Reimbursement for Diagnostic Tests

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Reimbursement for Diagnostic Tests

Analytic Validity

- Stability and robustness of assay

Clinical Validity

- Accuracy or ability to diagnose, predict or measure a clinical condition

Clinical Utility

- Ability to change patient management or outcomes
- Impact on cost of care

- Well characterized samples – clinically and analytically
- Clearly defined standard use with samples from that population
- Clinical relevance verified by community, literature, guidelines
- Demonstration that test is medically necessary and actionable
- Aligned with TPP, PRD, and product launch/marketing strategies

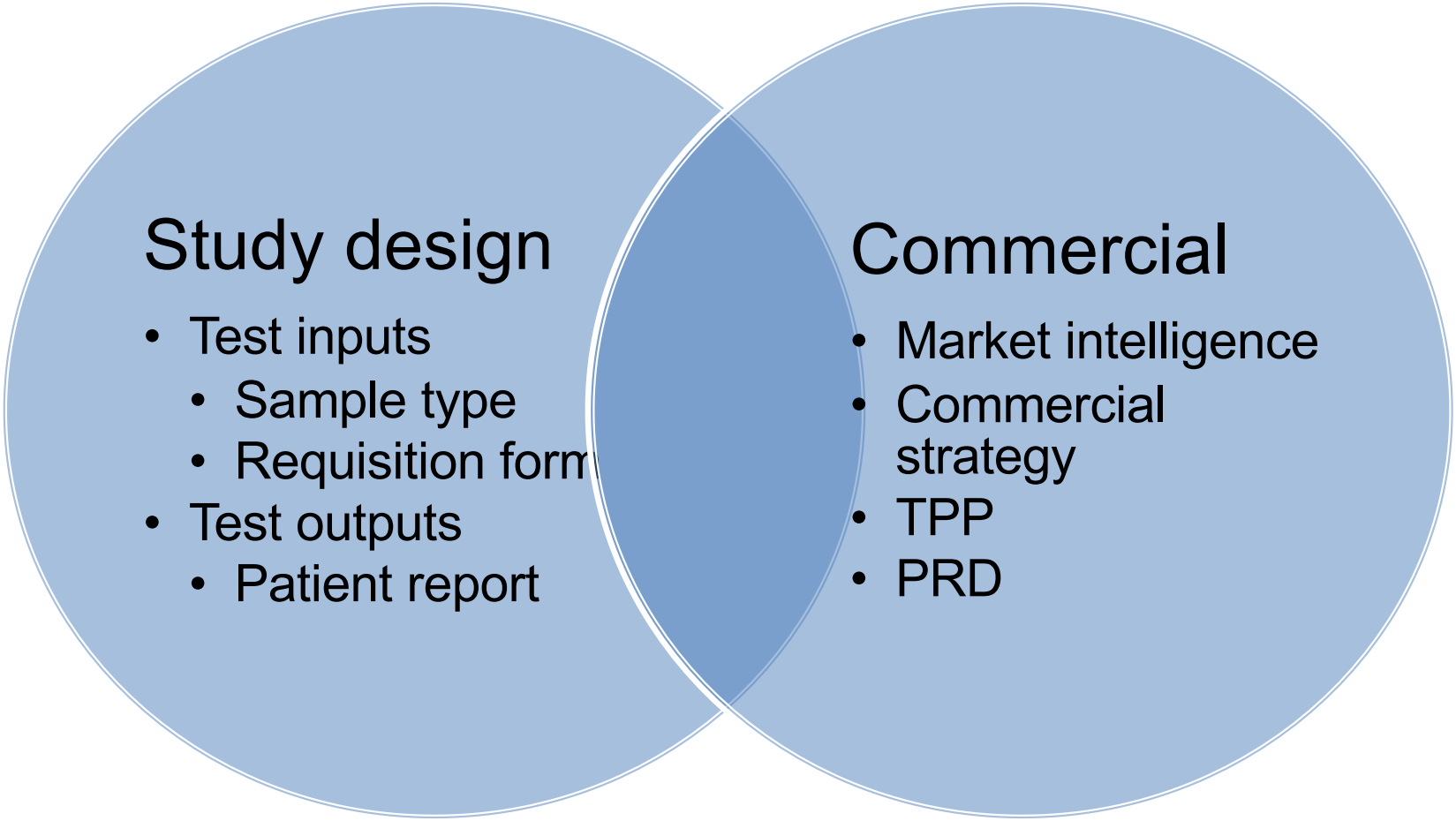
TPP: target product profile
PRD: product requirements document

