental breast examinations.

(d) For purposes of this section:

(1) "Breast magnetic resonance imaging" means a diagnostic tool that uses a powerful magnetic field, radio waves, and a computer to produce detailed pictures of the structures within the breast.

(2) "Breast ultrasound" means a noninvasive diagnostic tool that uses high-frequency sound.

(3) "Cost-sharing" means a deductible, coinsurance, or copayment, and any maximum limitation on the application of that deductible, coinsurance, or copayment, or a similar out-of-pocket expense.

(4) "Diagnostic breast examination" means a medically necessary and appropriate examination of the breast, including an examination using diagnostic mammography, breast magnetic resonance imaging, or breast ultrasound that is either of the following:

(A) Used to evaluate an abnormality seen or suspected from a screening examination for breast cancer.

(B) Necessary based on personal or family medical history or additional factors, including known genetic mutations, that may increase the individual's risk of breast cancer.

(5) "Diagnostic mammography" means a diagnostic tool that uses x-ray and is designed to evaluate an abnormality in the breast.

(6) "Supplemental breast examination" means a medically necessary and appropriate examination of the breast, including an examination using breast magnetic resonance imaging or breast ultrasound that is either of the following:

(A) Used to screen for breast cancer when an abnormality is not seen or suspected.

(B) Necessary based on personal or family medical history or additional factors that may increase the individual's risk of breast cancer.

***SEC. 3**. Section 10123.81 of the Insurance Code is amended to read:*

10123.81. (a) An individual or group policy of disability insurance or self-insured employee welfare benefit plan shall be deemed to provide coverage for mammography for screening or diagnostic purposes upon the referral of a participating nurse practitioner, participating certified nurse-midwife, participating physician assistant, or participating physician, providing care to the patient and operating within the scope of practice provided under existing law.

~~(b)This section does not prevent the application of copayment or deductible provisions in a policy, nor does this section require that a policy be extended to cover any other procedures under an individual or a group policy. This section does not authorize a policyholder to receive the services required to be covered by this section if those services are furnished by a nonparticipating provider, unless the policyholder is referred to that provider by a participating physician, nurse practitioner, or certified nurse-midwife providing care.~~

(b) A health insurance policy issued, amended, or renewed on or after January 1, 2023, shall provide coverage for medically necessary diagnostic or supplemental breast examination for screening or diagnostic purposes upon the referral of a participating nurse practitioner, participating certified nurse-midwife, participating physician assistant, or participating physician, providing care to the patient and operating within the scope of practice provided under existing law.

(c) A health insurance policy issued, amended, or renewed on or after January 1, 2023, shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement for medically necessary diagnostic or supplemental breast examinations.

~~(c)~~

(d) This section shall not apply to specialized health insurance, Medicare supplement insurance, CHAMPUS supplement insurance, or TRI-CARE supplement insurance, or to hospital indemnity, accident-only, or specified disease insurance.

(e) For purposes of this section:

(1) "Breast magnetic resonance imaging" means a diagnostic tool that uses a powerful magnetic field, radio waves, and a computer to produce detailed pictures of the structures within the breast.

(2) "Breast ultrasound" means a noninvasive diagnostic tool that uses high-frequency sound.

(3) "Cost-sharing" means a deductible, coinsurance, or copayment, and any maximum limitation on the application of that deductible, coinsurance, or copayment, or a similar out-of-pocket expense.

(4) "Diagnostic breast examination" means a medically necessary and appropriate examination of the breast, including an examination using diagnostic mammography, breast magnetic resonance imaging, or breast ultrasound that is either of the following:

(A) Used to evaluate an abnormality seen or suspected from a screening examination for breast cancer.

(B) Necessary based on personal or family medical history or additional factors, including known genetic mutations, that may increase the individual's risk of breast cancer.

(5) "Diagnostic mammography" means a diagnostic tool that uses x-ray and is designed to evaluate an abnormality in the breast.

(6) "Supplemental breast examination" means a medically necessary and appropriate examination of the breast, including an examination using breast magnetic resonance imaging or breast ultrasound that is either of the following:

(A) Used to screen for breast cancer when an abnormality is not seen or suspected.

(B) Necessary based on personal or family medical history or additional factors that may increase the individual's risk of breast cancer.

***SEC. 4**. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.*

~~SECTION 1.Section 1367.65 of the Health and Safety Code is repealed.~~

~~SEC. 2.Section 1367.65 is added to the Health and Safety Code, to read:~~

~~1367.65. (a)A health care service plan contract issued, amended, or renewed on or after January 1, 2023, shall provide coverage for medically necessary diagnostic or supplemental breast examination.~~

~~(b)Cost-sharing imposed for a diagnostic or supplemental breast examination shall be the same as the cost-sharing imposed for mammography under a health care service plan contract issued, amended, or renewed on or after January 1, 2023.~~

~~(c)For purposes of this section:~~

~~(1)"Breast magnetic resonance imaging" means a diagnostic tool that uses a powerful magnetic field, radio waves, and a computer to produce detailed pictures of the structures within the breast.~~

~~(2)"Breast ultrasound" means a noninvasive diagnostic tool that uses high-frequency sound.~~

