Evaluation of Evidence Informing Medicare's Coverage with Evidence Development Decision Updates

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Background

- In 2005, the Centers for Medicare and Medicaid Services (**CMS**) introduced the **Coverage with Evidence Development (CED) program.**
- Under the CED program**,** items and services **with limited evidence of benefit or harm** will be covered while **requiring participation in clinical studies** approved by the CMS.
- The goal is to **generate clinical evidence** to evaluate whether these items and services meet the statutory "reasonable and necessary" criteria for Medicare coverage.
- After an unspecified period of time, CMS reconsiders CED decisions based on the newly generated evidence:
  - CMS could **remove the CED requirement**
  - CMS could **require continuation** of CED-approved studies
  - CMS could **revoke** the national **coverage** and refer the coverage to local Medicare Administrative Contractors (MACs)

Objective

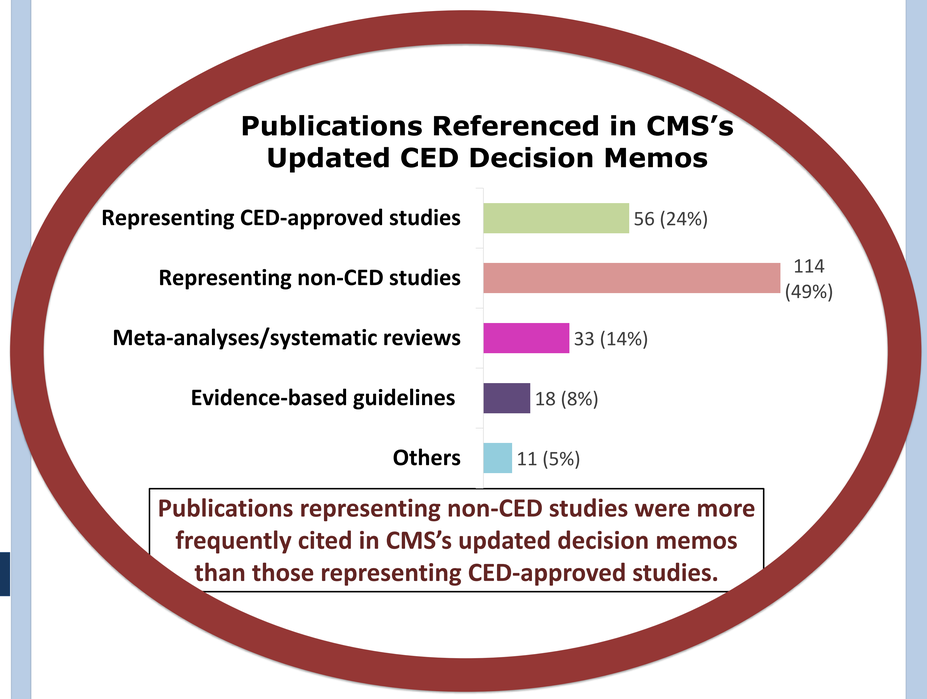
To **examine** the **evidence** used by the CMS when **reconsidering** its **coverage decisions** for items and services covered under the CED program

Methods

- **Study Type**: Cross sectional
- **Data source**:
  - CMS's CED webpage
  - ClinicalTrials.gov registries and peer-reviewed publications
- **Sample**: All items and services covered under the CMS's CED program with reconsidered coverage decisions

Results

- Overall, **26 items and services** covered under the **CED program** from 2005 to 2023.
- Of these, **10** (38%) had **updated coverage decisions.**
- Median **duration between** first and subsequent **coverage decisions**: **7.9** (IQR, 6.6-12.1) **years**.



Upon coverage reconsideration, CMS removed the CED requirements for 30%, continued the CED requirements for 30%, and revoked the coverage for 30% of items and services.

Updated coverage decisions for items/services covered under CED program	
Ongoing CED (i.e., requiring continuation of CED-approved studies)	30%
Converted to NCD without CED	30%
Converted to NCD without CED for a subpopulation + deferred coverage to local MACs for other patients	10%
NCD revoked and coverage was deferred to local MACs	30%

Results

The majority of CED-approved studies were randomized clinical trials. Non-CED studies had less robust study design, enrolled fewer participants, and were mainly conducted outside the U.S.

CED-approved studies (56 publications representing 15 studies)	
Study type	
Randomized clinical trial	60%
Non-randomized clinical trial	7%
Prospective cohort	13%
Retrospective cohort	20%
Total patient population size	
Median (IQR)	1,000 (286-2,492)

Non-CED studies (114 publications representing 93 studies)	
Study type	
Randomized clinical trial	13%
Non-randomized clinical trial	1%
Prospective cohort	44%
Retrospective cohort	40%
Cross-sectional	2%
Total patient population size	
Median (IQR)	122 (51-570)
Population of the cited evidence	
U.S Medicare Beneficiaries only	2%
U.S unspecified (Medicare and Non-Medicare)	38%
International, including U.S.	4%
Non-U.S.	56%

Conclusion

CMS leverages CED requirements to generate clinical evidence about new items and services; however, updated decision memos more often cited publications from non-CED studies, many of which had less robust study designs and enrolled non-US participants.

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