Why build the reimbursement strategy early?

- Informs
  - Study design
  - Sample accrual plan
  - Establishment of milestones and timelines: study completion, product launch, billing infrastructure
- Align with TPP, PRD and marketing strategy
- Informs pricing, revenue and time to cash-positivity
- Important to investors

TPP: target product profile
PRD: product requirements document

Align study design with commercial strategy



Centers for Medicare and Medicaid Services (CMS)

Demonstrate the test is medically necessary

- Safe and effective
- Not experimental or investigational
- Appropriate, including duration and frequency
- Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed body member
- Furnished in a setting appropriate to the medical needs and condition
- Ordered and furnished by qualified personnel
- Meets but does not exceed medical need

Centers for Medicare and Medicaid Services. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c03.pdf

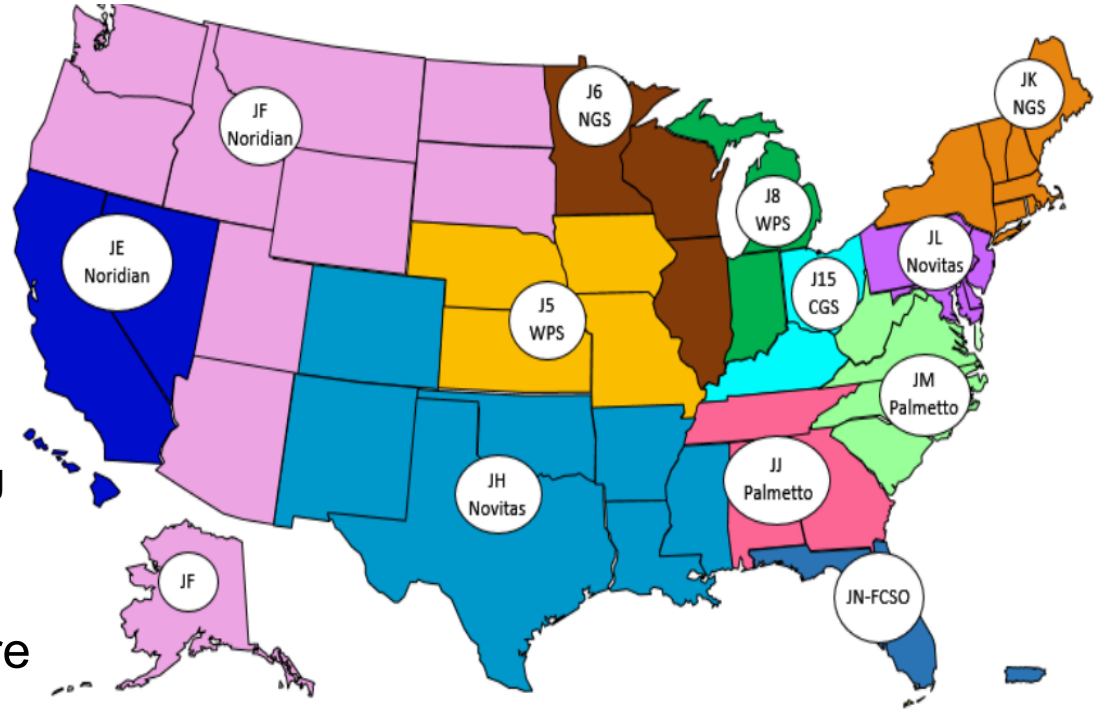
ACCE Model Process for Evaluating Genetic Tests CDC-supported EGAPP initiative