~~(3)"Cost-sharing" means a deductible, coinsurance, or copayment, and any maximum limitation on the application of that deductible, coinsurance, or copayment, or a similar out-of-pocket expense.~~

~~(4)"Diagnostic breast examination" means a medically necessary and appropriate examination of the breast, including an examination using diagnostic mammography, breast magnetic resonance imaging, breast ultrasound, or contrast-enhanced mammography that is either of the following:~~

~~(A)Used to evaluate an abnormality seen or suspected from a screening examination for breast cancer.~~

~~(B)Necessary based on personal or family medical history or additional factors that may increase the individual's risk of breast cancer.~~

~~(5)"Diagnostic mammography" means a diagnostic tool that uses x-ray and is designed to evaluate an abnormality in the breast.~~

~~(6)"Supplemental breast examination" means a medically necessary and appropriate examination of the breast, including an examination using breast magnetic resonance imaging or breast ultrasound that is either of the following:~~

~~(A)Used to screen for breast cancer when an abnormality is not seen or suspected.~~

~~(B)Necessary based on personal or family medical history or additional factors that may increase the individual's risk of breast cancer.~~

~~SEC. 3.Section 10123.81 of the Insurance Code is repealed.~~

~~SEC. 4.Section 10123.81 is added to the Insurance Code, to read:~~

~~10123.81. (a)A health insurance policy issued, amended, or renewed on or after January 1, 2023, shall provide coverage for medically necessary diagnostic or supplemental breast examination.~~

~~(b)Cost-sharing imposed for a diagnostic or supplemental breast examination shall be the same as the cost-sharing imposed for mammography under a health insurance policy issued, amended, or renewed on or after January 1, 2023.~~

~~(c)For purposes of this section:~~

~~(1)"Breast magnetic resonance imaging" means a diagnostic tool that uses a powerful magnetic field, radio waves, and a computer to produce detailed pictures of the structures within the breast.~~

~~(2)"Breast ultrasound" means a noninvasive diagnostic tool that uses high-frequency sound.~~

~~(3)"Cost-sharing" means a deductible, coinsurance, or copayment, and any maximum limitation on the application of that deductible, coinsurance, or copayment, or a similar out-of-pocket expense.~~

~~(4)"Diagnostic breast examination" means a medically necessary and appropriate examination of the breast, including an examination using diagnostic mammography, breast magnetic resonance imaging, breast ultrasound, or contrast-enhanced mammography that is either of the following:~~

~~(A)Used to evaluate an abnormality seen or suspected from a screening examination for breast cancer.~~

~~(B)Necessary based on personal or family medical history or additional factors that may increase the individual's risk of breast cancer.~~

~~(5)"Diagnostic mammography" means a diagnostic tool that uses x-ray and is designed to evaluate an abnormality in the breast.~~

~~(6)"Supplemental breast examination" means a medically necessary and appropriate examination of the breast, including an examination using breast magnetic resonance imaging or breast ultrasound that is either of the following:~~

~~(A)Used to screen for breast cancer when an abnormality is not seen or suspected.~~

~~(B)Necessary based on personal or family medical history or additional factors that may increase the individual's risk of breast cancer.~~

~~SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.~~

APPENDIX B LITERATURE REVIEW SPECIFICATIONS

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach*.[27] To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance;
- Direction of effect;
- Size of effect; and
- Generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- Clear and convincing evidence;
- Preponderance of evidence;
- Limited evidence;
- Inconclusive evidence; and
- Insufficient evidence.

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

A grade of *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.

A grade of *insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

Search Terms

Medical Effectiveness Keywords

- Condition/Test Keywords:
    - Breast/diagnostic imaging
    - Magnetic Resonance Imaging/ Nuclear magnetic resonance imaging * breast cancer
    - Mammography * breast cancer

[27] Available at: http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

  - Adjunctive screening * breast cancer
  - Digital breast tomosynthesis (TBD) * breast cancer
  - Ultrasonography * breast cancer
  - Ultrasound breast cancer
  - Breast imaging
  - Harms/risks * breast cancer imaging

- Medical Effectiveness Outcomes:
  - Confirmatory screening * breast cancer
  - Early detection breast cancer
  - High risk breast cancer
  - Breast cancer imaging harms/risk

APPENDIX C COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

With the assistance of CHBRP's contracted actuarial firm, Milliman, Inc, the cost analysis presented in this report was prepared by the faculty and researchers connected to CHBRP's Task Force with expertise in health economics.[28] Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impacts analyses are available at CHBRP's website.[29]

This appendix describes analysis-specific data sources, estimation methods, caveats, and assumptions used in preparing this cost impact analysis.

Analysis-Specific Data Sources

Current coverage of breast imaging services for commercial enrollees was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represent 51% of commercial/ enrollees with health insurance that can be subject to state benefit mandates. In addition, CalPERS, DHCS, and the four largest (by enrollment) DMHC-regulated plans enrolling Medi-Cal beneficiaries were queried regarding related benefit coverage.

