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 testes (e.g. white blood cell count) to biomarkers for genetic variations.
## Analytic Approach

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- 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)
- Clinical Pharmacogenetics Implementation Consortium (CPIC)
- Several diseases or conditions
- Reasons for testing vary
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

~100%
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 can be cost effective
  - 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
- Multi-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