

MEDCAC Meeting:
Analysis of Coverage with Evidence Development (CED) Criteria

Medical Imaging & Technology Alliance
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Financial Conflict of Interest Disclosure

Foley Hoag LLP is a paid consultant to the Medical Imaging & Technology Alliance (MITA), which is comprised of medical device and imaging manufacturers.

Summary of Key Points

- MITA has significant experience with CED over the past two decades
- CED studies should only be used to expand Medicare coverage for new technologies when beneficiaries would not otherwise have access
- MITA recommends that the Final Report:
 - Prioritize improving the CED process and reconsideration timeline to promote more efficient studies and expedite the review of study data to improve beneficiary access to new treatments
 - Establish appropriate outcome measures that better evaluate advance imaging and diagnostic radiopharmaceuticals based on their impact on patient management
 - Exclude on-label drugs and biologicals from CED requirements and qualify traditional pass-through status to any drug or device under a CED study

MITA's History with CED Studies

- MITA's comments on the AHRQ report are informed by its long standing involvement with CEDs
- Positron emission tomography (PET) technology has more CED studies and NCDs than any other technology
 - Includes 3 CED studies and eight NCD reconsiderations
- PET technology has been extensively validated in clinical studies occurring over nearly two decades
 - Involved in the first CED requirement in 2005 requiring National Oncologic PET Registry (NOPR) reporting for many cancer PET scans
 - Recently involved in the Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) Study and New IDEAS

CED Should Be Used Selectively Only to Expand Beneficiary Access

- CED studies should only be used to expand Medicare coverage for new technologies when beneficiaries would not otherwise have access
- In general, CED should not be applied to on-label indications of FDA-approved drugs and biologicals
- Data collection requirements can be burdensome and the reconsideration process is lengthy and lacks transparency

Streamlined CED Processes

- Current data collection requirements in CED studies are designed and implemented without a transparent timeline for coverage reconsideration
 - Oftentimes, multiple CED studies produce substantial clinical evidence and CED coverage requirements remain
- Very few studies have achieved the retirement of data collection requirements
 - Of the 27 CED programs approved since the CED began in 2005, only 4 evidence development requirements were retired, suggesting that barriers remain to accessing CED therapies
- The lack of a reconsideration timeline in the CED process slows the coverage of new treatments and limits beneficiary access to new therapies

Case Study: Beta Amyloid PET

- In September 2013, CMS issued an NCD covering beta amyloid test under CED
 - IDEAS study enrolled more than 18,000 Medicare beneficiaries and completed data collection in December 2017
- Analyses of data from various studies of beta amyloid PET over the past decade confirm the consistent impact of PET imaging in evaluating of patients with cognitive impairment
 - Beta amyloid PET contributed to diagnostic revisions in approximately 30% of patients and a 67% change in patient management
 - Medication changes were observed in approximately 40% of patients, with the most common type of change in management being the initiation or discontinuation of planned Alzheimer's medication
 - Other types of management changes included referral to clinical trials, Alzheimer's genetic testing, addition or removal of planned diagnostic tests, and counseling
- Despite this evidence, the NCD was reconsidered earlier this year without any discussion of expanding coverage of beta amyloid PET outside of CED

Additional Recommendations on AHRQ Proposed Criteria

- Clarify CED outcome requirements for diagnostics to include impact on patient management
 - Measures needed that better evaluate advance imaging and diagnostic radiopharmaceuticals and their impact on patient management
- Provide patients more ethical and equitable coverage of innovative treatments
 - CED studies involving RCTs are often extremely resource intensive and data collection is lengthy
- Exclude on-label uses of drugs and biologicals from CED requirements
 - Historically, CMS took the position that “drugs or biologicals approved for marketing by FDA are safe and effective when used for indications specified in their labeling”
 - Undermines the FDA’s determination of whether a drug or biological is safe and effective for its indicated uses
- Integrate real-world evidence and claims data into CED studies to generate necessary evidence more efficiently
 - RWE enables investigators to efficiently generate evidence for CMS and MACs to make coverage decisions