Expanding Access to Genetic Testing through Biomarker Testing Legislation

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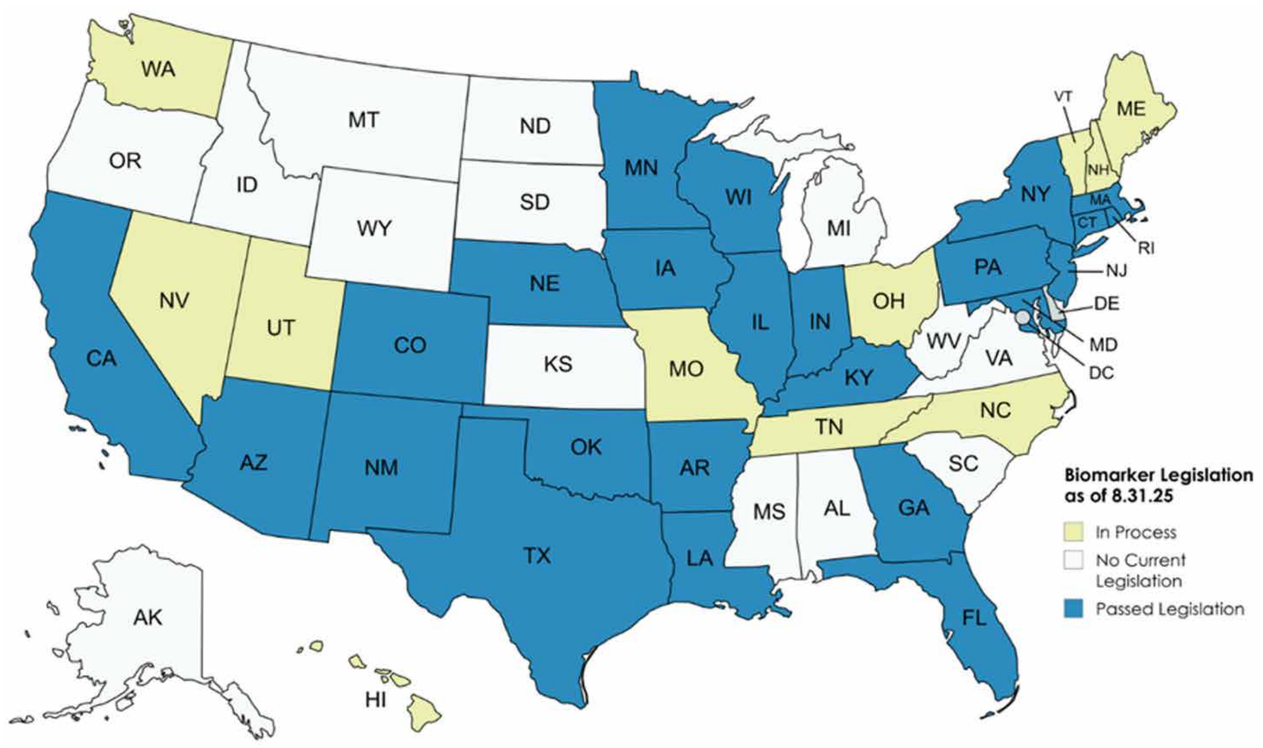
INTRODUCTION

- Biomarkers indicate the presence of current or future disease. With genetic testing, these are generally alterations within DNA, RNA, or proteins.
- These biomarkers can be tested by targeted gene or analyte panels, or by broader genomic and transcriptomic sequencing and other multiomic approaches.
- Testing genetic biomarkers allows for disease diagnosis, treatment determination, or surveillance of emergent symptoms. This information often provides recurrence risk and other useful information for patients' families as well.
- Within the United States, a review of each state's status for passing biomarker testing legislation is described.

