LEAVING MEDICARE BENEFICIARIES IN LIMBO

PARTNERSHIP TO FIGHT CHRONIC DISEASE

Medicare's Coverage with Evidence Development (CED) Requirement Limits Access:

30
CED REQUIREMENTS ISSUED SINCE THE PROGRAM'S START IN 2005

23
HAVE NOT BEEN RESOLVED

41
LARGEST NUMBER OF CLINICAL TRIALS REPORTED FOR AN ACTIVE CED

11.5 YEARS
AVERAGE TIME FROM CED START TO RETIREMENT*

15 YEARS
OF LONGEST ONGOING CED WITH REGISTRIES

1
CED REQUIREMENT FOR FDA-APPROVED THERAPIES FOR MEDICALLY APPROPRIATE, CLINICALLY APPROVED USE (ALZHEIMER'S DISEASE)

Coverage with Evidence Development (CED)s:

LIMITS ACCESS TO FDA APPROVED TREATMENT:
CEDs limit Medicare coverage only to beneficiaries participating in an approved clinical registry. No one has coverage unless and until the clinical registry is open, is enrolling patients, and the patient meets the necessary eligibility requirements for the study and is enrolled.

DELAYS COVERAGE AND RESTRICTS ACCESS:
CED's stated purpose is to collect additional data Medicare will use to re-assess coverage in the future. But the CED process has taken 11.5 years on average – during that time beneficiaries have limited access and no clear time frame for when the coverage limitations will be revisited.

ADVERSELY IMPACTS CERTAIN COMMUNITIES, LIKE RURAL AMERICANS:
CED registries favor large, urban medical centers and often leave out rural populations. Similarly, CED clinical trials and registries have historically had a poor record of enrolling Black and Hispanic participants.

AMERICANS WITH ALZHEIMER'S SHOULDN'T HAVE TO WAIT TO ACCESS FDA-APPROVED TREATMENTS. CED REQUIREMENTS ARE NOT THE ANSWER.

Learn more at pfcdalz.org.

*Once a CED requirement is deemed completed by Medicare, Medicare will cover the product without requiring participation in a clinical study.

Source: E Zeitler, L Gilstrap, et al. Coverage with Evidence Development: Where Are We Now? Am J Manag Care. 2022;28(8):382-389; *information updated from CMS CED website as of August 6, 2025.*