- Defined disorder/clinical setting
- Analytic validity
- Clinical validity
- Clinical utility
- Ethical, legal and social implications

Centers for Disease Control and Prevention. https://www.cdc.gov/genomics/gtesting/acce/index.htm

Medicare Reimbursement – MolDx

- Medicare Administrative Contractor (MAC)
  - Private insurer acting as a multi-state, regional contractor
  - Administers Medicare Parts A and B
- JE A/B MAC
  - Administered by Noridian Healthcare Solutions
  - Technical assessment, coverage, coding and pricing provided by Palmetto GBA MolDx
- Technical provider: Change Healthcare (formerly McKesson)



Dossier Requirements

- Executive Summary, including
  - Assay description
  - Intended patient population
  - Intended purpose
- Technical Assessment Summary Form – all platforms except NGS
- Analytical Performance Specifications form
- Clinical utility (CU) studies: published only
- Clinical validity (CV) studies: relevant data
- Analytic validity (AV) studies: relevant data
- Economic value studies: relevant economic impact studies

Palmetto GBA MolDx. https://www.palmettogba.com/palmetto/moldx.nsf/DocsCatHome/MolDx

Technical Assessment Process

- Obtain unique test identifier
  - DEX Z-Code
  - Administered by Change Healthcare/McKesson
- Submit dossier to MolDx
- Subject matter experts (academia, industry) review for
  - Analytic validity
  - Clinical validity
  - Clinical utility
  - Fulfillment of CMS reasonable and necessary criteria
  - Follows CDC ACCE criteria

Palmetto GBA MolDx. https://www.palmettogba.com/palmetto/moldx.nsf/DocsCatHome/MolDx
Change Healthcare DEX™ Diagnostics Exchange. https://app.dexzcodes.com/login

Possible Local Coverage Determination (LCD)

- Covered without limitations beyond those inherent in its design and purpose
- Limited coverage (i.e. for specific diagnosis, clinical indications)
- Coverage with data development (CDD) (very specific coverage criteria)
- Non-covered determination because the test was not found to be medically reasonable and necessary for the diagnosis and/or treatment of the patient

Palmetto GBA MolDx. https://www.palmettogba.com/palmetto/moldx.nsf/DocsCatHome/MolDx

Pricing

- Evaluated compared with previous “like tests”
- For new MDTs and LDTs, MolDx uses the 2011 stacking codes if applicable to establish a baseline for new tests consistent with values developed for established tests
- Factors considered in pricing include:
  - Innovator tests
    - Performed by a single lab or offered by an IVD test kit manufacturer
    - Considers innovator’s cost of R&D and evidence of CV and CU
  - Economic Impact – value of information in patient decision-making, achieving improvement in health outcomes and effect on cost

Additional Studies

- Additional studies are not substitutes for well-design clinical utility studies but may
  - Inform/enhance the dossier
  - Impact private payer decisions
- Examples include
  - Impact on physician-decision-making
    - Survey – case studies
    - Decision to biopsy/not biopsy based on test results
  - Economic and cost-effectiveness modeling
    - Per patient impact
    - Societal impact
  - Registry monitoring patient management post-test in commercial population over time

Clinical Utility Study Design
Randomized control trials (RCT)

Biomarker-stratified design

- Classic clinical trial design
- All comers randomized
- Large sample size

Enrichment design

- All patients tested
- Only test-positive continue to treatment/management
- Smaller sample size

Biomarker-strategy design

- Randomization to arm that uses test to direct therapy or control arm that does not

Prospective-Retrospective Analysis of Previously Conducted RCTs

- RCT design using existing sample cohort
- Faster and less expensive

Frieidlin B, McShane LM, Korn EL. J Natl Cancer Inst 2010; Simon RM, Paik S, Hayes DF. J Natl Cancer Inst 2009; Center for Medical Technology Policy, 2013

