Barriers to Personalized Medicine: Policy, Not Science, May Be Our Greatest Hurdle

Paul Sheives, JD
Director of Personalized Medicine and Diagnostics Policy
Biotechnology Industry Organization

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Industry Stakeholder Map of Personalized Medicine

- Therapeutic Drugs/Biologics
- Single-source Innovative Labs
- Lab Services and Hospitals
- Dx Kit Developers
- Research Tools
The PM Industry Lacks Sufficient Incentives for the Development of Innovative Dx

- There is currently no adequate mechanism to incentivize first-to-market innovative Dx
- For example, characteristics of Dx development do not lend parallel protections afforded to drugs:
  - Shorter product life cycle and lower volume utilization
  - Patents – ease of work-around and pace of change
  - FDA exclusivity – LDTs vs. FDA-approved/cleared
  - Lack of adequate coding system to create premium pricing model
- How then can we incentivize innovative Dx?

Extension of Drug/Biologic Exclusivity: Piggybacking on an Established System

- Drug exclusivity is well-established, litigated and provides solid protection
- For those tests intended to be paired with specific drugs/biologics, MODDERN introduces an extension of data exclusivity to drugs and biologics
- Provides extra incentives for drugs and biologics where development may be stymied by shrinking patient populations
Lack of Specificity in Current Coding for Innovative Dx Tests

• To specifically identify a new Dx test, the AMA uses CPT and HCPCS Level II codes to describe a new test
• In the absence of a specific code, the billing practice has been to bill aggregated pathology procedure codes
  – Results in wide-ranging billing practices, large discrepancies in payment between different payers, and a lack of transparency of the product being billed

AMA Efforts to Bolster the Coding System

• The AMA formed in late 2009 the Molecular Pathology Coding Workgroup
  – Currently, ~100 codes for Dx tests have been pushed through, and are expected to go into effect in 2013
  – Codes sufficiently specific and adequate to describe other Dx tests are still under development
• The AMA will retire the code-stacking practice in 2013
  – Coding requests will sharply increase and may further delay
Lag in Acquiring Billing Codes for Novel Dx: Chicken and the Egg

- Uptake in the marketplace by private and public payers is difficult without a specific code
  - Billing under NOC codes is cumbersome
- Acquiring a code can take up to 2 years or longer from the date of FDA launch
  - AMA requires evidence that the test is well established and expects to see sales data to back it up
  - However, sales are difficult to generate in the absence of a code to describe the product

MODDERN Seeks to Create a Temporary National Code for Novel Dx

- To address this dilemma, MODDERN seeks to create a temporary national code to describe the test while the traditional avenues are pursued
- Updated more frequently than current system to prevent delays
Reimbursement System Does Not Provide Adequate Payment for Innovative Dx

• Cross-walking – match payment to something already on the CLFS that most closely resembles
  – Does not account for differences in development costs or resources required to perform test
• Gap-filling – a virtual blackbox that produces an amount for tests that cannot be crosswalked
  – Factors considered in the gap-filling process focus on cost of the test itself
  – Factors do not address costs of development or resources required to perform the test

MODDERN Introduces Factors to Account for Costs of Development and Resources

• In the absence of a new payment model, the current mechanisms must be modified to account for the costs of development, the value of the test to patient care and the resources needed to perform the tests
• To this end, MODDERN allows CMS to consider factors that account for the costs of development and the resources required for performance