COVERAGE WITH EVIDENCE DEVELOPMENT

A PROPOSED FRAMEWORK FOR SUCCESSFUL IMPLEMENTATION

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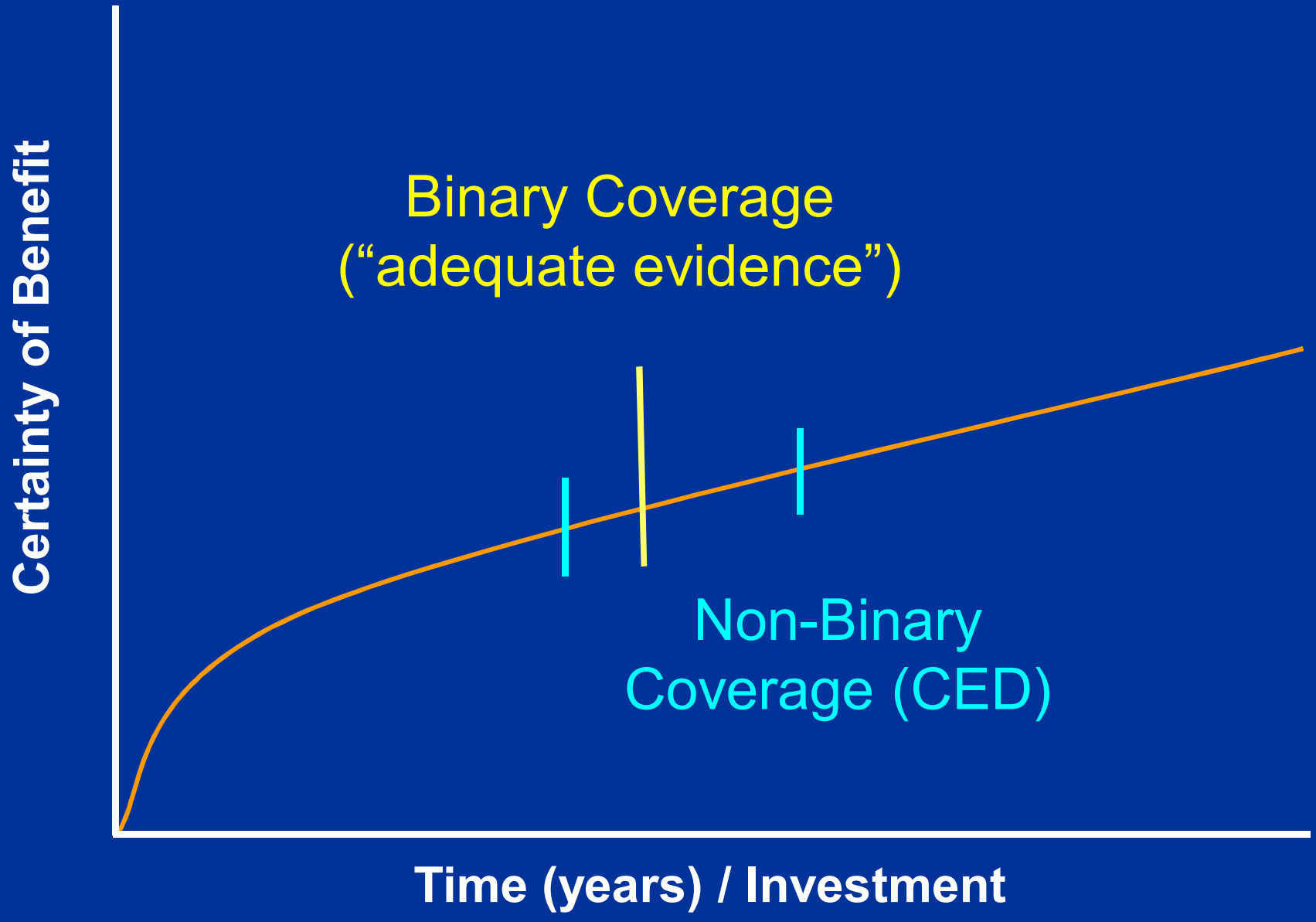
CENTER FOR MEDICAL TECHNOLOGY POLICY

CED DEFINITION AND PURPOSE

- Reimbursement that is contingent on patient participation in clinical studies
- Payer determines appropriate technologies, research questions and study design
- Provides mechanism to support high priority research, generate relevant evidence, and allow early access to promising technologies.

