

CMS Activities to Advance Evidence-based Medicine:

Comparative Effectiveness Research

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Is CMS conducting comparative effectiveness studies?

- CMS does not conduct clinical research
- CMS does cover certain medical services provided to Medicare beneficiaries participating in clinical research studies

Clinical Trial Policy

Medicare covers routine costs of a clinical trial which includes all items and services that are otherwise generally available to Medicare beneficiaries including the investigational item or service itself if covered outside the trial

Coverage with Evidence Development

CMS, through the NCD process, may require that coverage of an item or services occur only in the context of a clinical research study.

What are the responsibilities of CMS for advancing evidence-based health?

- Sound foundation of evidence about which treatments work best is essential to help doctors and patients achieve the best quality care
- Beneficiaries in Medicare & Medicaid and their doctors need better information about costs and benefits of treatment for common health problems with multiple treatment options available
- Better evidence on what works is a centerpiece of the prescription drug benefit and other reforms being implemented by CMS right now to bring the Medicare program up to date

What roles are CMS playing in advancing evidence-based health?

- Coverage decisions
- Value-based purchasing
 - Hospital Compare
 - PQRI
 - P4P
- Data release
- Research community education

Research Community Education: What does Medicare need to know?

- Evidentiary priorities
- Types of CE studies
 - Product A versus Product B
 - Condition X versus Condition Y
 - Population segmentation (age, gender, geographic location (rural vs. urban, high/low altitude), income, race/ethnicity, genetic or other risk profiles)
 - Short-term vs. long-term
 - Research setting vs. community (“real world”)
 - Inpatient vs. outpatient
 - Hospital vs. SNF vs. home health vs. other
 - Cost

What are CMS challenges in evidence-based health?

- Adequate information on what works and who performs best
- Ability to continue moving from payer to public health agency

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