CMS/Payer Perspectives

Understanding Disparities in Access to Genomic Medicine

Sean Tunis MD, MSc  |  June 27, 2018

CENTER FOR MEDICAL TECHNOLOGY POLICY
Affordability is Center Stage

Source: Mass Budget and Policy Center

NOTE: Dollar figures are inflation adjusted using a measure specific to government spending as developed by the U.S. Bureau of Labor and Statistics.
Framing workshop topic

- Reducing disparities in access to genomic medicine
- Reducing health disparities through targeted use of genomic medicine
What are payers thinking?

• Coverage decisions
• Value-based payment
• Population health
Coverage Decisions
(Medical Necessity)
Medicare Guidelines for Evaluation of DX Tests

• **Question 1:** *Is the evidence adequate to determine whether the test provides more accurate diagnostic information?*

• **Question 2:** *If the test changes accuracy, is the evidence adequate to determine how the changed accuracy affects health outcomes?*
Generating and evaluating evidence of the clinical utility of molecular diagnostic tests in oncology

Patricia Deverka, MD, MBE¹, Donna A. Messner, PhD¹, Robert McCormack, PhD², Gary H. Lyman, MD, MPH³, Margaret Piper, MD, MPH⁴, Linda Bradley, PhD⁵, David Parkinson, MD⁶, David Nelson, PhD⁷, Mary Lou Smith, JD, MBA⁸, Louis Jacques, MD⁹, Tania Dutta, MS, MPP¹ and Sean R. Tunis, MD, MSc¹

Purpose: Enthusiasm for molecular diagnostic (MDx) testing in oncology is constrained by the gaps in required evidence regarding its impact on patient outcomes (clinical utility (CU)). This effectiveness guidance document proposes recommendations for the design and evaluation of studies intended to reflect the evidence expectations of payers, while also reflecting information needs of patients and clinicians.

Methods: Our process included literature reviews and key informant consultations with stakeholders from payers, providers, and patients. We developed a common framework for designing and evaluating studies of the clinical validity and CU of MDx tests, achieving a balance between scientific rigor and patient value.

The guidance also describes circumstances under which alternatives to RCTs could be considered, specifying conditions under which test developers could use prospective-retrospective studies with banked biospecimens, single-arm studies, prospective observational studies, or decision-analytic modeling techniques that make a reasonable case for CU.

Conclusion: Using a process driven by multiple stakeholders, we developed a common framework for designing and evaluating studies of the clinical validity and CU of MDx tests, achieving a balance between scientific rigor and patient value.

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Evidence for MDx Testing

Selected Recommendations

• Change in pt management insufficient
• RCTs generally preferred whenever feasible
• Observational studies may be adequate in specific circumstances, and when RCTs not feasible
• Decision modeling may show the relationship between test results and downstream patient outcomes
Value-based Payment
(shifting risk to providers)
Evolution of Healthcare Payment Models

Low Provider Risk
- Fee-For-Service
- Pay for Performance
- Shared Savings

High Provider Risk
- Bundled Payments / ACOs
- Partial / Global Capitation
- Alternative Payment Models

Pay for Volume

Pay for Value
Current Landscape - Medicare

2016
- All Medicare FFS
  - 85%
- FFS Linked to Quality
  - 30%
- Alternative Payment Models
  - 50%

2018
- All Medicare FFS
  - 90%
- FFS Linked to Quality
  - 50%
- Alternative Payment Models
  -
Population Health
National Healthcare Quality and Disparities Report

Chartbook on Effective Treatment

September 2016

This presentation contains notes. Select View, then Notes page to read them.
This chartbook is organized around eight conditions that are the leading causes of mortality and morbidity in the United States:

- Cardiovascular disease
- Cancer
- Chronic kidney disease
- Diabetes
- HIV and AIDS
- Mental health and substance abuse
- Musculoskeletal diseases
- Respiratory diseases
Adult admissions with congestive heart failure by income

Key: Q = quartile.
Denominator: U.S. resident population age 18 and over.
Note: For this measure, lower rates are better. Area income is based on the median income of a patient's ZIP Code of residence.

2008 Achievable Benchmark: 195 Admissions per 100,000 Population
Age-adjusted breast cancer deaths by race/ethnicity

Key: API = Asian or Pacific Islander; AI/AN = American Indian or Alaska Native.
Denominator: U.S. population.
Note: For this measure, lower rates are better. Total rate is age adjusted to the 2000 U.S. standard population.
Dialysis patients receiving transplant by race

Key: NHOPI = Native Hawaiian or Other Pacific Islander; AI/AN = American Indian or Alaska Native.
Note: Hispanic includes all races. The cohort includes patients from 2000-2013 who were younger than 70 at the initiation of ESRD. Percentages are calculated as the number of patients placed on the deceased donor organ waiting list or receiving a deceased donor transplant within 1 year of initiation, divided by the number of patients without a living donor available (i.e., patients receiving a living donor transplant are excluded), and are estimated using the Kaplan-Meier methodology.

2011 Achievable Benchmark: 20.6%
Addressing Disparities in GM

To increase level of interest from payers / providers in promoting access to genomic medicine

- Focus on major public health priorities
- Look for empirical evidence of disparities in care
- Identify in what way genomic medicine could help
- Link to or create quality / value-based payment initiatives
- Generate some evidence to demonstrate better outcomes and value