California Health Benefits Review Program

Analysis of California Assembly Bill (AB) 2764 Health Care Coverage: Mammography

A Report to the 2015-2016 California State Legislature

May 6, 2016



Key Findings: Analysis of California Assembly Bill (AB) 2764 Mammography

Summary to the 2015-2016 California State Legislature, May 2016



AT A GLANCE

AB 2764 would mandate coverage for digital mammography and digital breast tomosynthesis (DBT).

Enrollees covered. CHBRP estimates that in 2016, 25.2 million Californians have state-regulated coverage that would be subject to AB 2764.

- **Background.** Digital mammography is frequently used as a breast cancer screening test. Less frequently, DBT is added to digital mammography when screening for breast cancer.
- **Medical effectiveness.** There is *clear and convincing* evidence that compared to no screening digital mammography alone leads to reduced breast cancer–related mortality, and may detect breast cancer at an earlier stage among some subgroups of women. There is insufficient evidence to indicate whether adding DBT to digital mammography for breast cancer screening would alter these key clinical outcomes.
- **Benefit coverage.** AB 2764 would not alter the fact that 100% of enrollees have coverage for digital mammography but would increase coverage for DBT (from 61% of enrollees to 100%).
- **Utilization.** Utilization of screening digital mammography would increase by 4% and utilization of DBT would increase by 91%.
- **Expenditures.** AB 2764 would increase total expenditures (premiums and cost sharing) by \$39,500,000 (0.03%).
- **Public Health.** Due to 100% coverage, CHBRP projects no impacts on health outcomes attributable to digital mammography. Due to insufficient evidence of increased medical effectiveness for use of DBT, CHBRP finds impacts on health outcomes attributable to DBT to be unknown.
- Long Term Impacts. AB 2764's impacts on utilization and expenditures would increase after the first postmandate year, as DBT technology becomes more available. However, the impact on health outcomes of the later years' increased DBT utilization is unknown.

BACKGROUND

Mammography provides an x-ray picture of the breast, and can be conducted as a screening or diagnostic test. As a screening test, its purpose is to identify potentially cancerous abnormalities in asymptomatic women. As a diagnostic test, it further investigates identified abnormalities or checks for abnormalities among women previously treated for breast cancer.

CHBRP's full report discusses diagnostic tests, but this key findings section focuses on breast cancer screening and the related impacts that would result from AB 2764.

Film and digital mammography are frequently used as breast cancer screening tests. Both produce twodimensional images. In recent years, digital mammography has become the much more commonly used form. Digital breast tomosynthesis (DBT) takes multiple cross-sectional images of the breast and then uses a computer algorithm to reconstruct a threedimensional image. DBT images for screening are generally obtained in combination with digital mammography. Breast cancer screening generally consists of digital mammography alone although it is sometimes accompanied by DBT.

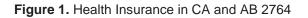
In either case, when results indicate an abnormality that may be breast cancer, additional tests (additional mammographic views and/or other tests - possibly breast ultrasound, and/or biopsies) may also be performed to verify the presence of cancer.

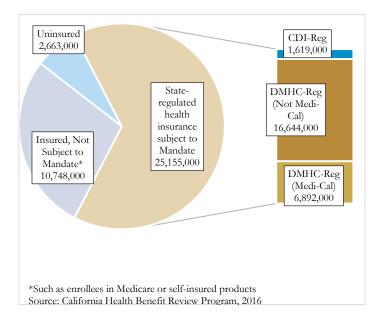
BILL SUMMARY

AB 2764 would amend a current benefit mandate law to specify "mammography" as inclusive of both digital mammography, which is generally covered, as well as DBT, which is frequently not covered. Both can be used as screening and/or diagnostic tests for breast cancer.

AB 2764, as noted in Figure 1, would affect the health insurance of enrollees in plans regulated by the California Department of Managed Health Care (DMHC) as well as

the health insurance of enrollees in policies regulated by the California Department of Insurance (CDI).





Medical Effectiveness

Film and digital mammography are comparable as breast cancer screening tests for "average-risk women." Numerous clinical guidelines recommend film or digital mammography as breast cancer screening tests. Examples include current guidelines and recommendations issued by the following national sources:

- American Academy of Family Physicians (AAFP)
- American Congress of Obstetrics and Gynecology (ACOG)
- American College of Radiology (ACR)
- American Cancer Society (ACS)
- National Comprehensive Cancer Network (NCCN)
- United States Preventive Services Task Force (USPSTF)

The 2016 USPSTF recommendations noted evidence that screening mammography (film or digital) impacts clinically significant health outcomes, reducing breast-cancer specific mortality among women aged 40 to 74 years and also reducing cancer stage at diagnosis among women aged 50 years and older. Although the ACR concludes that DBT is no longer an investigational modality and "improves key screening parameters compared to digital mammography," the ACS, as well as the AAFP, ACOG,

NCCN, and USPSTF, citing insufficient evidence, have not recommended DBT as a screening tool for breast cancer.