Yes/No Coverage vs. CED



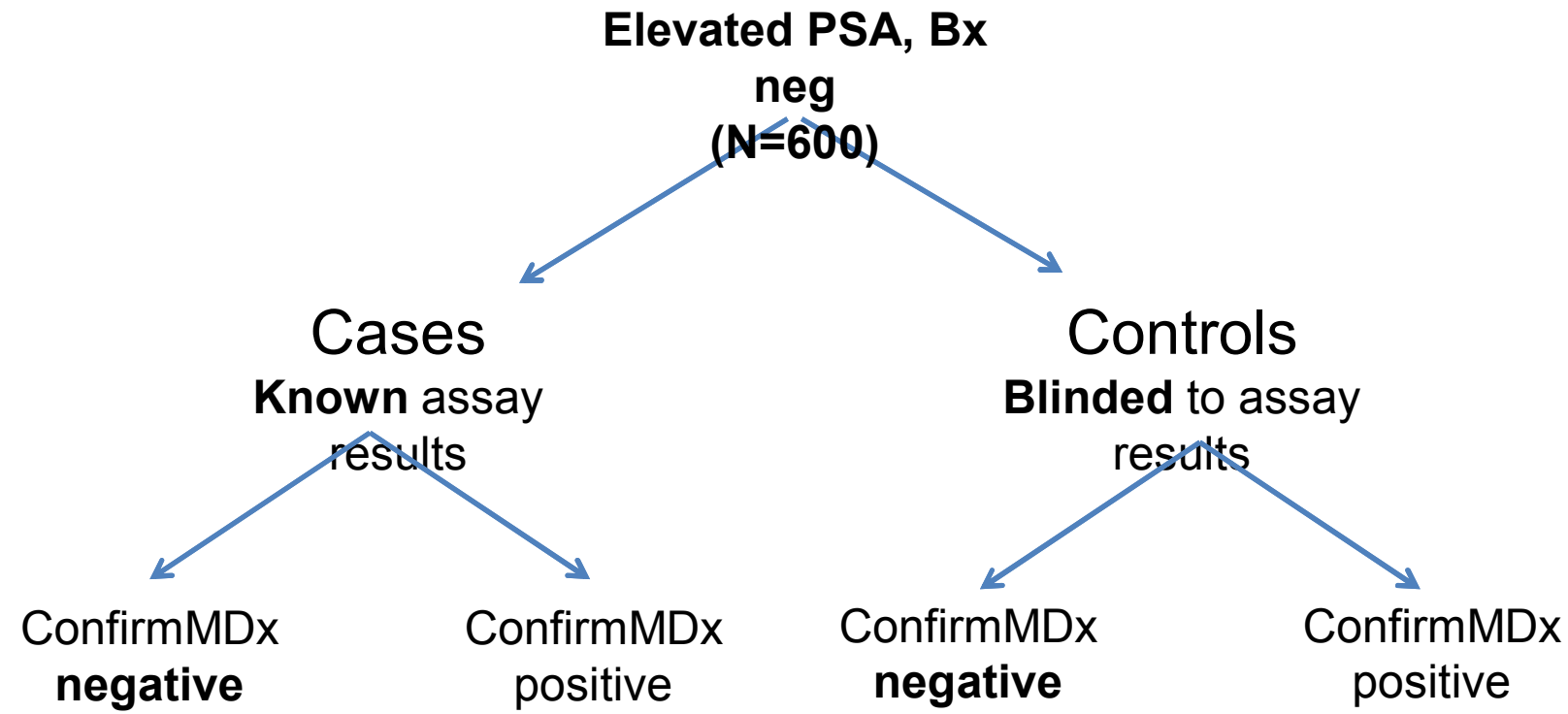
EXAMPLES OF MEDICARE CED

- Lung volume reduction surgery (pre-CED)
- FDG-PET for suspected dementia
- Off-label use of drugs for colorectal cancer
- Implantable defibrillator for primary prevention of SCD
- FDG-PET for oncology
- Genetic testing for warfarin sensitivity
- Platelet-rich plasma for treatment of chronic wounds
- Transcatheter aortic value replacement

