



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

NCOIL Spring Meeting

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Agenda

- About CHBRP
- Senate Bill 912 Biomarker Testing
- Key deliverables and findings
- Status of legislation
- Conclusion



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

CHBRP's Charge

Policy Context

Background

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
 - National coverage determination from CMS or a local coverage determination from Medicare contractor
 - Nationally recognized clinical practice guidelines and consensus statements

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 tests (e.g. white blood cell count) to biomarkers for genetic variations.

Analytic Approach

| | Traditional Approach |
|-----------------------|--|
| Medical Effectiveness | What is the effectiveness of the test/treatment/service? |
| Benefit Coverage | What is baseline benefit coverage and how will benefit coverage change? |
| Change in Utilization | How will utilization of the test/treatment/services change as a 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

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

National
Comprehensive
Cancer Network
(NCCN)

Reasons for
testing vary

Clinical
Pharmacogenetics
Implementation
Consortium (CPIC)

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)

Average annual cost of biomarker testing ranges between

\$677 and \$984

for commercial enrollees and

\$426 and \$488

for California Medicaid (Medi-Cal) beneficiaries

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

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
- Mutli-disciplinary team able to provide previously unknown information about benefit coverage
- Reference to multiple forms of clinical guidelines can result in conflicting requirements
 - Also a challenge for regulators to implement and confirm compliance
- Some Californians have insurance not subject to state-regulation

Thank you!
Any questions?

Available at
www.chbrp.org:

Analysis of Senate Bill 912
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