



# Coverage with Evidence Development

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# The Original (Ongoing) Dilemma

- Intense public interest in coverage of certain (usually new) technologies
- Published evidence base often suggestive, but insufficient to support a confident positive R&N decision
- In general, clinical trials under-enroll subjects representative of the beneficiary population
- In general, clinical trials do not focus on clinical utility outcomes of interest to CMS

# Some CED National Coverage Determinations

| Topic                          | Year | Status                                      |
|--------------------------------|------|---|
| PET for Susp Dementia          | 2004 | No study done                               |
| PET for 6 CA                   | 2005 | NOPR results 2008. NCD reconsideration 2009 |
| Chemotx for CRC                | 2005 | No completed studies                        |
| Cochlear Implants              | 2005 | No study to date                            |
| ICDs                           | 2005 | Collecting data, analysis begun             |
| Home Use of O <sub>2</sub>     | 2006 | LOTT enrolling                              |
| Artificial Hearts              | 2008 | No completed studies                        |
| CPAP for OSA                   | 2008 | No study to date                            |
| PET for Solid Tumors           | 2009 | NOPR 2009 AHRQ enrolling                    |
| PGx Warfarin                   | 2009 | Studies developed                           |
| Allogeneic Stem Cell           | 2010 | Studies developed, ongoing                  |
| Home O <sub>2</sub> Cluster HA | 2011 | Protocol development                        |
| MRI Unlabeled Implant          | 2011 | MagnaSafe study                             |
| TAVR                           | 2012 | ACC STS Registry + Clinical Trials          |



# NATIONAL BIOECONOMY BLUEPRINT

**Expanding the Coverage with Evidence Development Program to Drive Innovation:** Reimbursement for medical treatments is a powerful driver of industry investment. Under the Coverage with Evidence Development (CED) program, Medicare reimburses for promising new technologies that do not currently meet the standard for full coverage. The CED program requires more evidence to be collected to determine full potential benefit of new technologies. The CED authority has existed for more than a decade but has been applied sparingly. The Centers for Medicare & Medicaid Services (CMS) is poised to implement the next phase of CED by better defining the parameters and guidance for CED so it can be used more widely and effectively as a driver of innovation. CMS believes that the lessons learned during the initial implementation of CED can inform its more frequent use and create predictable incentives for innovation while providing greater assurance that new technologies in fact fulfill their initial claims of benefit.

[http://www.whitehouse.gov/sites/default/files/microsites/ostp/national\\_bioeconomy\\_blueprint\\_april\\_2012.pdf](http://www.whitehouse.gov/sites/default/files/microsites/ostp/national_bioeconomy_blueprint_april_2012.pdf)

# Questions for the Panel

# Definitions

## Binary Coverage Paradigm:

“Yes or No” final coverage decision without planned reconsideration of prespecified clinical outcomes.

## Non-Binary Coverage Paradigm\*:

Qualified coverage decision that may evolve as evidence base changes over time, with planned reconsideration based on the achievement of prespecified clinical outcomes.

\*CED is an example of a non-binary coverage paradigm.

# Question 1

Are there significant, practical differences between binary and non-binary coverage paradigms?

If the answer favors “Yes” please discuss the advantages and disadvantages of non-binary paradigms.

# Question 2

Can an evidentiary threshold be defined to invoke CED?

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.

# Question 3

How would an evidentiary threshold to invoke CED influenced by the following?

- a. whether the item or service is a diagnostic v. a therapeutic technology;
- b. the severity of the disease;
- c. the safety profile of the technology;
- d. the availability of acceptable alternatives for the same disease/condition
- e. other factor(s)
- f. a combination or tradeoff involving two or more of the above

# Question 4

How would an evidentiary threshold to invoke CED be influenced if the outstanding questions focused only on the generalizability of a strong but narrow evidence base to

- i. additional settings;
- ii. additional practitioners;
- iii. broader clinical indications for related or unrelated diseases#?

# An example of a related condition might include a different stage of the same cancer. An example of an unrelated condition might include the use of a cancer drug for a rheumatologic disease.

