

FACTSHEET

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Access to Biomarker Testing

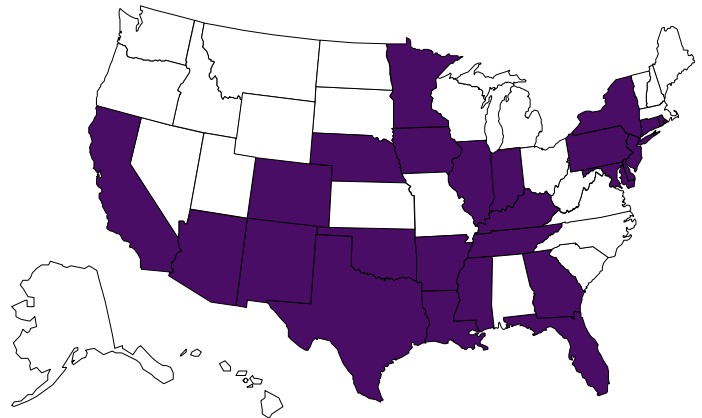
What is a biomarker test and what tests exist for Alzheimer's disease?

- A biomarker (biological marker) is a characteristic — such as a specific gene mutation or protein expression — that can be measured to indicate elevated risk of developing a disease, the presence of a disease, or the stage of a disease.
- A biomarker test is the analysis of an individual for the presence of, or change in, a biomarker. Common methods of biomarker testing include collecting bodily fluids such as blood or saliva.
- Currently, no single test can positively determine if an individual is living with Alzheimer's disease. However, blood tests can be important tools in diagnosing Alzheimer's.
- The U.S. Food and Drug Administration (FDA) has cleared multiple blood tests to aid in diagnosing individuals with signs and symptoms of cognitive impairment. The tests help detect whether amyloid plaques — a hallmark of Alzheimer's disease — are present.

Why is biomarker testing for Alzheimer's disease needed?

- Nearly 4 in 5 adults aged 45 and older believe an early Alzheimer's diagnosis is very important, and more than 9 in 10 would be interested in testing when experiencing early symptoms.
- Yet as many as half of those with Alzheimer's may be undiagnosed, and nearly 4 in 10 primary care providers are never or only sometimes comfortable making an Alzheimer's diagnosis.

States with Legislation Requiring Some Insurance Coverage of Biomarker Testing



How can biomarker testing improve access to treatments?

- FDA-approved Alzheimer's treatments — such as Leqembi (lecanemab) and Kisunla (donanemab) — can be effective at slowing cognitive decline, but only in the earliest stages of the disease.
- Accurate early-stage testing would help ensure more Americans are diagnosed while they remain eligible for existing Alzheimer's treatments.

What can states do?

- Half of states do not require private insurance carriers or Medicaid to cover biomarker testing for Alzheimer's disease.
- States must require appropriate coverage of biomarker testing across insurance programs to help ensure access to treatment.