

# THE LONG ROAD TO TREATMENT

## Medicare's CED Clinical Trial Policy Delays Patient Access

In an unprecedented decision, Medicare strictly limited coverage of new monoclonal antibody Alzheimer's therapies approved by FDA under Accelerated Approval for many living with mild Alzheimer's Disease. Under this new drug Coverage with Evidence Development (CED) policy, it could take up to **3 years** after a new drug is approved before patients have the opportunity to enroll in a qualifying CED clinical trial and receive treatment. At each step of the CED clinical trial process, there are multiple instances where patients could fail to receive the treatment they need.



PARTNERSHIP TO FIGHT  
CHRONIC DISEASE



SPONSOR  
FOLLOW-UPS  
& REPORTING  
TO CMS



FINISH:  
Medicare Covers  
Treatment



START: Therapy  
Approved by FDA  
under Accelerated  
Approval

CMS Sets  
Up NCD  
with CED  
(9 to 12  
months)



Outreach  
to patients

Set up  
CED clinical  
trial: 18-24  
-month process



Screening  
for clinical  
trial eligibility



Enrollment  
confirmed



TREATMENT GROUP:  
PATIENT TESTING  
& OTHER REQUIRED  
VISITS.

Assigned  
to Placebo—  
Dead end:  
no treatment

No Access to Trials

- Very few spots available
- Limits on providers
- Limited locations/  
Poor to no rural access

Dead end: no treatment



Enrollment  
rejected —  
Dead end: no  
treatment



**3000**  
PEOPLE A DAY  
PROGRESS  
FROM MILD  
TO MODERATE  
ALZHEIMER'S  
DISEASE.

Medicare beneficiaries shouldn't have to wait to receive FDA-approved treatments. CED requirements are not the answer.

Learn more at [pfcdalz.org](https://pfcdalz.org).