# Question 5

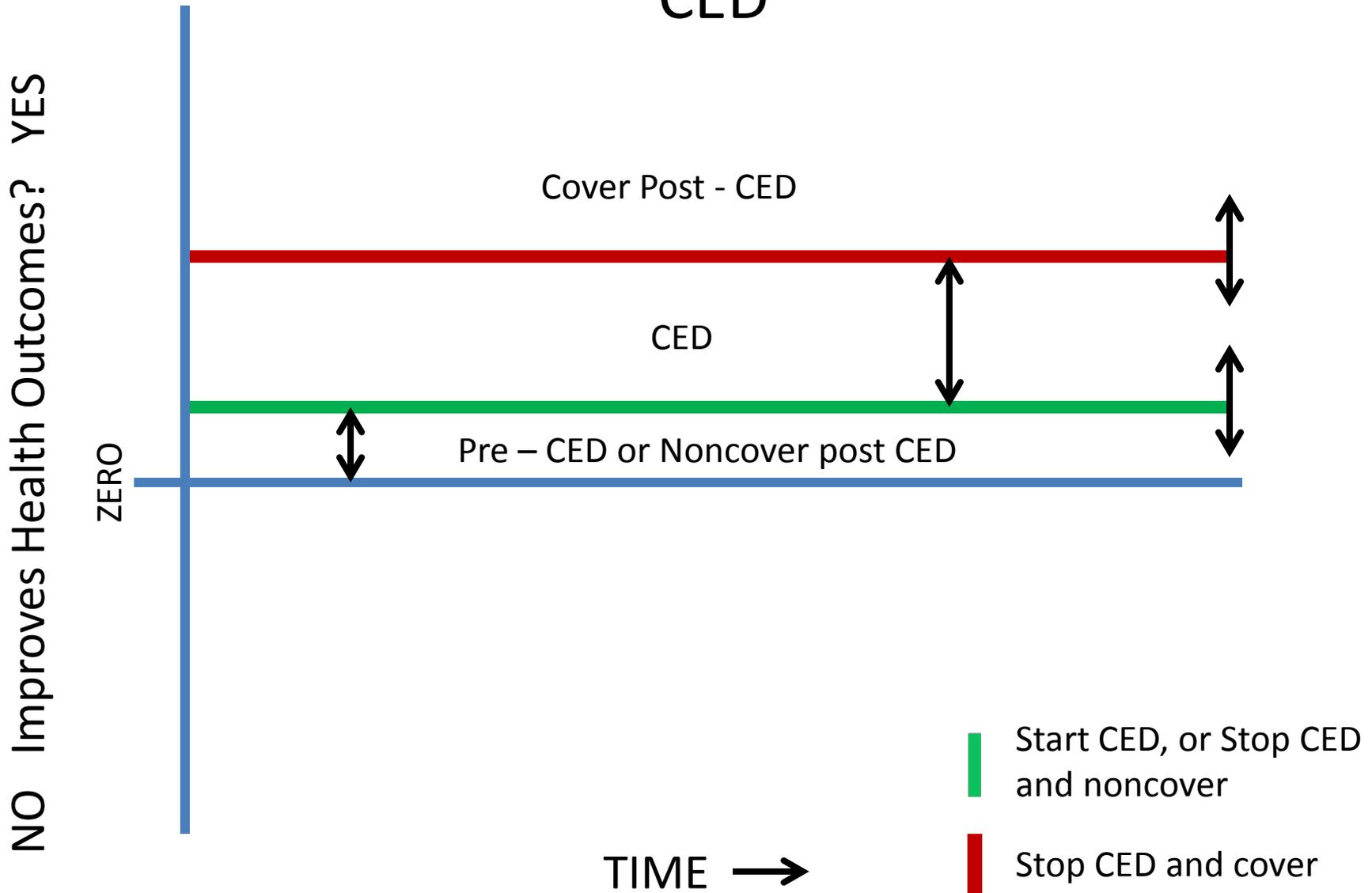
Can an evidentiary threshold be defined to trigger an evidentiary review to determine if CED should cease, continue or be modified?

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.

# Finding the Evidentiary Window for CED



# Considering Confidence

