



MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF **NEMA**

Medicare Evidence Development and Coverage Advisory Committee: Coverage with Evidence Development

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Introduction to MITA

- MITA represents medical imaging, radiation therapy and radiopharmaceutical manufacturers
- We have been pleased to work with CMS to ensure appropriate use of and access to our members' life-saving technologies
- We appreciate this opportunity to provide comments to MEDCAC on CED

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

- Yes, there are significant, practical differences between binary and non-binary coverage paradigms
- Non-binary coverage paradigms, such as CED, can be burdensome and inconclusive, whereas a binary paradigm is more likely to produce predictable and clear coverage decisions
- To minimize the burdens associated with non-binary coverage paradigms, CMS should:
 - Ensure that studies conducted under these paradigms employ well-defined, relevant, and pragmatic endpoints
 - Use CED rarely, and not when a binary coverage paradigm is justified by the available evidence
 - Cover the labeled indications of FDA-approved technologies under binary coverage determinations

2. Can an evidentiary threshold be defined to invoke CED?

- An evidentiary threshold can and should be defined prior to invoking CED
- The threshold may differ depending on the type of technology and indications under review
- CMS should work with stakeholders to define the threshold for each potential application of CED
- CMS also should continue to work with stakeholders to develop clear guidance that will explain the general criteria for determining whether there is enough evidence for CED, but not enough for a binary coverage determination

3. How would an evidentiary threshold to invoke CED be 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?

- Each of these factors can influence the evidentiary threshold to invoke CED
- Diagnostics are different and should be measured against diagnostic outcomes, not therapeutic outcomes
- Because numerous factors affect the evidentiary threshold, CMS needs to be pragmatic about setting thresholds
- CMS also should be sensitive to the fact that the “acceptable alternatives” may be different for each patient, as judged by the patient and his or her physician

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?

- The labeled indications of FDA-approved technologies should not be subject to CED
- At times, CED might be appropriate for additional indications, after considering the factors identified in question 3

Question 5: Can an evidentiary threshold be defined to trigger an evidentiary review to determine if CED should cease, continue or be modified?

- An evidentiary threshold that triggers review to determine if CED should cease, continue, or be modified should be defined at the time the CED decision is announced
- The threshold likely will vary from technology to technology
- The threshold should be established based on agreement from the technology's sponsor, CMS, and any relevant professional societies based on the need for CED and the research protocols to be applied under CED

Conclusion

- We appreciate this opportunity to share our views on CED to the MEDCAC
- We would be happy to answer any questions you have