For its analysis of AB 2764, CHBRP focused on reviewing the comparative effectiveness for breast cancer screening of (1) digital mammography alone and (2) digital mammography with DBT.

The previously mentioned guidelines and recommendations, as well as a number of systematic evidence reviews, provide *clear and convincing* evidence that digital mammography alone, leads, to reduced breast cancer-related mortality, and may detect breast cancer at an earlier stage among some subgroups of women.

As noted most guidelines and recommendations cite insufficient evidence to recommend DBT as an addition to digital mammography. In addition, CHBRP located no studies of digital mammography with DBT that evaluated key clinical outcomes such as reduced breast cancerrelated mortality or earlier stage diagnosis. Therefore, CHBRP concludes that there is *insufficient* evidence to determine the effectiveness of adding DBT to screening digital mammography on key clinical outcomes.

There is *preponderance* of evidence, from low- to moderate-quality studies, that in comparison to digital mammography alone, digital mammography with DBT may reduce recall (for further testing) by 1.6-2.6%, decreasing to 6.4% to 13.6% with the addition of DBT to digital mammography from 9.3% to 16.2% with digital mammography alone, and that the addition of DBT may increase breast cancer detection by as many as 1 per 1,000 tests, from 4 cancers per 1,000 exams to 5 cancers per 1,000 exams. However, there is insufficient long-term follow up evidence to conclude that the additional tests led to improved outcomes.

Although screening mammography (generally digital mammography alone) reduces mortality from breast cancer in women aged 40 to 75 years, it is associated with some harms. The USPSTF cites the key harm as overdiagnosis (diagnosis of a cancer that would not have progressed to clinical significance) and subsequent overtreatment.

In addition to the previously described harms associated with digital mammography, DBT, like digital mammography, involves radiation exposure. Although the exposure for both is limited, DBT and digital mammography together result in greater radiation exposure than does digital mammography alone.



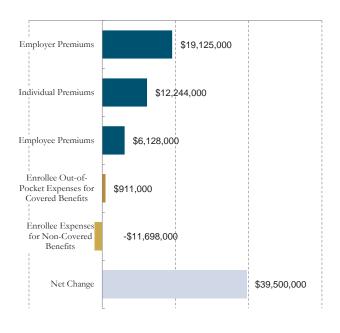
Benefit Coverage

Although 100% of enrollees in DMHC-regulated plans and CDI-regulated policies have coverage for digital mammography, premandate only 61% of these enrollees have coverage for DBT. AB 2764 would increase the second figure to 100%.

Utilization

In 2017, among enrollees with health insurance that could be subject to AB 2764, CHBRP estimates that there would be 2,832,000 screening digital mammograms, and that 862,000 of those would be accompanied by DBT tests. Postmandate, both figures would rise, screening digital mammograms to 2,950,000 (an increase of 4%), a hastening of the general trend away from film mammography to digital mammography. Accompanying DBT tests would also increase, to 1,646,000 (an increase of 91%).

Figure 2. Impacts on Premiums and Cost Sharing



Expenditures

As detailed in Figure 2, as a result of the increased utilization, total expenditures (premiums and cost sharing) would increase \$39,499,000 (0.03%). This figure assumes cost sharing only for diagnostic digital/film mammography and DBT (no cost sharing for screening test) and represents a reduction in payments by enrollees for non-covered DBT.

Public health

Because the review found insufficient evidence to suggest that the use of DBT in addition to digital mammography would improve clinically meaningful health outcomes (i.e., breast cancer-related morbidity and mortality), the public health impact in the first year, postmandate, is unknown. Please note that the absence of evidence is not "evidence of no effect." Impacts — desirable and/or undesirable could result, but current evidence is insufficient to inform an estimate.

Long-Term Impacts

Impacts on utilization during the 12 months following enactment of AB 2764 would be constrained by availability of DBT technology, but CHBRP would expect, postmandate, for DBT to accompany over half of digital mammograms postmandate (an increase from a premandate estimate of one third). In later years, as DBT technology is made more accessible, impacts could increase so that over 90% of enrollees utilizing screening digital mammography may simultaneously utilize DBT. Such an increase in utilization would be expected to have concomitant impacts on expenditures. However, the impact on meaningful health outcomes of the additional utilization is unknown.