

Leading experts and advocates highlight both the promise of new Alzheimer' diagnostic tools and therapies and the urgent need to address barriers to access.

## New Hope: The FDA Cleared Innovative Blood Tests to Diagnose Alzheimer's

The FDA has approved a groundbreaking blood test for Alzheimer's biomarkers, that can detect early signs of the disease with 90% accuracy... Early diagnosis widens the window of opportunity for people with the disease to benefit from today's treatments and tomorrow's breakthroughs. It reduces the lifetime cost of care, which is estimated at a staggering \$400,000 for the average patient..."

- Louise Fisher, caregiver

"I'm optimistic that these tests will be a game-changer...The quest to stop Alzheimer's has never had more momentum." – Bill Gates, technologist, business leader, and philanthropist

"...we stand at a new frontier in health care delivery with the potential to bring testing and care directly to people in every community..." – Dr. Jeff Burns, University of Kansas Alzheimer's Disease Research Center

"We have reached a historic moment... the next step is making these tests widely available." – <u>Jim Taylor</u>, CEO of Voices of Alzheimer's

As more people benefit from diagnostic tools, we must simultaneously improve access to FDA-approved therapies that slow disease progression...



## Policymakers Must Modernize Policies, Remove Red Tape for Early-Stage Therapies

"One of the most significant barriers today stems from Medicare's decision to restrict access to FDA-approved Alzheimer's therapies by requiring enrollment in <u>cumbersome (CED) registries</u> an administrative quagmire disguised as research." – <u>Candace</u>

<u>DeMatteis</u>, Policy Director at Partnership to Fight

Chronic Disease

"CMS applied...CED for the first time to medications – which restricted coverage for an entire class of new Alzheimer's therapies..." – Joseph Grogan, University of Southern California's Schaeffer Institute

"...unless CED is removed, people with an Alzheimer's diagnosis will be discouraged and even prevented from benefiting from medicines that can slow the disease and help them live longer with more independence." – Wayne Winegarden, Ph.D., Pacific Research Institute

"Applying Coverage with Evidence
Development (CED) to Medicare drugs
duplicates the regulatory role that the FDA
plays by requiring new clinical evidence even
if the FDA has already deemed a drug safe
and effective..." – The American Commitment

"CED policy has not lived up to its promise, even blocking treatments approved by the FDA with an abundance of clinical trial data." – David Williams, TaxPayers Protection Alliance "CED is unnecessarily duplicative as it adds additional approval processes to drugs already proven safe and effective. Requiring patients to participate in trials for FDA-approved drugs inhibits patient care and wastes government resources...Rather than expanding access, the program restricts it." – Consumer Action for a Strong Economy

## Policymakers Can Help Ensure a Brighter Future for Alzheimer's:

- Encourage CMS to remove the therapeutic coverage with evidence development (CED) requirement
- Ensure coverage for blood biomarkers across all payers
- Invest in expanded screening and public awareness

Together, we can ensure current and future patients can benefit from the latest advances in Alzheimer's detection and treatment. Learn more at PFCDALZ.org