Analysis-Specific Caveats and Assumptions

The analytic approach and key assumptions are determined by the subject matter and language of the bill being analyzed by CHBRP. As a result, analytic approaches may differ between topically similar analyses, and therefore the approach and findings may not be directly comparable.

Methodology and Assumptions for Baseline Benefit Coverage

- The population subject to the mandated offering includes individuals covered by DMHC-regulated commercial insurance plans, CDI-regulated policies, CalPERS plans subject to the requirements of the Knox-Keene Health Care Service Plan Act, and Medi-Cal HMOs.
- We assumed 100% of the population in plans and policies subject to mandated offerings currently receive some form of coverage for screening and diagnostic breast imaging.
- We assumed Medi-Cal enrollees do not pay for screening or diagnostic breast imaging. Although Medi-Cal HMOs are subject to the bill, enrollees will not have a cost impact.
- We assumed that enrollees in DMHC-regulated commercial insurance plans, CDI-regulated policies and CalPERS HMOs receive breast imaging for screening purposes without cost sharing. Under the ACA, nongrandfathered plans are required to provide such services for women aged 40 to 74 years without cost sharing. In our examination of claims data, we determined that cost sharing for women in other age groups and plans was negligible. For this analysis, we assumed zero cost sharing for breast imaging for screening. Enrollees in these plans will not have a cost impact for screening services.

[28] CHBRP's authorizing statute, available at https://chbrp.org/about_chbrp/index.php, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
[29] See method documents posted at http://chbrp.com/analysis_methodology/cost_impact_analysis.php; in particular, see 2022 Cost Analyses: Data Sources, Caveats, and Assumptions.

Methodology and Assumptions for Baseline Utilization and Cost

- The average cost and utilization rates for breast imaging are based on the 2019 Consolidated Health Cost Guidelines Sources Database (CHSD). The data were limited to California commercial and Medicaid enrollees.
- "Screening breast imaging" and "diagnostic breast imaging" claims were identified using procedure codes (CPT and HCPCS). We did not distinguish supplemental screening as a separate category due to data limitations. The procedure codes used to identify and classify breast imaging claims are in Table B-1. No other procedure codes were included in the cost per case.
- Diagnostic breast imaging utilization was trended from 2019 to 2023 using 0.5% trend. Allowed costs and cost sharing per case were trended using 4.5% trend from the 2021 Milliman Health Cost Guidelines.

Table B-1. Breast Imaging Procedure Codes

CPT/HCPCS	Long Description	Modality	Purpose
0159T	Computer-aided detection, including computer algorithm analysis of MRI image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation, breast MRI (List separately in addition to code for primary procedure)	MRI	Diagnostic
3014F	Screening mammography results documented and reviewed (PV)	Mammogram	Screening
76641	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete	Ultrasound	Diagnostic
76642	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited	Ultrasound	Diagnostic
76645	Ultrasound, breast(s) (unilateral or bilateral), real time with image documentation	Ultrasound	Diagnostic
77051	Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further review for interpretation, with or without digitization of film radiographic images; diagnostic mammography (List separately in addition to code for primary procedure)	Mammogram	Diagnostic
77052	Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further review for interpretation, with or without digitization of film radiographic images; screening mammography (List separately in addition to code for primary procedure)	Mammogram	Screening
77055	Mammography; unilateral	Mammogram	Screening
77057	Screening mammography, bilateral (2-view study of each breast)	Mammogram	Screening
77059	Magnetic resonance imaging, breast, without and/or with contrast material(s); bilateral	MRI	Diagnostic
77061	Digital breast tomosynthesis; unilateral	DBT	Diagnostic
77062	Digital breast tomosynthesis; bilateral	DBT	Diagnostic
77063	Screening digital breast tomosynthesis, bilateral	DBT	Screening
77065	Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral	Mammogram	Diagnostic
77066	Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral	Mammogram	Diagnostic
77067	Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed	Mammogram	Screening

C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral	MRI	Diagnostic
C8906	Magnetic resonance imaging with contrast, breast; bilateral	MRI	Diagnostic
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral	MRI	Diagnostic
C8937	Computer-aided detection, including computer algorithm analysis of breast MRI image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation (list separately in addition to code for primary procedure)	MRI	Diagnostic
G0202	Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (cad) when performed	Mammogram	Screening
G0204	Diagnostic mammography, including computer-aided detection (cad) when performed; bilateral	Mammogram	Diagnostic
G0206	Diagnostic mammography, including computer-aided detection (cad) when performed; unilateral	Mammogram	Diagnostic
bG9899	Screening, diagnostic, film, digital or digital breast tomosynthesis (3d) mammography results documented and reviewed	DBT	Screening
G9900	Screening, diagnostic, film, digital or digital breast tomosynthesis (3d) mammography results were not documented and reviewed, reason not otherwise specified	DBT	Screening
S0613	Annual gynecological examination; clinical breast examination without pelvic evaluation	Mammogram	Screening

Methodology and Assumptions for Baseline Cost Sharing

- The paid-to-allowed ratios for breast imaging services were calculated using the CHSD database. The cost-sharing incidence and levels vary by type of services, as shown in Table B-2 of this Appendix.
- The CHSD commercial claims database is representative of the large group market. We relied upon the Milliman Health Cost Guidelines 2021 radiology utilization adjustment factors to adjust the utilization rates from the data to estimate utilization in the absence of cost sharing.
- To adjust for average plan benefit differentials by line of business, we calculated utilization adjustment factors for each line of business and multiplied the zero-cost–sharing utilization by these factors.

