

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)

Enrollment
rejected –
Dead end: no
treatment



Outreach
to patients



Enrollment
confirmed



TREATMENT GROUP:
PATIENT TESTING
& OTHER REQUIRED
VISITS.

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



Screening
for clinical
trial eligibility



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



2000
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 www.fightchronicdisease.org.