

# Medicare's use of coverage with evidence development

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# Agenda

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- Summarize Medicare's coverage with evidence development activities
- Present case studies on CED studies
- Discuss two key challenges Medicare has faced in implementing coverage with evidence development policies

# What is coverage with evidence (CED) development?

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- An approach to pay for potentially beneficial services that lack clear evidence showing their clinical effectiveness among the elderly and disabled
- Links Medicare payment to a requirement for prospective data collection
- CED provides an approach that permits payers to move beyond yes/no coverage decisions

# Why is CED important?

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- Tension between developing evidence-based policies and being responsive to the pressure to pay for medical services
- Goal is to provide access to a service while address research questions unlikely to be done otherwise
- Using CED, Medicare will be able to develop more informed evidence-based policies

# How does Medicare implement CED?

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- Medicare implements CED through its national coverage determination process
- Service's payment linked to participation in a clinical research protocol such as:
  - Observational study including registry
  - Randomized clinical trial

# Examples of CED studies

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- Surgery: lung volume reduction surgery
- Imaging services: FDG-PET for dementia and for solid cancers
- Devices: ICDs, cochlear implantation, artificial heart
- Diagnostic test: pharmacogenomic testing for warfarin response
- Drugs: off-label colorectal cancer drugs

# Case study: National Emphysema Treatment Trial (NETT)

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- Use of lung volume reduction surgery was increasing despite limited clinical evidence
- Medicare payment linked to participation in NIH sponsored trial (NETT) in 1995
- 7-year trial that included about 1,200 patients

# Case study: National Emphysema Treatment Trial (NETT)

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- Lessons learned:
  - Possible to provide access to a service while gathering clinical data
  - Medicare refined its coverage policies based on clinical trial results

# Case study: Use of ICDs for primary prevention for sudden cardiac death

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- Clinical trials did not answer all questions about benefits/risks in specific populations
- Medicare payment linked to participation in prospective registry in 2005
- A broad range of stakeholders involved in implementing registry
- Additional longitudinal study launched in 2007

# Case study: Use of ICDs for primary prevention for sudden cardiac death

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- Lessons learned:
  - Registries are capable of collecting large amounts of data but ongoing modifications may be necessary
  - Cooperation and financial support obtained from private and public sector but obtaining sustained funding may cause delays

# Two key challenges in Medicare using CED

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- Medicare's statutory foundation to use CED
- Funding CED's research costs

# Medicare's statutory foundation to use CED

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- Generally, CED's statutory authority generally stems from Medicare's authority to cover services that are "reasonable and necessary"
- Clearer statutory foundation might enable:
  - Development of a formal mechanism to identify and select services for CED
  - Development of more articulated standards to conduct CED studies

# Funding CED's research costs

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- Public sources (NIH) and private sources pay for costs to design and implement prospective study either via registry or trial
- Instances in which funding delayed start of CED study

# Issues in funding CED's research costs

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- Funding source
- Influence of funding source on study design and implementation

# Discussion issues

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- Value of CED to the Medicare program
- Clarifying Medicare's ability to use CED
- Issues with funding CED's research costs
- Other comments?