Non-RCT Study Design

Single-arm studies

- Test developed to be used with a FDA-approved drug
- Adequate archived samples not available to conduct prospective-retrospective trial
- Feasible to use response as endpoint
- Comparable response data in comparative cohort exists

Prospective observational studies

- Patient registries
- Multiple group, pretest/posttest design
- Acceptable if compelling rationale for not doing RCT is addressed

Decision-analytic modeling

Clinical Performance and Value (CPV) vignettes

- *In silico* simulation of clinical behavior change
- Builds clinical utility case early – completion of validation not required
- Validated against actual practice
- Not affected by patient variation

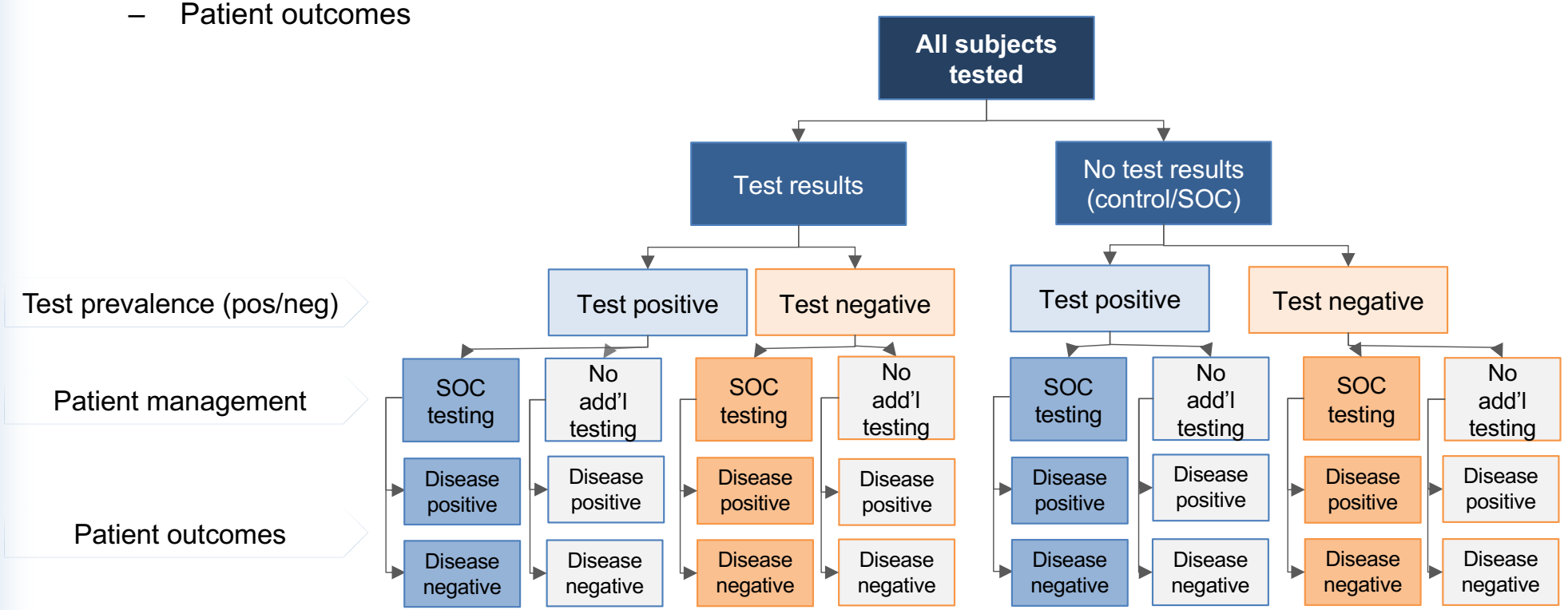
Cost-effectiveness

- Can be compelling for payers
- May not be sufficient for coverage but should be employed as part of reimbursement strategy

