



# Evidentiary Characteristics for Coverage with Evidence Development (CED)

Medicare Evidence Development and Coverage Advisory Committee Meeting

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## Question 5

**Can an evidentiary threshold be defined to trigger an evidentiary review to determine if CED should cease, continue, or be modified?**

- If the answer favors “Yes,” please discuss how this threshold should be identified.
- If the answer favors “No,” please discuss the impediments and recommend strategies to overcome them.
- Please discuss whether the factors identified in Questions 3 and 4 are relevant to Question 5.

## Medtronic's Core Position on CED

- Medtronic is committed to the development of clinical evidence and supports CMS' interest to ensure adequate evidence on the clinical benefit of technologies for the Medicare population
- Given that the stated goal of CED has been to increase access to medical advancements, CMS should only apply CED rarely in NCDs and only in circumstances where the alternative is national non-coverage.
- The objective of CED should be to generate evidence and information that will be directly applicable to the key open issues in determining whether the item or service is “reasonable and necessary” for the Medicare population, and therefore fully coverable (with no further continuing CED requirement)
- Several changes in process are necessary to assure that CED most appropriately achieves its goals, and does so in a transparent and inclusive manner.

## Key Proposed Improvements to CED

CMS intent to consider CED stated at the outset of an NCA – if not sooner.

Research questions for CED clearly specified in advance.

CED implementation steering committee – with full stakeholder role – to develop and operationalize key details of CED.

Interim coverage policy to ensure patient access while CED is being implemented.

Clear timelines for completion of CED evidence generation and coverage reconsideration.

# Can an Evidentiary Threshold Be Defined to Trigger an Evidentiary Review to Determine if CED Should Cease?

- It is difficult – if not impossible – to establish a uniform evidentiary threshold for all technologies and services that, if met, should lead to a reconsideration of the evidence collection.
- The reconsideration timeline must be technology or service-specific.
- Key factors will affect each individual case:
  - Intervention being considered: Drug, device, diagnostic, surgical procedure, etc.
  - Patient population
  - Setting of care
  - Research questions
  - Study design
  - Etc.

## Absent a Uniform Evidentiary Threshold, When Should a CED Be Stopped?

- In order to determine when to stop CED for a given item or service, the agency must explicitly identify the key research questions.
  - **We can only determine when to stop if we know where we are going.**
- A steering committee for each CED, comprised of all relevant stakeholders, will be vital to developing a clear framework for the:
  - Research design
  - Access and ownership to data collection
  - Funding of data collection
  - Timelines for reconsideration

## Absent a Uniform Evidentiary Threshold, When Should a CED Be Stopped? (continued)

- CMS should clearly outline a timeline to reconsider coverage for the item or service under CED in the final decision memo.
- CMS must have a central role in the implementation of CED.
- CMS should continually monitor data collection efforts to ensure that they are aligned with CMS' key research questions.
- Alternative studies, in addition to CED, should also be evaluated when reconsidering coverage.
- Once the research questions are addressed by CED, CMS should reconsider the decision based on the new evidence.

## Previous CEDs Have Had No Stopping Rules

- In 2005, CMS implemented CED on ICDs via registry mandated in NCD.
- Essential details on data collection requirements not established until 5 years after registry launch.
- Even after establishment of registry, no formal agreement between CMS and registry on protocol with well-defined research questions or timeline.
- No timetable for stopping the CED or reconsidering the evidence generated by it.
- Medtronic conducted OMNI study to address questions raised in CED.

Adopting policy that would require the establishment of research questions and timelines at the outset of CED would greatly improve overall process for CED and specific process for determining when to reconsider the evidence and end CED data collection requirements.

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- Please discuss whether the factors identified in Questions 3 and 4 are relevant to Question 5.