

Analysis of California Senate Bill 912 Biomarker Testing on Behalf of the California Legislature

NCOIL Spring Meeting

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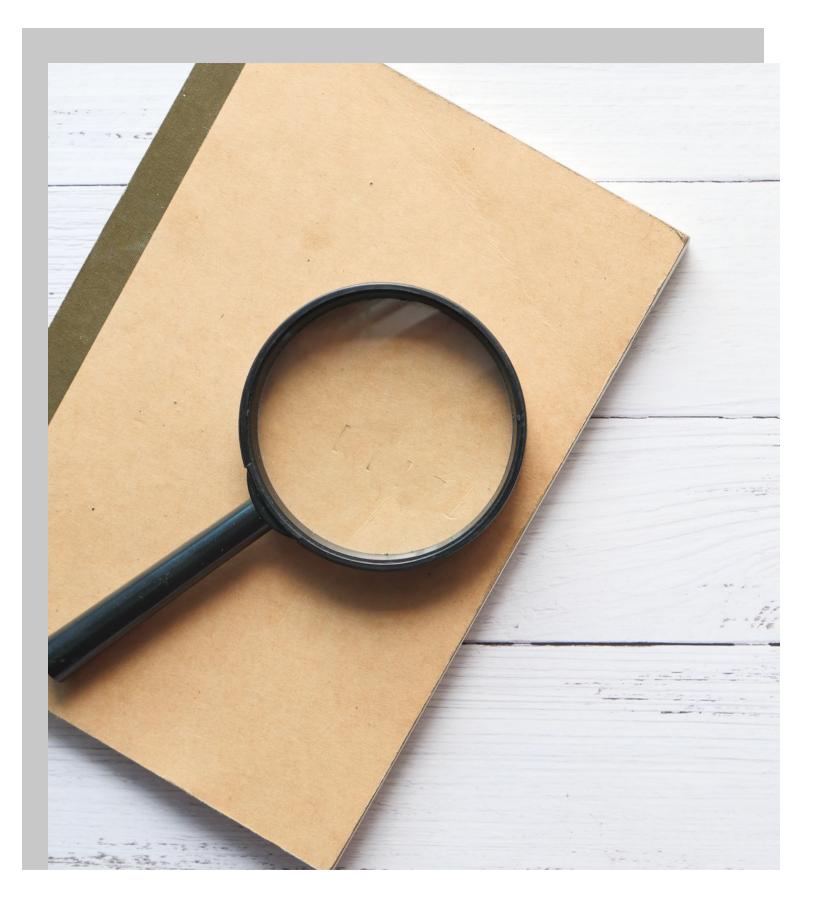


Agenda

- About CHBRP

- Status of legislation
- Conclusion

Senate Bill 912 Biomarker Testing Key deliverables and findings



California Health Benefits Review Program (CHBRP)

- Independent analytic resource located in the University of California
- Multi-disciplinary
- Provides rapid, evidence-based information to the Legislature
- Neutral analysis of introduced bills at the request of the Legislature