Methodology and Assumptions for Postmandate Utilization

- We normalized the CHSD data to the postmandate zero-cost–sharing utilization levels using Milliman's 2019 Health Cost Guidelines.
- Different procedures have different incidence rates and levels of cost sharing in the data. We developed adjustment factors for the procedure-specific share of the claims with cost sharing, and blended these factors with a factor of 1.00 for the share of claims with no cost sharing. The incidence rates, cost-share rate, and adjustment factors are show in Table B-2 of this Appendix.
- Breast imaging services indicating potential breast cancers typically lead to additional diagnostic breast imaging and/or breast biopsies. We assumed that enrollees would, if indicated, receive an ultrasound prior to a biopsy, and that ultrasounds would be followed by biopsy in 11.3% of cases

(Vlahiotis et al, 2018). The cost of additional biopsies resulting from the increased utilization of breast imaging is shown in Table 1.

Table B-2. Premandate Cost-Sharing Incidence and Share and Utilization Adjustment Factors

Modality	Percentage of Procedures with Cost Sharing	Per-Unit Average Enrollee Cost-Share*	Zero Cost-Share Utilization Adjustment Factor**
Mammogram	54.8%	$133.35	1.149
MRI	50.2%	$569.38	1.149
Ultrasound	59.2%	$104.65	1.149
DBT	7.7%	$47.13	1.102

* Average cost-share is calculated using only services for which member cost-share was not zero.

**Utilization Adjustment Factor is applied only to the share of utilization with non-zero cost shares.

Methodology and Assumptions for Postmandate Cost

- We assumed there would be no change in per-unit cost postmandate.
- Allowed costs per breast imaging service were trended from 2019 to 2023 using 4.5% trend.
- Allowed costs for additional postmandate biopsies were identified in the 2019 CHSD data by the procedure codes provided in Vlahiotis et al. (2018), as shown in **Table B-3** of this Appendix. We did not rely upon the ICD-9 procedure codes shown in that source. Allowed costs per biopsy service were trended from 2019 to 2023 using 3.5% trend.

Table B-3. Breast Biopsy Procedure Codes

CPT/HCPCS	Long Description
10021	Fine needle aspiration biopsy, without imaging guidance; first lesion
10022	Fine needle aspiration; with imaging guidance
19081	Biopsy, breast, with placement of breast localization device(s) (e.g., clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including stereotactic guidance
19083	Biopsy, breast, with placement of breast localization device(s) (e.g., clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including ultrasound guidance
19085	Biopsy, breast, with placement of breast localization device(s) (e.g., clip, metallic pellet), when performed, and imaging of the biopsy specimen, when performed, percutaneous; first lesion, including magnetic resonance guidance
19100	Biopsy of breast; percutaneous, needle core, not using imaging guidance (separate procedure)
19101	Biopsy of breast; open, incisional
19102	Biopsy of breast; percutaneous, needle core, using imaging guidance
19103	Biopsy of breast; percutaneous, automated vacuum assisted or rotating biopsy device, using imaging guidance
19120	Excision of cyst, fibroadenoma, or other benign or malignant tumor, aberrant breast tissue, duct lesion, nipple or areolar lesion (except 19300), open, male or female, 1 or more lesions
19125	Excision of breast lesion identified by preoperative placement of radiological marker, open; single lesion

19126	Excision of breast lesion identified by preoperative placement of radiological marker, open; each additional lesion separately identified by a preoperative radiological marker (List separately in addition to code for primary procedure)
19281	Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance
19282	Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including mammographic guidance (List separately in addition to code for primary procedure)
19283	Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including stereotactic guidance
19286	Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including ultrasound guidance (List separately in addition to code for primary procedure)
19287	Placement of breast localization device(s) (e.g. clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including magnetic resonance guidance
19288	Placement of breast localization device(s) (e.g. clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; each additional lesion, including magnetic resonance guidance
19290	Preoperative placement of needle localization wire, breast
19291	Preoperative placement of needle localization wire, breast; each additional lesion (List separately in addition to code for primary procedure)
19295	Image guided placement, metallic localization clip, percutaneous, during breast biopsy/aspiration (List separately in addition to code for primary procedure)
76098	Radiological examination, surgical specimen
76942	Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation
77021	Magnetic resonance imaging guidance for needle placement (e.g., for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation
77031	Stereotactic localization guidance for breast biopsy or needle placement (e.g., for wire localization or for injection), each lesion, radiological supervision and interpretation
77032	Mammographic guidance for needle placement, breast (e.g., for wire localization or for injection), each lesion, radiological supervision and interpretation

Methodology and Assumptions for POSTMANDATE Cost Sharing

- We assumed that there would be no cost sharing for diagnostic breast imaging postmandate.
- We assumed that the bill would have no impact on cost sharing for breast biopsies postmandate.