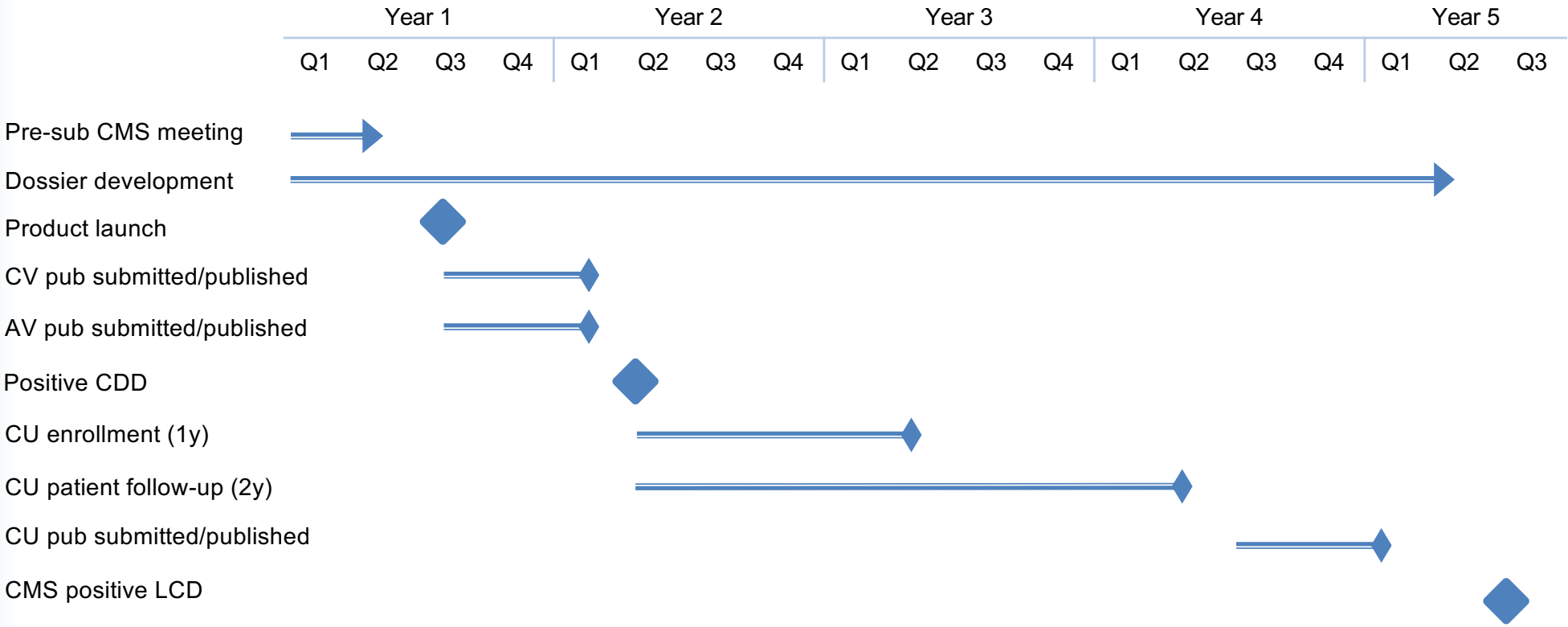
Peabody et al. Am J Managed Care 2014; Center for Medical Technology Policy, 2013

Case Study: RCT Study Design

- Biomarker stratified design (example)
- Subjects enrolled in 1 year
- All subjects tested through CLIA lab; randomized to receive or not receive results
- Subjects followed for 2 years to measure
  - Change in patient management
  - Patient outcomes



Sample timeline



CMS: Centers for Medicare and Medicaid Services; CV: clinical validation; AV: analytic validation; CU: clinical utility; CDD: coverage with data development; LCD: local coverage determination

THANK YOU

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