

Key Findings:

Analysis of California Assembly Bill 2342

BRCA Gene Mutations: Screening, Counseling, and Testing

Summary to the 2017–2018 California State Legislature, April 16, 2018



AT A GLANCE

The version of California Assembly Bill 2342 analyzed by CHBRP would require that plans and policies provide coverage for breast cancer susceptibility gene (BRCA) screening, and if indicated, genetic counseling and genetic testing for women who meet certain criteria.

1. CHBRP estimates that, in 2019, of the 23.4 million Californians enrolled in state-regulated health insurance, 23.4 million of them will have insurance subject to AB 2342.
2. **Benefit coverage.** CHBRP estimates that AB 2342 would not change benefit coverage because coverage at baseline is 100%. The bill would not be likely to exceed the essential health benefits (EHBs).
3. **Utilization.** Due to 100% baseline coverage for screening, genetic counseling and testing for BRCA gene mutations, CHBRP estimates there will be no measurable change in utilization of these services.
4. **Expenditures.** CHBRP estimates no change in expenditures as utilization will remain steady.
5. **Medical effectiveness.** Regarding **screening**, there is a preponderance of evidence that familial risk screening tools are effective in accurately identifying women at risk for a BRCA mutation. Regarding **counseling**, there is a preponderance of evidence that genetic counseling before testing improves risk perception accuracy, decreases breast-cancer related worry and decreases intention to pursue genetic testing among women unlikely to be mutation carriers. Regarding **testing**, the diagnostic accuracy of BRCA mutation genetic tests — or the tests' ability to correctly identify mutation carriers - appears to be well established.
 - a. CHBRP finds insufficient evidence to conclude whether screening, counseling, and testing for BRCA gene mutations leads to reduced incidence of BRCA-related cancer or reduced mortality due to the lack of studies addressing this question.
6. **Public health.** Because utilization is not expected to change, CHBRP estimates no measurable public health impact.
7. **Long-term impacts.** It appears unlikely that AB 2342 will have long-term cost or public health impacts due to existing coverage for BRCA screening, counseling, and testing as a grade "B" U.S. Preventive Services Task Force (USPSTF) recommended service. If the Affordable Care Act is repealed or altered, AB 2342 would preserve coverage in California for BRCA screening, counseling, and testing.

CONTEXT

BRCA1 and *BRCA2* are cancer susceptibility genes that create tumor suppressor proteins.¹ Individuals with inherited mutations in these genes experience an increased risk of developing some types of cancer, including breast and ovarian cancer. BRCA gene mutations can impact both men and women's risk of developing certain kinds of cancer.

BILL SUMMARY

The bill requires that health care service plans and policies provide coverage for **screening for risk of BRCA genetic mutations** for women who have not been diagnosed with a BRCA-related cancer and are asymptomatic, but may have an increased risk for mutations in breast or ovarian cancer susceptibility genes. AB 2342 requires plans and policies to provide coverage for BRCA screening for asymptomatic women who meet one or more of the following family history criteria:

1. Breast cancer diagnosis before 50 years of age.
2. Bilateral breast cancer.
3. Breast and ovarian cancer.
4. Presence of breast cancer in at least one male family member.
5. Multiple cases of breast cancer in the family.
6. At least one family member with two types of BRCA-related cancer.
7. Ashkenazi Jewish ancestry.

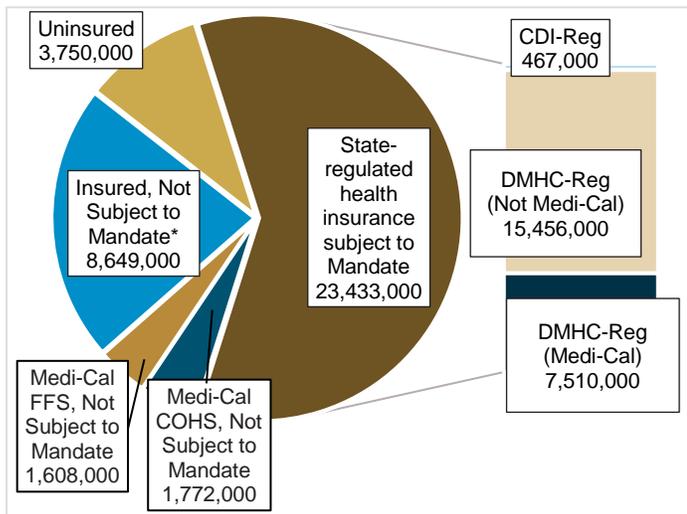
Following use of a generally accepted screening tool to identify family history that may be associated with an increased risk for mutations in *BRCA1* or *BRCA2* genes, AB 2342 requires that plans and policies also cover genetic counseling and genetic testing, if indicated. For women who receive positive screening results, the bill requires that plans and policies provide coverage for **genetic counseling**. If indicated after counseling, AB 2342 also requires coverage for BRCA mutation **genetic**

¹ Refer to CHBRP's full report for full citations and references.

testing. The full text of AB 2342 can be found in Appendix A.