Determining Public Demand for the Proposed Mandate

CHBRP reviews public demand for benefits relevant to a proposed mandate in 2 ways. CHBRP:

1. Considers the bargaining history of organized labor; and

2. Compares the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and therefore not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that in general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask carriers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

Second-Year Impacts on Benefit Coverage, Utilization, and Cost

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of AB 2024 would have a substantially different impact on utilization of either the tests, treatments, or services for which coverage was directly addressed, the utilization of any indirectly affected utilization, or both. CHBRP reviewed the literature and consulted content experts about the possibility of varied second-year impacts and determined the second year's impacts of AB 2024 would be substantially the same as the impacts in the first year (see Table 1). Minor changes to utilization and expenditures are due to population changes and general health care price inflation between the first year postmandate and the second year postmandate.

REFERENCES

Agency for Healthcare Research and Quality. Clinician Summary: Core-Needle Biopsy for Breast Abnormalities. December 2019. Effective Health Care Program, Agency for Healthcare Research and Quality, Rockville, MD. Available at: https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/breast-biopsy-update_clinician.pdf. Accessed April 7, 2022.

American Cancer Society (ACS), California Department of Public Health, California Cancer Registry. California Cancer Facts & Figures 2017. Alameda, CA: American Cancer Society, Inc. California Division; 2017.

American Cancer Society (ACS). Cancer Statistics Center. Cancer at a Glance: Breast. 2022a. Available at: https://cancerstatisticscenter.cancer.org/#!/state/California. Accessed March 2, 2022.

American Cancer Society (ACS). Breast Cancer Risk Factors You Cannot Change. December 16, 2021. Available at: www.cancer.org/cancer/breast-cancer/risk-and-prevention/breast-cancer-risk-factors-you-cannot-change.html. Accessed March 2, 2022.

American Cancer Society (ACS). Ductal Carcinoma In Situ (DCIS). November 19, 2021b. Available at: www.cancer.org/cancer/breast-cancer/about/types-of-breast-cancer/dcis.html. Accessed April 9, 2022.

American College of Obstetricians and Gynecologists (ACOG). Committee on Gynecologic Practice. Management of Women With Dense Breasts Diagnosed by Mammography. Number 625, March 2015. 2017. Available at: www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2015/03/management-of-women-with-dense-breasts-diagnosed-by-mammography.pdf. Accessed March 3, 2022.

American College of Radiology (ACR). ACR Appropriateness Criteria: Supplemental Breast Cancer Screening Based on Breast Density. 2021. Available at: https://acsearch.acr.org/docs/3158166/Narrative/. Accessed March 8, 2022.

American Society of Clinical Oncology. Breast Cancer: Risk Factors and Prevention. Cancer.Net website. 2020. Available at: www.cancer.net/cancer-types/breast-cancer/risk-factors-and-prevention. Accessed March 4, 2022.

Benndorf M, Baltzer PA, Vag T, Gajda M, Runnebaum IB, Kaiser WA. Breast MRI as an adjunct to mammography: does it really suffer from low specificity? A retrospective analysis stratified by mammographic BI-RADS classes. *Acta Radiologica (Stockholm, Sweden: 1987).* 2010;51(7):715-721.

California Cancer Registry. Age-Adjusted Invasive Cancer Incidence Rates by County in California, Female Breast, 2016 - 2017. 2019. Available at: http://cancer-rates.info/ca/. Accessed March 18, 2022.

California Cancer Registry. Breast Cancer in California, 2012-2016. Available at: www.ccrcal.org/download/72/cancer-fact-sheets/7914/breast-cancer-in-california-2012-2016-new.pdf. Accessed March 3, 2022.

California Department of Health Care Services (CA DHCS). Every Woman Counts: Expenditure and Caseload, Second Biannual Report to the Legislature Fiscal Year 2019-20. November 2020. Available at: www.dhcs.ca.gov/formsandpubs/Documents/Legislative%20Reports/Every%20Woman%20Counts%20Reports/EWC-Second-Biannual-Report-FY2019-20.pdf. Accessed March 2022.

California Health Benefits Review Program (CHBRP). Resource: 2023 Estimates, Deductibles in State-Regulated Health Insurance. Berkeley, CA. Available at: https://chbrp.org/other_publications/index.php. Accessed March 2022.

Center on Budget and Policy Priorities. Key Facts: Cost-Sharing Charges. 2018. Available at www.healthreformbeyondthebasics.org/cost-sharing-charges-in-marketplace-health-insurance-plans-answers-to-frequently-asked-questions/. Accessed March 31, 2020.

Centers for Disease Control and Prevention (CDC). Breast Cancer Screening Guidelines for Women. eptember 22, 2020. Available at: www.cdc.gov/cancer/breast/pdf/breast-cancer-screening-guidelines-508.pdf. Accessed March 14, 2022.

Centers for Disease Control and Prevention (CDC). BRCA Gene Mutations. September 27, 2021(a). Available at: www.cdc.gov/cancer/breast/young_women/bringyourbrave/hereditary_breast_cancer/brca_gene_mutations.htm. Accessed March 2, 2022.