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CHBRP's Charge

Policy Context

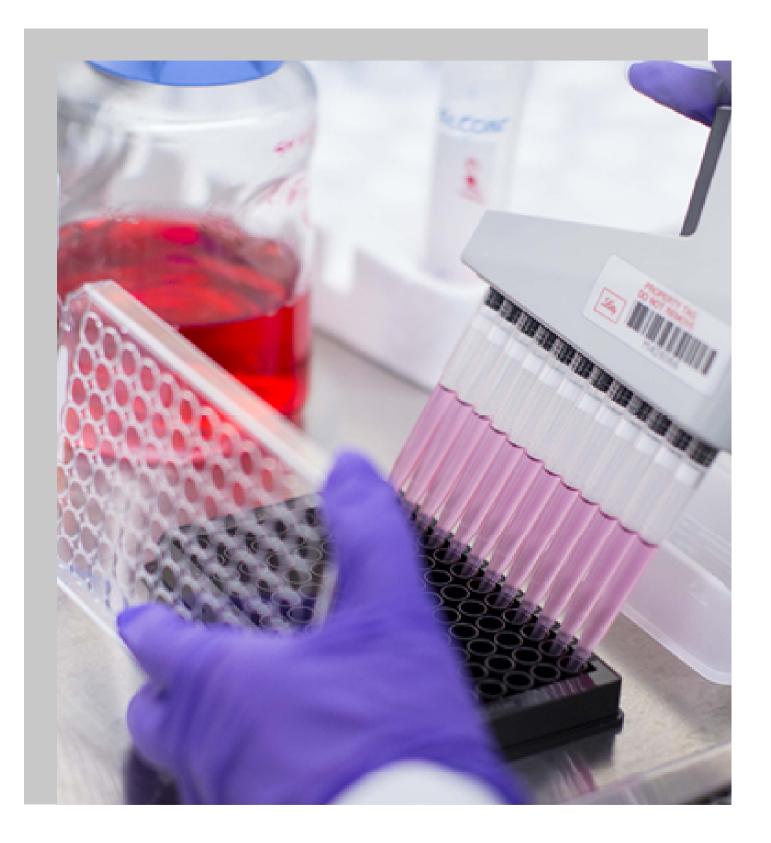
Background

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Medical Effectiveness

Benefit Coverage and Costs

Public Health Impacts



Senate Bill 912 **Biomarker Testing**

- Introduced in early 2022
- Would have required coverage of biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition
- Only for biomarker tests supported by medical and scientific evidence
 - Label indication from the FDA or an indicated test for an FDA-approved medication
 - coverage determination from Medicare contractor consensus statements
 - National coverage determination from CMS or a local Nationally recognized clinical practice guidelines and

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SB 912 Definitions of Biomarker and Biomarker Testing

- Biomarker characteristic objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacological responses to a specific therapeutic intervention. Includes but is not limited to gene mutation and protein expression.
 - Similar to the FDA's definition
- Biomarker testing analysis of an individual's tissue, blood, or other biospecimen for the presence of a biomarker. Includes but is not limited to single-analyte tests, multiplex panel tests, and whole genome sequencing.
- Definitions encompass a vast array of biomarkers and tests, ranging from traditional biomarker testes (e.g. white blood cell count) to biomarkers for genetic variations.

Analytic Approach

	Traditional Approach
Medical Effectiveness	What is the effectiveness of th
Benefit Coverage	What is baseline benefit cover change?
Change in Utilization	How will utilization of the test/ result of this bill?

- CHBRP identified more than 500 biomarker tests likely to fall under the purview of SB 912
- 60-day timeline
- Modified approach examined biomarker tests generally

ne test/treatment/service?

rage and how will benefit coverage

c/treatment/services change as a

Overview: Clinical Practice Guidelines

- Multiple clinical guidelines that would meet the definition included in SB 912
- Do these guidelines align or conflict?

Insurer internally developed or established guidelines

Reasons for testing vary

Clinical **Pharmacogenetics** Implementation Consortium (CPIC)

National Comprehensive Cancer Network (NCCN)

> Several diseases or conditions

Benefit Coverage

- Prior authorization requirements
- Use of clinical guidelines mentioned by the bill language varied by insurer
- May result in some new coverage, but CHBRP was unable to estimate exactly which biomarker tests were not covered at baseline



Enrollees generally have coverage for biomarker testing that is supported by medical and scientific evidence and is determined medically necessary

Utilization of Biomarker Tests

More than

300.000

Californians receive biomarker tests annually at baseline (out of 24.5 million Californians subject to the bill)

for California Medicaid (Medi-Cal) beneficiaries

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Average annual cost of biomarker testing ranges between