Figure 1 notes the number of Californians with health insurance that would be subject to AB 2342, those with insurance coverage not subject to AB 2342, and Californians that are uninsured.

Figure 1. Health Insurance in CA and AB 2342



Source: California Health Benefits Review Program, 2018.

Notes: *Medicare beneficiaries, enrollees in self-insured products, etc.

Key: CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Care; FFS = Fee-for-Service.

IMPACTS

Benefit Coverage, Utilization, and Cost

The Affordable Care Act (ACA) requires that certain preventive services be covered without cost sharing for private nongrandfathered plans (individual, small group, and large group).

Based on the recommendation of the U.S. Preventive Services Task Force (USPSTF), nongrandfathered group and individual health insurance plans and policies are required to cover, without cost sharing, screening, genetic counseling, and testing, if indicated, for women whose family history is associated with an increased risk for *BRCA1* or *BRCA2* gene mutations.

Benefit Coverage

CHBRP estimates 100% of enrollees with health insurance that would be subject to AB 2342 have coverage for screening of family history risk for breast cancer susceptibility genes (*BRCA*), genetic counseling, and *BRCA* mutation testing.

Current coverage of *BRCA* family history screening, genetic counseling, and testing was determined by a survey of the largest (by enrollment) health insurers in California. Responses to this survey represent 78% of enrollees in privately funded health insurance market that can be subject to state mandates, 59% of enrollees with coverage through a Medi-Cal Managed Care Plan.

Utilization

Because an estimated 100% of enrollees have coverage for the benefits outlined in AB 2342, CHBRP estimates no measurable change in utilization following enactment of AB 2342. Because AB 2342 will not lead to a change in benefits for health plans, CHBRP assumes health plans will not invest in new marketing or documentation changes that may raise provider awareness or education.

Expenditures

AB 2342 would result in no measurable change in total net annual expenditures, premiums, or enrollee expenses for covered and/or noncovered benefits.

Among publicly funded DMHC-regulated health plans, CHBRP estimates no impact on Medi-Cal Managed Care. Because AB 2342 does not apply to Medi-Cal Fee-for-Service or Medi-Cal County Organized Health Systems, CHBRP estimates no impact on these market segments.

CalPERS

CHBRP estimates no measurable impact projected on CalPERS plans.

Number of Uninsured in California

CHBRP estimates no measurable impact on the number of people who are uninsured in California.

Medical Effectiveness

Although there is no direct evidence that the clinical pathway outlined in AB 2342 — familial risk screening, genetic counseling, and then genetic testing — leads to reductions in the incidence of BRCA-related cancer, cancer-related mortality, or all-cause mortality, there is indirect evidence supporting that each of these activities, as well as risk-reducing interventions for women identified as *BRCA1* or *BRCA2* mutation carriers, are effective. Through CHBRP’s review of the 2013 systematic review to inform the USPSTF, as well as studies published since 2012, CHBRP finds evidence that:

- Familial risk screening tools can accurately identify women at risk for BRCA mutations.
- Genetic counseling before genetic testing improves risk perception accuracy and decreases intention to pursue testing among women unlikely to be BRCA carriers.
- Positive BRCA mutation test results accurately predicts the risk of developing BRCA-related cancer.
- Risk-reducing interventions (intensive screening, medications, and surgery) can mitigate some BRCA-related cancer risk, particularly for BRCA-related breast cancer, leading to reduced incidence of breast cancer and mortality.

Public Health

Although the continuum of screening services for BRCA gene mutations — family-history based risk screening, genetic counseling, and genetic testing — is medically effective, CHBRP concludes that passage of AB 2342 would have no short-term public health impact on breast

cancer outcomes or disparities in screening among women in California due to no population level changes in coverage or utilization for BRCA screening services.

Long-Term Impacts

It appears unlikely that AB 2342 will have long term cost or public health impacts due to existing coverage for BRCA screening, counseling and testing as a grade “B” USPSTF recommended service. If the Affordable Care Act is repealed or altered, it is possible that AB 2342 would preserve coverage for BRCA screening, counseling and testing.

Essential Health Benefits and the Affordable Care Act

Nongrandfathered individual and small group plans are required to cover essential health benefits, including preventive services with a grade “A” or “B” from the US Preventive Services Task Force (USPSTF). At the time of this report’s publication, the USPSTF recommends (with a grade “B”) that primary care providers screen women who have a family history of BRCA-related cancer (i.e., family members with breast, ovarian, tubal, or peritoneal cancer). The risk requirements described in AB 2342 include several similar family history risk requirements, but also include Ashkenazi Jewish ancestry independent of family history. The USPSTF also recommends with a grade “B” that women who screen positive should then receive genetic counseling and, if indicated, genetic testing for BRCA gene mutations. The USPSTF recommendation does not apply to men.

AB 2342 would not require coverage for a new state benefit mandate, but would rather define the risk requirements for screening for *BRCA1* and *BRCA2* gene mutations. The bill requirements appear not to exceed the definition of EHBs in California.