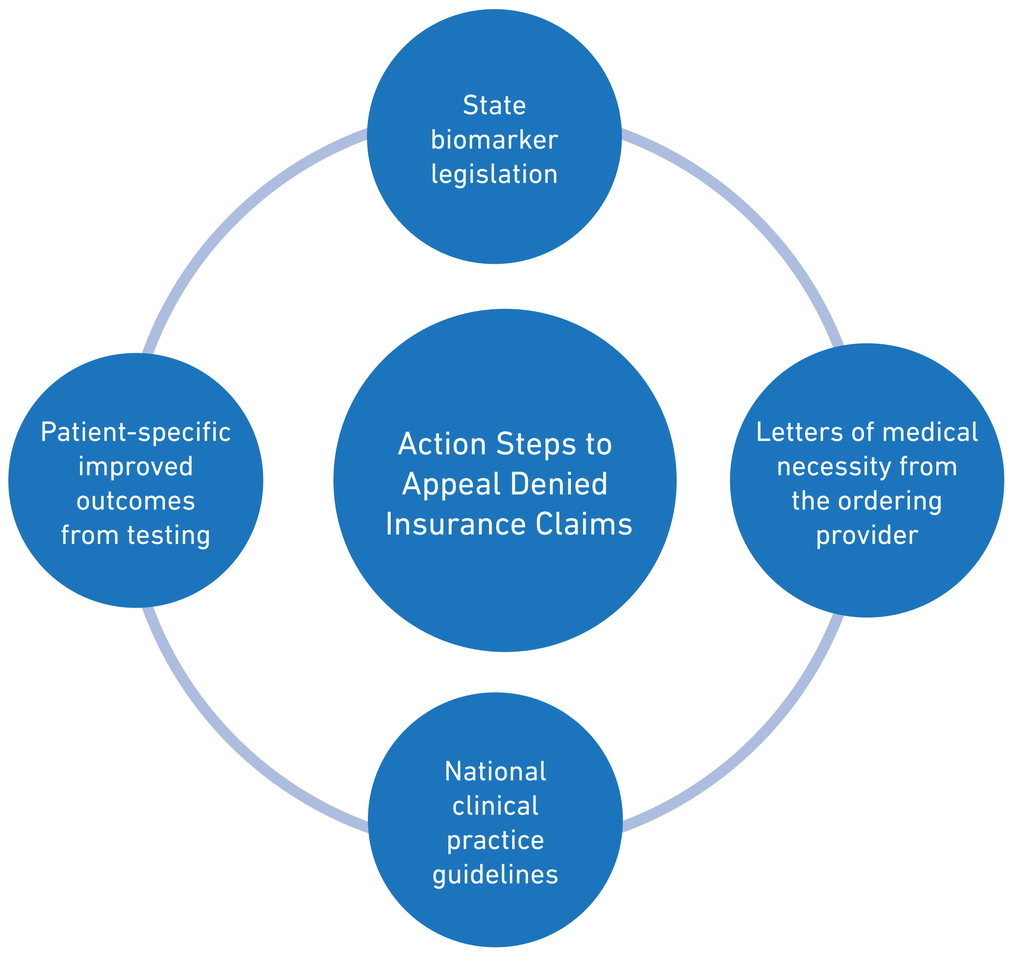


METHODS

- Each state's legislature page(s) was reviewed to determine the status of biomarker testing as of August 31, 2025.

RESULTS

- There are 24 states (AZ, AR, CA, CO, CT, FL, GA, IL, IN, IA, KY, LA, MA, MD, MN, NE, NM, NJ, NY, OK, PA, RI, TX, WI) have passed biomarker legislation.
- Another 11 states (HI, ME, NC, NH, OH, NV, MO, TN, UT, VT, WA) having pending biomarker legislation.
- This leaves 15 states (AK, AL, DE, ID, KS, MI, MS, MT, ND, OR, SC, SD, WY, WV, VA) and DC with no current legislation in process.



CHIP/MEDICAID COVERAGE

- As of May 2025, 37 million children were enrolled in their state Children's Health Insurance Program (CHIP) or in their state's Medicaid program, representing 47.6% of total Medicaid and CHIP enrollment.[1]

CANCER

- Over 15,000 children are diagnosed with cancer in the United States every year.[2]
- There are four states (AR, CA, LA, and NV) that specifically reference coverage of cancer biomarkers in their legislation.[3]

RARE DISEASE

- 1 in 10 children have a rare disease.[4] We estimate that about 1 in 1000 (0.1%) children would receive exome or genome sequencing.[5]
- The diagnostic yield of exome and genome sequencing across clinical indications is expected to be up 43%.[6] Genomic sequencing has been shown to provide fast, cost-effective diagnoses.[7]
- In 2023, Texas passed SB 989 that directly references "whole genome sequencing" as a form of biomarker testing. This provides a strong legal foundation when appealing a denial for this testing under a state-regulated plan.[8]

CONCLUSIONS

- Over two-thirds of states have passed biomarker legislation or have currently pending legislation.
- Biomarker legislation increases genetic testing access for patients. This is especially true with Medicaid, which provides health insurance to a high proportion of patients.
- Access to genetic testing, especially for patients with rare disease and cancer, contributes to faster diagnoses and lower costs for patients, families, and the healthcare system.
- Without legislation, patients are more likely to experience barriers to necessary genetic testing. Efforts to advocate for and introduce legislation should be supported by legislators, medical societies, patient advocacy groups, and other organizations.

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Reference:
1) www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights [accessed 9/19/25]
2) www.acco.org/us-childhood-cancer-statistics/ [accessed 9/19/25]
3) PMID: 38739406
4) www.globalgenes.org/rare-disease-facts/ [accessed 9/19/25]
5) PMID: 34811359
6) PMID: 34211152
7) PMID: 36670656
8) legiscan.com/TX/text/SB989/id/2810386 [accessed 9/19/25]