Medicare Begins: 1965

President Lyndon B. Johnson at the signing ceremony July 30, 1965, at the Truman Library in Independence, Missouri.

Source: CMS / ORDI
Reasonable and Necessary

- Medicare coverage process: how CMS answers:
  - “is an item or service reasonable and necessary for the diagnosis or treatment of an illness or injury for Medicare beneficiaries?”

  - This process is called ‘the National Coverage Determination Process’ or ‘the NCD process’.
R&N ≡ Evidence of Improved Outcomes

- **Working definition** of ‘reasonable and necessary’:

  = ‘adequate evidence exists to conclude that the item or service improves clinically meaningful health outcomes for the Medicare population’.
Key Evidence for the NCD Process

- **Analytical validity:**

- **Clinical validity:**

- **Clinical utility:**
  - Is available evidence adequate to conclude that testing for genetic variants leads to changes in physician decisions about therapy which improve patient outcomes?

- **Ethical, legal, and social implications**

*Source: http://www.cdc.gov/genomics/gtesting/ACCE/index.htm*
Medical Evidence Development and Coverage Advisory Committee Meeting (MEDCAC)

1. Convened at CMS’ option to provide guidance on evidence assessment and interpretation on specific topics; and

2. Includes input from subject matter experts, ethicists, clinical trialists, and patient representatives.

3. Three MEDCAC meetings have focused on genetic or genomic testing since 2009.
Assessing evidence from clinical trials
About testing for genetic variants

- **More value** associated with:
  - Prospective trials
  - Controlled trials
  - Objective comparators and endpoints
  - Using techniques to reduce bias, such as randomization, masking
  - Proper use of statistical tools and well-powered studies

- **Less value** associated with:
  - Retrospective studies
  - Uncontrolled studies
  - Studies based only on self-reported survey data
  - Small studies
Coverage with Evidence Development (CED)

- **Role:** Addressing the Evidence Dilemma
  - “... CED ... has been used by CMS under certain scenarios and has been recommended by the IOM for the development of cancer biomarkers.”

- **Example:** Pharmacogenomic testing for warfarin responsiveness (2009) – A CED Determination
  - Specific variants: *VKORC1* (A/B); *CYP2C9* *2* and *3*
    - Purpose: If warfarin dosing is based on results of testing for these variants, do outcomes improve for patients starting anticoagulation?
    - Status: Two Medicare-approved clinical studies in progress
Key question for coverage

Does testing for genetic variants lead to improved, clinically meaningful outcomes?

- “… the next step must be to mount clinical trials in which patients are stratified according to their biologic signature to determine whether knowledge of this information leads to better clinical outcomes. If personalized medicine is going to become a reality, we need to design and execute these critical trials.”
  
For more information about coverage:

- CMS website, including the database of Medicare coverage decisions, available at

  www.cms.gov
Brought to you by:

CMS, especially:

- Center for Medicare Management
  - Hospital & Ambulatory Policy Group
  - Division of Ambulatory Services

- Office of Clinical Standards and Quality
  - Coverage and Analysis Group
  - Division of Items and Devices