

Evidentiary Threshold to Invoke CED and Related Observations



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Medicare CED Experience to Date

- Several encouraging successes, but some challenges with past implementation
- Proposed approach based on review of Medicare CED for MedPAC and multiple stakeholder interviews and workshops

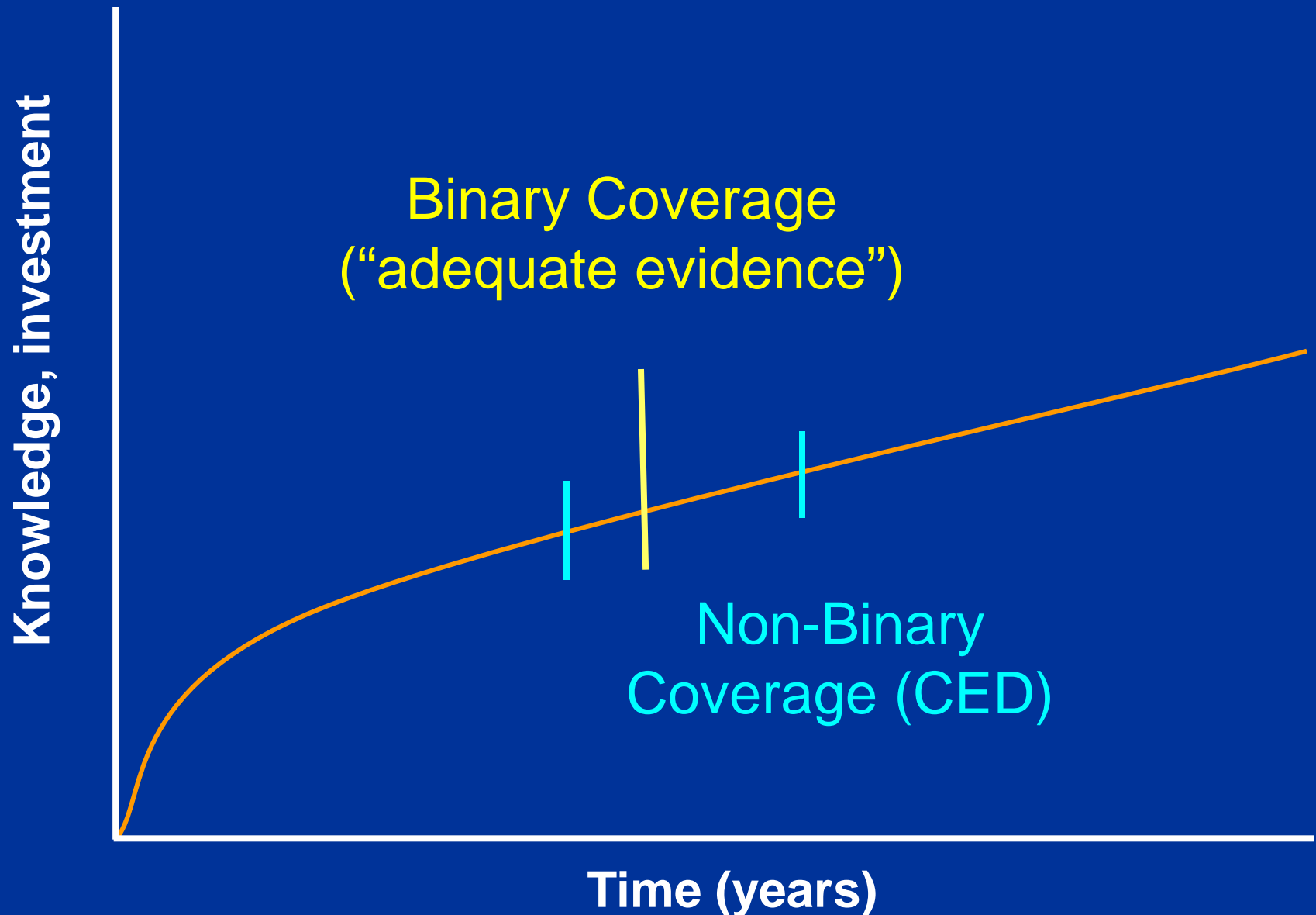
Policy Objectives of CED

- Rapid access to promising technologies; promote innovation for Medicare population
- Generate evidence to address important uncertainties
- Aligned with Medicare's programmatic aims to improve health and use resources wisely

Minimum Requirements for CED

- Technology to diagnose or treat a serious disease or condition, or for important unmet health need in the Medicare population
- Intervention can be plausibly anticipated to:
 - substantially improve health outcomes with same or lower level of aggregate health spending
 - Produce comparable health outcomes at substantially reduced aggregate spending
- Quality improving, cost increasing technologies addressed through binary coverage process

Binary vs. Non-Binary Coverage



Evidence threshold to initiate CED

- A moderate level of confidence based on available evidence that the item or service will improve health outcomes.
 - Benefits considered more likely than not to exceed risks
 - Higher confidence should not apply CED
- Threshold met through two mechanism
 - “Deemed” categories (primary mechanism)
 - CMS determination

Moderate Confidence - Deemed

- Interventions being evaluated in prospective, CER/PCOR studies funded by NIH, AHRQ or PCORI
 - Drugs, devices, diagnostics, surgical procedures, etc.
- Drugs and biologics granted accelerated approval by the FDA
- Medical devices approved through 510(k) process, when additional clinical data has been provided
- In-vitro diagnostics approved or cleared by the FDA based on clinical validity, but not clinical utility
- Deemed categories could be refined and augmented through NCD process (as with Clinical Trials NCD)

Moderate confidence – CMS Determination

- For all interventions, one high quality study shows improvement in intermediate or surrogate outcomes
- High quality studies demonstrating effectiveness but for which patient population, setting, etc not representative of the Medicare population
- Drugs and devices approved by the FDA with significant post-approval study requirements
- For diagnostic tests, clinical validity has been clearly demonstrated, but evidence of clinical utility limited
- Surgical procedures for which one high quality observational study demonstrates effectiveness

Additional Requirements

- Study protocol approved that will address specified key uncertainties approved in advance
- Sufficient funds have been identified to cover all clinical and research costs
- Study results available within reasonable time frame (e.g. less the 5 years)
- CED process must be transparent, predictable and consistent

CED as Primary Emphasis for Medicare National Coverage Process

- Limited impact from the current NCD process
 - Over past decade, most product developers avoid NCD process, work through regional contractors
 - Number of NCDs per year decreasing over time
- Most binary coverage policy can continue to be developed and updated by regional contractors
- National coverage process should be primarily focused on implementation of CED to promote access to and evidence for promising technologies
 - Proposed framework would selectively promote new technologies that improve health and/or reduce costs

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