Centers for Disease Control and Prevention (CDC). NCHHSTP Social Determinants of Health: Frequently Asked Questions. March 10, 2014; Available at: www.cdc.gov/nchhstp/socialdeterminants/faq.html. Accessed August 27, 2015.

Centers for Disease Control and Prevention (CDC). What Are the Risk Factors for Breast Cancer? September 20, 2021(b). Available at: www.cdc.gov/cancer/breast/basic_info/risk_factors.htm. Accessed March 1, 2022.

Centers for Disease Control and Prevention (CDC). What Does It Mean to Have Dense Breasts? September 22, 2021(c). Available at: www.cdc.gov/cancer/breast/basic_info/dense-breasts.htm. Accessed March 12, 2022.

Centers for Medicare and Medicaid Services (CMS). Notice of Benefit and Payment Parameters for 2022 Final Rule Part Two Fact Sheet. 2021. Available at: www.cms.gov/newsroom/fact-sheets/notice-benefit-and-payment-parameters-2022-final-rule-part-two-fact-sheet. Accessed November 15, 2021.

Chen H-L, Zhou J-Q, Chen Q, Deng Y-C. Comparison of the sensitivity of mammography, ultrasound, magnetic resonance imaging and combinations of these imaging modalities for the detection of small (</=2 cm) breast cancer. *Medicine (Baltimore).* 2021;100(26):e26531.

Chiu K, Tirada N, Vachhani P, Robinson L, Khorjekar G. Why Patients Decline Digital Breast Tomosynthesis? Results From a Patient Survey in an Urban Academic Breast Center. *Current Problems in Diagnostic Radiology*. 2020;49(6):412-416.

Co M. Ductal carcinoma in situ of the breasts: over-diagnosis, over-treatment and a decade of lost direction. *Precision Medical Sciences*. 2020;9(1):4-8.

Ezratty C, Vang S, Brown J, Margolies LR, Jandorf L, Lin JJ. Racial/ethnic differences in supplemental imaging for breast cancer screening in women with dense breasts. *Breast Cancer Research and Treatment.* 2020;182(1):181-185.

Freer PH, Slanetz PJ. Breast density and screening for breast cancer. UpToDate. February 2022. Available at: www.uptodate.com/contents/breast-density-and-screening-for-breast-cancer. Accessed March 12, 2022.

Gehlert S, Hudson D, Sacks T. A critical theoretical approach to cancer disparities: breast cancer and the social determinants of health. *Frontiers in Public Health*. 2021;9:674736.

Haas JS, Hill DA, Wellman RD, et al. Disparities in the use of screening magnetic resonance imaging of the breast in community practice by race, ethnicity, and socioeconomic status. *Cancer.* 2016;122(4):611-617.

Health Resources and Services Administration (HRSA). Women's Preventive Services Guidelines. 2022. Available at: www.hrsa.gov/womens-guidelines/index.html. Accessed March 22, 2022.

Hill DA, Prossnitz ER, Royce M, Nibbe A. Temporal trends in breast cancer survival by race and ethnicity: a population-based cohort study. *PLoS One.* 2019;14(10): e0224064.

Hofvind S, Hovda T, Holen AS, et al. Digital breast tomosynthesis and synthetic 2D mammography versus digital mammography: evaluation in a population-based screening program. *Radiology.* 2018;287(3):787-794.

Hooshmand S, Reed WM, Suleiman ME, Brennan PC. A review of screening mammography: the benefits and radiation risks put into perspective. *Journal of Medical Imaging and Radiation Sciences.* 2022;53(1):147-158.

Hooshmand S, Reed WM, Suleiman ME, Brennan PC. Screening mammography: diagnostic efficacy-issues and considerations for the 2020s. *Radiation Protection Dosimetry.* 2021;197(1):54-62.

Houssami N, Skaane P. Overview of the evidence on digital breast tomosynthesis in breast cancer detection. *Breast.* Apr 2013;22(2):101-108.

Huang SQ, Houssami N, Brennan M, Nickel B. The impact of mandatory mammographic breast density notification on supplemental screening practice in the United States: a systematic review. *Breast Cancer Research and Treatment*. 2021;187(1):11-30.

John EM, Miron A, Gong G, et al. Prevalence of pathogenic BRCA1 mutation carriers in 5 US racial/ethnic groups. *JAMA.* 2007;298(24):2869-2876.

John M. Eisenberg Center for Clinical Decisions and Communications Science. Having a Breast Biopsy: A Review of the Research for Women and Their Families. 2016 May 26. In: Comparative Effectiveness Review Summary Guides for Consumers [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2005–. PMID: 27336123.

Killelea BK, Lannin DR, Horvath LJ, Horowitz NR, Chagpar AB. Factors associated with breast MRI use: a population-based analysis. *Annals of Surgical Oncology*. 2013;20(6):1798-1805.

Ko MJ, Park DA, Kim SH, et al. Accuracy of digital breast tomosynthesis for detecting breast cancer in the diagnostic setting: a systematic review and meta-analysis. *Korean Journal of Radiology.* 2021;22(8):1240-1252.

