Pay-For-Value Genetic Tests
A design for coverage determination that encourages innovation
January 13, 2014

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While the Coverage with Evidence Determination (CED) provides an effective coverage determination process for many new devices and treatments, it fails to capitalize on the opportunities in the molecular diagnostics (MDx) market, and does not adequately account for the unique challenges of precision medicine. Although MDx tests offer significant opportunity to reign in healthcare costs and influence health outcomes, the possibility of coverage-related delays in the development and clinical use of laboratory tests needed to drive new patient therapies is all too real.

To overcome coverage determination challenges for new genetic tests and realize their full benefit, a technology-enabled, risk-sharing, data-driven process is needed to provide the speed and agility demanded by patients and physicians, the real-world utilization data required by laboratories, and demonstrated value demanded by payors.

CED and Molecular Diagnostics
One in four Americans receives benefits through the Centers for Medicare & Medicaid Services, (CMS) putting them in a unique position to make coverage determinations and negotiate low pricing for beneficiaries, and establish precedent for the coverage and pricing administered by other payors.

The CED process used by CMS, with its classically designed studies and data collection techniques, was created for drugs and biologics. The process is not well suited to targeted molecular diagnostics and the vast amounts of data produced by these tests that must flow freely between the requisite stages of coverage determination. MDx also presents unique financial, timetable, and scientific benefits relative to other diagnostics, which cannot be leveraged by the CED process.

CED -- by design -- can take years, and the diagnostics going through the process may be saddled with an unrecoverable cost burden, private insurer non-coverage, or be eclipsed by advanced technology before ever reaching market. The CED process may also stifle innovation for smaller, venture-backed companies that do not have the resources to survive the extended period of data gathering required.

A Market-Driven, Self-Regulating Approach
A proposed alternative to the CED process leverages advances in technology to facilitate risk sharing and data exchange for a more fluid market-driven, self-regulating, pay-for-value approach to coverage determination.

An important aspect of this pay-for-value approach involves managing risk through decision support tools. As part of sharing risk, payors must also collaborate with diagnostic providers to ensure they can provide correct guidance for physicians so that the right tests are ordered at the right time to facilitate the right treatment decision.

The risk-sharing model is based on the idea that the lab should be paid if the diagnostic test produces actionable results. The lab, using its own data, defines the risk it is willing to take that the diagnostic will produce actionable results. This confidence level can then be used by payors to make a coverage determination.

Data Exchange Supports an Outcomes-Driven Reimbursement Model

Data exchange involves the collection of data, a repository in which the data is stored, and expert analysis and formulation of the data into decision support tools for physicians to guide the ordering of molecular diagnostics and the interpretation of the results.

The collection of data needs to include phenotypes exhibited or indicators observed, specific biomarkers and methodologies, and clinical outcomes to provide the physician with as much data as possible to guide decision-making. Unlike therapeutics, where outcomes may not be known for years, the "outcomes," or "actionable results," of most diagnostics are known within days. An incentive system must be put in place, potentially as part of the final laboratory report, where reimbursement is tied to improved stratification or diagnosis, prognosis, monitoring or predicting response.

Considerations for Reimbursement Rates

Assuming a philosophy of shared risk/payment for MDx tests based on the degree to which the diagnostic altered the course of treatment, an appropriate price for a test must be determined based on the medical benefit derived. Pricing for new diagnostics with analytes similar to other known diagnostics can be determined based on the relative medical benefit of the new diagnostic. Compared to the existing diagnostic is the new diagnostic more precise? Does the new diagnostic allow for earlier diagnosis? Does the new diagnostic change the therapy and what is the benefit of this change?

Pricing for completely novel diagnostics, or "first in class" tests is largely set on the medical value of the result. What is the cost or quality of life benefit of the result? In most cases the price determination is negotiated between payors and laboratories based on all of the known data, the risks each party is willing to take, and the demand from the diagnostic result.

Under a fee-for-service model, laboratories want to maximize the use of diagnostics and payors want to minimize their use, and the needs of the physician and patient are largely excluded from the calculation. Shared risk and information sharing can align the motivations of all parties. With the support of physicians, payors and laboratories, a technology-enabled coverage determination process can provide a unique opportunity for a self-regulating system that inherently optimizes patient outcomes, payor costs, and developer profits.

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(Editor's note: Article excerpted from "A Pay-for-Value, Data-Driven Approach for the Coverage of Innovative Genetic Tests," co-authored by Richard Ding, CEO bioTheranostics, Inc., Dr. Paul Billings, CMO Life Technologies Inc., and XIFIN CEO Lâle White, VP of Commercialization Strategies Rina Wolf, and Director of Business Development David Lorber, PhD.)