MEDICARE LOCAL COVERAGE UNDER CED

- Palmetto GBA issued first LCD with “CED”
- Epigenetic assay for patients with suspected prostate cancer, negative bx, to inform repeat biopsy decision
- Substantial evidence of clinical validity and retrospective evidence of clinical utility considered “promising”
- Prospective, randomized study proposed to be conducted under CED
- Protocol developed through multi-stakeholder process

PASQUAL - BASIC STUDY DESIGN



PROPOSED FRAMEWORK

CORE ELEMENTS OF FRAMEWORK

- Technology addresses an important health need and/or specific payer priority
- Existing evidence is adequate to conclude that the technology is “promising”
- Proposed study will generate valid and relevant evidence to inform future clinical/policy decisions
- Study is reasonably likely to be feasible
- Credible process exists to assess all above elements

SELECTING TECHNOLOGIES

- Technology intended to diagnose or treat a serious disease, important unmet health need
- Intervention can be plausibly anticipated to:
  - substantially improve health outcomes with modest increase in or similar net health spending
  - Produce comparable health outcomes at substantially reduced aggregate spending
- Other compelling scientific, clinical or institutional justification

EVIDENCE THRESHOLD FOR "PROMISING"

- 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 ("preponderance of evidence")

MODERATE CONFIDENCE - CRITERIA

- One high quality study shows improvement in intermediate or surrogate outcomes
- Product approved by FDA breakthrough device
- 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
- Interventions being evaluated in prospective, real world studies funded by NIH, AHRQ or PCORI

STUDY DESIGN REQUIREMENTS

- Evaluates whether an intervention improves meaningful, patient-centered health outcomes
- Study protocol adopts recommended methods for high quality comparative effectiveness research
- The study is feasible to conduct with reasonable chance of reaching target sample size
- Protocol developed with multi-stakeholder input

OTHER CONSIDERATIONS

- Important to ensure that sufficient funds have been identified to cover all clinical and research costs
- Study results should be available within reasonable time frame (e.g. less the 5 years)
- Legal / regulatory issues for private health plans can be complicated
  - Avoid linking CED policy to “medical necessity”

FINAL THOUGHTS

- Increasing demands for real world, comparative evidence with long term, functional outcomes
- CED-like approaches offer one way to reconcile greater evidence demands with innovation
- Encouraging examples of CED achieved
- Business case for private payers is not clear

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EXTRA SLIDES

CENTER FOR MEDICAL TECHNOLOGY POLICY

INSIGHTS FROM MEDICARE EXPERIENCE

- Medicare CED is improving
- Primary challenges are known / addressable
  - Selecting high priority technologies
  - Defining evidence threshold for “promising”
  - Acceptable study designs
  - Adequate funding for clinical and research costs
  - Ethical, legal, regulatory issues
- Variable interest, some activity among private payers

STATUTORY / LEGAL AUTHORITY

- Statutory foundation for CED in controversial
  - §1862(a)(1)(A) – reasonable, necessary
  - §1862(a)(1)(E) – AHRQ research authority
- Non-specific legal authority for CED impede clear, consistent implementation
- Private payers – works best as extra-contractual benefit, not via medical necessity

PRIORITY SETTING

- CED topic selection is reactive
- Each CED project created de novo
  - Guided by what is feasible, not what is desirable; labor intensive
- Time frame and high stakes of coverage process impose difficult constraints
- Horizon-scanning, priority setting criteria and process needed to identify good topics early

FUNDING FOR RESEARCH COSTS

- Several CED efforts have been impeded by funding challenges
- Design and oversight of studies influenced by entity that provides funding
- Competitive research funding process too slow and has different priorities
- Dedicated resources would be helpful