Lee CI, Zhu W, Onega T, et al. Comparative access to and use of digital breast tomosynthesis screening by women's race/ethnicity and socioeconomic status. *JAMA Network Open.* 2021;4(2):e2037546.

Lei J, Yang P, Zhang L, Wang Y, Yang K. Diagnostic accuracy of digital breast tomosynthesis versus digital mammography for benign and malignant lesions in breasts: a meta-analysis. *European Radiology.* 2014;24(3):595-602.

Mann RM, Kuhl CK, Moy L. Contrast-enhanced MRI for breast cancer screening. *Journal of Magnetic Resonance Imaging.* 2019;50(2):377-390.

Marinovich ML, Hunter KE, Macaskill P, Houssami N. Breast cancer screening using tomosynthesis or mammography: a meta-analysis of cancer detection and recall. *Journal of the National Cancer Institute.* 2018;110(9):942-949.

Melnikow J, Fenton JJ, Whitlock EP, et al. Supplemental screening for breast cancer in women with dense breasts: a systematic review for the U.S. Preventive Services Task Force. *Annals of Internal Medicine.* 2016;164(4):268-278.

Naeim RM, Marouf RA, Nasr MA, et al. Comparing the diagnostic efficacy of digital breast tomosynthesis with full-field digital mammography using BI-RADS scoring. *Egyptian Journal of Radiology and Nuclear Medicine.* 2021;52(44):1-13.

National Cancer Institute (NCI). Cancer Trends Progress Report. Breast Cancer Screening. July 2021. Available at: https://progressreport.cancer.gov/detection/breast_cancer. Accessed March 28, 2022.

National Cancer Institute (NCI). Dense Breasts: Answers to Commonly Asked Questions. Updated July 14, 2020a. Available at: www.cancer.gov/types/breast/breast-changes/dense-breasts. Accessed March 3, 2022.

National Cancer Institute (NCI). Mammograms: What Is 3-D Mammography (Also Known as Tomosynthesis Mammography)? September 30, 2020(b). Available at www.cancer.gov/types/breast/mammograms-fact-sheet#what-is-3-d-mammography-also-known-as-tomosynthesis-mammography. Accessed March 4, 2022.

National Cancer Institute (NCI). PDQ Breast Cancer Treatment (Adult) (PDQ®)–Health Professional Version. Bethesda, MD: National Cancer Institute, PDQ® Adult Treatment Editorial Board. January 20, 2022. Available at: www.cancer.gov/types/breast/hp/breast-treatment-pdq. Accessed March 3, 2022.

National Cancer Institute (NCI). Risk Calculator. The Breast Cancer Risk Assessment Tool. Available at: https://bcrisktool.cancer.gov/. Accessed March 4, 2022.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice in Oncology (NCCN Guidelines). Breast Cancer Screening and Diagnosis. Version 1.2021. 2021. Available at: www.nccn.org/login?ReturnURL=https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf. Accessed March 20, 2022.

Nelson HD, Pappas M, Cantor A, Griffin J, Daeges M, Humphrey L. Harms of breast cancer screening: systematic review to update the 2009 U.S. Preventive Services Task Force Recommendation. *Annals of Internal Medicine*. 2016;164(4):256-267.

Newman LA. Breast cancer disparities: socioeconomic factors versus biology. *Annals of Surgical Oncology.* 2017;24(10):2869-2875.

Norris HC, Richardson HM, Benoit M-AC, Shrosbree B, Smith JE, Fendrick AM. Utilization impact of cost-sharing elimination for preventive care services: a rapid review. *Medical Care Research and Review*. 2022;79(2):175-197.

Office of Disease Prevention and Health Promotion. Healthy People 2020: Social Determinants of Health. 2019; Available at: www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health. Accessed August 29, 2019.

Oppong BA, Obeng-Gyasi S, Relation T, Adams-Campbell L. Call to action: breast cancer screening recommendations for Black women. *Breast Cancer Research and Treatment.* 2021;187(1):295-297.

Pan I-W, Oeffinger KC, Shih Y-CT. Cost-sharing and out-of-pocket cost for women who received MRI for breast cancer screening. *Journal of the National Cancer Institute*. 2022;114(2):254-262.

Radhakrishna S, Agarwal S, Parikh PM, et al. Role of magnetic resonance imaging in breast cancer management. *South Asian Journal of Cancer.* 2018;7(2):69-71.

Rebner M, Pai VR. Breast cancer screening recommendations: African American women are at a disadvantage. *Journal of Breast Imaging*. 2020;2(5):416-421.

Siu AL, U.S. Preventive Services Task Force (Sui and USPSTF). Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. *Annals of Internal Medicine.* 2016;164(4):279-296.

Tran L, Chetlen AL, Leslie DL, Segel JE. Effect of out-of-pocket costs on subsequent mammography screening. *Journal of the American College of Radiology*. 2022;19(1 Pt A):24-34.

van der Borden CL, Stoffers S, Lips EH, Wesseling J. Avoiding overtreatment of ductal carcinoma in situ. *Trends in Cancer*. 2019;5(7):391-393.

