


Facilitating Development and Utilization of Genome-Based Diagnostic Technologies:
Advancing utility and adoption of clinical genomic diagnostics – Part II

November 15, 2011
Louis I. Hochheiser, M.D.
Chief Medical Leader

HUMANA®

Challenges

Lack of evidence standards

+

Questionable test validation

+

Complex genomic science

+

High test costs

+

Fast-paced GT pipeline

Variable coverage decisions among public and private payer policies (NCDs vs. LCDs vs. Private medical policy)

AND

Poor predictability for test developers

Focus on Solutions

- Solutions need to place the patient & improving health outcomes as the primary focus
  - Protects public and is “the right thing to do”
  - Education necessary for provider and public
  - Assure cost effectiveness
- Need clear stakeholder acceptance from all: physicians, patients, lab/diagnostic companies, payers, regulators (CMS & FDA), pharmaceutical companies, policymakers, etc.
  - Who will set and maintain standards?

College of American Pathologists

HUMANA

Focus on Solutions

- CMS and other payers clarify expectations about the clinical value of technologies
  - Clarify criteria for coverage
    - e.g., test results provide incremental value beyond existing tools, comparative effectiveness analysis, cost comparison information, etc.
    - Early payer/industry dialog has the potential to inform study design and evaluate reasonable price points for GTs
  - Clarify evidence needed
    - e.g., CDC ACCE model, study design

Focus on Solutions

Creating agreed upon criteria for success:

- **Analytic validity** - Quality of testing
  - Variances in GT processing making them subject to pre-, intra-, and post-analytic error
- Clinical validation
  - Tests are marketed on the strength of association between a genotype/phenotype and a specific disorder (**clinical validity**)
  - Evidence is lacking that GT leads to better outcomes (missing **clinical utility**)
- Cost effectiveness
- Appropriate level of testing for a condition

Standards

- Testing must
  - Go beyond connection of mutation to condition or drug
  - Be reproducible
  - Available
  - Provide value in outcomes or efficiency

Value of Agreed Upon Standards

- Allows for more rapid deployment (currently waiting for peer reviewed publication)
- Allows all payers to make consistent decisions about availability of tests
- Allows for uniformity of CMS policy
- Public and providers can be comfortable with decisions to adopt tests
- Allows for further validation over time

Payer Participation

- Payer responsibility for clarifying clinical value of new technologies
- Payer to consider new coverage models when long term studies are not practical or study populations are small or rare:
  - Risk based models
  - Coverage with evidence development when the risk of patient harm is minimal and clinical benefit appears highly likely and measurable.
- Early dialog with industry to inform studies and evaluate reasonable price points

Payer Participation

- Payers & labs work together to minimize errors and variances in testing methodologies that lead to clinical misdirection.
  - Quality expectations for specimen sampling and handling, lab methods, and end-user reporting.
- Education: Testing companies provide information on test accuracy, results/interpretation, and limitations of testing to physicians & patients
  - End users understand the risk/benefits of test results

SUMMARY

- Absolute need for standards
- Collaboration at multiple levels
- A coordinated approach between government, academics, industry and payers
- Potential impact for public is too valuable not to take proactive steps


HUMANA®