\$677 and \$984

for commercial enrollees and

\$426 and \$488

Medications with Biomarkers in Drug Labels

• Use of biomarker tests

other health care utilization and expenditure impacts

- Biomarker tests can be cost effective
- Some medications require or indicate biomarker testing to be performed prior to use
 - Other medications include a biomarker reference, but testing is not routinely performed
- # users of medications > # users of medications w/biomarker testing
- Costs of medications vary
 - Medical benefit vs pharmacy benefit
 - Type of medication, frequency, clinician vs self-administered
 - For commercial enrollees, annual costs range between \$3,700 to \$146,000

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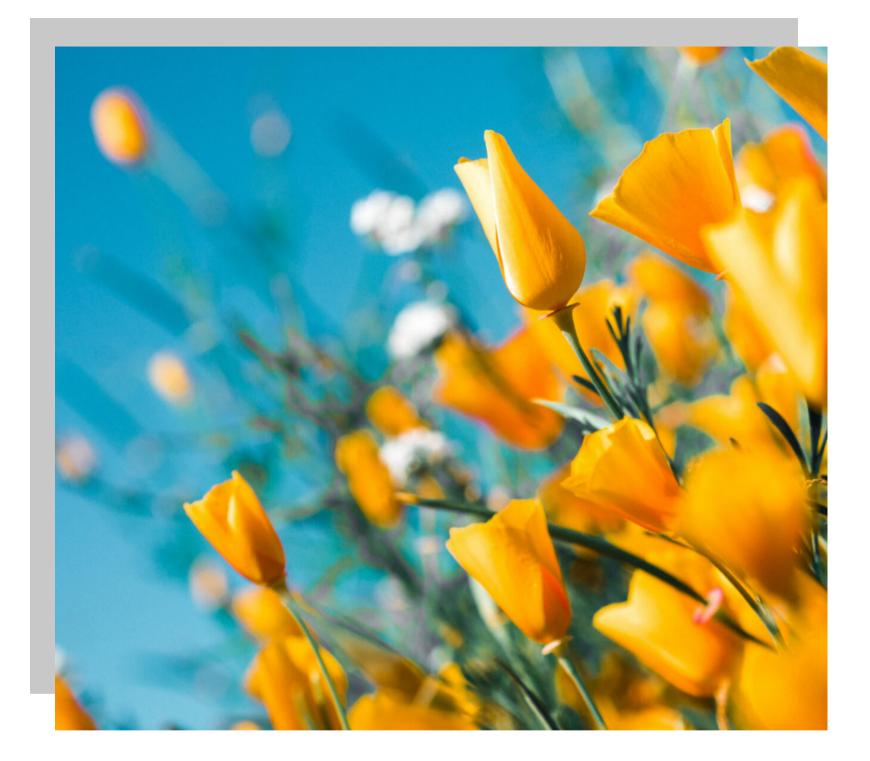
Biomarker **Testing Landscape**

- New biomarkers are being identified, tested, and approved for clinical use
- New medications or therapies with biomarker indications
- Reasons for biomarker tests vary
- Literature indicates there are disparities in biomarker testing by race or ethnicity, age, and socioeconomic status
- Clinical barriers impact whether patients receive testing: familiarity with guidelines and knowledge of best practices; expertise in genomic testing; access to a multidisciplinary team

What happened next?

- Senate Bill 912 vetoed by Governor Newsom: guidelines may conflict with each other
- Senate Bill 496 introduced in 2023
 - Bill language is similar to SB 912
 - Will potentially be heard by the Senate Committee on Health in April 2023





Conclusion

- Evidence-based analysis of broad legislation is challenging within a short time period
- benefit coverage
- requirements
- Some Californians have insurance not subject to state-regulation

- Mutli-disciplinary team able to provide
 - previously unknown information about
- Reference to multiple forms of clinical
 - guidelines can result in conflicting
 - Also a challenge for regulators to
 - implement and confirm compliance

Thank you! Any questions?

Available at www.chbrp.org:

Analysis of Senate Bill 912 (April 2022)

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