Vlahiotis A, Griffin B, Stavros AT, Margolis J. Analysis of utilization patterns and associated costs of the breast imaging and diagnostic procedures after screening mammography. *ClinicoEconomics and Outcomes Research*. 2018;10:157-167.

Wyatt R, Laderman M, Botwinick L, Mate K, Whittington J. Achieving Health Equity: A Guide for Health Care Organizations. IHI White Paper. Cambridge, MA: Institute for Healthcare Improvement; 2016.

Wharam JF, Zhang F, Lu CY, et al. Breast cancer diagnosis and treatment after high-deductible insurance enrollment. *Journal of Clinical Oncology*. 2018;36(11):1121-1127.

Wharam JF, Zhang F, Wallace J, Lu C, Earle C, Soumerai SB, Nekhlyudov L, Ross-Degnan D. Vulnerable and less vulnerable women in high-deductible health plans experienced delayed breast cancer care. *Health Affairs (Millwood)*. 2019;38(3):408-415.

You C, Zhang Y, Gu Y, et al. Comparison of the diagnostic performance of synthesized two-dimensional mammography and full-field digital mammography alone or in combination with digital breast tomosynthesis. *Breast Cancer.* 2020;27(1):47-53.

Zeng A, Brennan ME, Young S, Mathieu E, Houssami N. The effect of supplemental imaging on interval cancer rates in mammography screening: systematic review. *Clinical Breast Cancer.* 2022;22(3):212-222.

Zuley ML, Bandos AI, Ganott MA, et al. Digital breast tomosynthesis versus supplemental diagnostic mammographic views for evaluation of noncalcified breast lesions. *Radiology.* 2013;266(1):89-95.

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM COMMITTEES AND STAFF

A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing researchers and analysts who are **Task Force Contributors** to CHBRP from UC that conduct much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, **Milliman**, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

Faculty Task Force

Paul Brown, PhD, University of California, Merced
Timothy T. Brown, PhD, University of California, Berkeley
Janet Coffman, MA, MPP, PhD, *Vice Chair for Medical Effectiveness*, University of California, San Francisco
Todd Gilmer, PhD, University of California, San Diego
Sylvia Guendelman, PhD, LCSW, University of California, Berkeley
Elizabeth Magnan, MD, PhD, *Co-Vice Chair for Public Health*, University of California, Davis
Sara McMenamin, PhD, *Vice Chair for Medical Effectiveness and Public Health*, University of California, San Diego
Joy Melnikow, MD, MPH, *Co-Vice Chair for Public Health*, University of California, Davis
Aimee Moulin, MD, University of California, Davis
Jack Needleman, PhD, University of California, Los Angeles
Mark A. Peterson, PhD, University of California, Los Angeles
Nadereh Pourat, PhD, *Vice Chair for Cost*, University of California, Los Angeles
Dylan Roby, PhD, University of California, Irvine
Marilyn Stebbins, PharmD, University of California, San Francisco

Task Force Contributors

Bethney Bonilla, MA, University of California, Davis
Danielle Casteel, MA, University of California, San Diego
Shana Charles, PhD, MPP, University of California, Los Angeles, and California State University, Fullerton
Margaret Fix, MPH, University of California, San Francisco
Naomi Hillery, MPH, University of California, San Diego
Jeffrey Hoch, PhD, University of California, Davis
Julia Huerta, MPH, University of California, Davis
Michelle Keller, PhD, MPH, University of California, Los Angeles
Jacqueline Miller, University of California, San Francisco
Marykate Miller, MS, University of California, Davis
Amy Quan, University of California, San Francisco
Dominique Ritley, MPH, University of California, Davis
Emily Shen, University of California, San Francisco
Riti Shimkhada, PhD, University of California, Los Angeles

National Advisory Council

CHBRP Staff

California Health Benefits Review Program
MC 3116
Berkeley, CA 94720-3116
info@chbrp.org
(510) 664-5306

*Independent Contractor working with CHBRP to support analyses and other projects.

CHBRP is an independent program administered and housed by the University of California, Berkeley, under the Office of the Vice Chancellor for Research.

ACKNOWLEDGMENTS

CHBRP gratefully acknowledges the efforts of the team contributing to this analysis:

Steven Tally, PhD, of the University of California, San Diego, prepared the medical effectiveness analysis. Karen Andrews, MLS, of the University of California, Berkeley, conducted the literature search. Dominique Ritley, MPH, and Aimee Moulin, MD, both of the University of California, Davis, prepared the background section and the public health impact analysis. Shana Charles, PhD, MPP, of the University of California, Los Angeles, prepared the cost impact analysis. Dan Henry, FSA, MAAA, of Milliman, provided actuarial analysis. Content expert Joy Melnikow, MD, MPH, of the University of California, Davis, provided technical assistance with the literature search and expert input on the analytic approach. John Lewis, MPA, of CHBRP staff prepared the policy context and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see previous page of this report) and a member of the CHBRP Faculty Task Force, Timothy T. Brown, PhD, of the University of California, Berkeley, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

Garen Corbett, MS
Director

Please direct any questions concerning this document to: California Health Benefits Review Program; MC 3116; Berkeley, CA 94720-3116, info@chbrp.org, or www.chbrp.org