

VALUE-BASED REIMBURSEMENT FOR
PERSONALIZED MEDICINE: WHERE DO WE
STAND?

overview US health care value-based purchasing reforms,
explore implications for diagnostics
and personalized medicines



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Agenda

Regulatory Success

Antiquated Reimbursement Methodology

Coding Transparency Initiatives

Political Solutions

Affordable Care Act – VBP and ACOs

Regulatory Success

Hoffmann-LaRoche

- On August 17, 2011, the U. S. Food and Drug Administration approved vemurafenib tablets (ZELBORAF™, Hoffmann-La Roche Inc.) for the treatment of patients with unresectable or metastatic melanoma with the BRAFV600E mutation **as detected by an FDA-approved test.**
- The approval was based primarily on an international, randomized, open-label trial in patients with previously untreated metastatic or unresectable melanoma with the BRAFV600E mutation **as detected by the cobas® 4800 BRAF V600 Mutation Test (Roche Molecular Systems, Inc.).**
- **This companion diagnostic test was approved by the FDA concurrently with vemurafenib's approval.**

Regulatory Success

Pfizer

- On August 26, 2011, the U. S. Food and Drug Administration granted accelerated approval to crizotinib (XALKOR® Capsules, Pfizer Inc.) for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.
- The FDA approved the Vysis ALK Break-Apart FISH Probe Kit (Abbott Molecular, Inc.) concurrently with the crizotinib approval. This companion diagnostic test is designed to detect rearrangements of the anaplastic lymphoma kinase (ALK) gene in NSCLC.

Antiquated Reimbursement Methodology

Current Law:

- Under current Medicare law, clinical diagnostic tests are reimbursed under either the Clinical Laboratory Fee Schedule (CLFS) or the Medicare Physician Fee Schedule (MPFS).
- **Most advanced personalized diagnostic tests are reimbursed under the CLFS. CLFS tests typically do not require interpretation by a physician to generate patient-specific report.**
- By contrast, MPFS tests do require interpretation by a physician to generate a patient-specific test report.
- CLFS tests are reimbursed using established codes that are either analyte-specific (e.g., glucose) or method-specific (codes describing various steps in molecular analysis).
- The CLFS rates are based upon historical fee schedules fixed in time over 25 years ago with various limits and updates applied over the years.

Antiquated Reimbursement Methodology

New laboratory tests under the CLFS have rates set in one of two ways.

- (1) cross-walk the rate for the new test to that of a similar, established test (or combination of tests),
- (2) gap-fill the rate de novo.

Most new tests have rates assigned by cross-walk, which is helpful when a new test involves substantially similar methods to establish testing.

In the area of advanced personalized diagnostics, however, there are often no meaningfully similar tests on which to base a reasonable cross-walk.

Antiquated Reimbursement Methodology

Gap-fill allows for new rates to be developed for novel assay considering the following factors set forth in the regulations:

- Charges for the test and routine discounts to charges
- Resources required to perform the test
- Payment amounts determined by other payers
- Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.

Most Medicare contractors focus on resources required to perform the test – excluding the substantial resources required to develop advanced personalized diagnostic tests and without considering the value of the information provided by the test.

American Medical Association (AMA) Coding Initiatives

Molecular Pathology Coding Work Group

- ***Provide more current descriptions of technology required for these services and to more accurately identify and describe the services for all end users of the CPT code set***
- Focused on medical laboratory procedures involving non-microscopic analyses of nucleic acid to detect variants in genes that might be indicative of germline (eg constitutional) disorders, somatic (eg, neoplasia) conditions, or histocompatibility antigens (eg, HLA)
- Initial set of codes will be published in the CPT@2012 book.

AMA Coding Initiatives

In Vitro Diagnostic Multivariate Assays Meeting

- Impending deletion of the molecular pathology stacking codes
- The potential for addition of an unlisted code for multianalyte assays
- ***Would create difficulty in reporting and reimbursement, particularly since there are few CPT code applications for sole-source tests currently reported with stacking codes.***
- This is a work in progress

Palmetto GBA

Local Coverage Decision Draft

Indications and Limitations of Coverage and/or Medical Necessity

- This policy confirms 'non-coverage' for all molecular diagnostic tests that are not explicitly covered by a National Coverage Determination (NCD), a Local Coverage Determination (LCD) or coverage article published by Palmetto GBA.
- For the purposes of this policy, Palmetto GBA defines MDT as a single test (often with multiple components) that delivers one result and involves nucleic acids (DNA/RNA), proteins, enzymes and/or other metabolite detection. Most test results rely upon an algorithm or other form of data/evaluation derivation. In addition to this definition, this non-coverage policy applies to all tests that:
 1. ***Are Non-FDA cleared laboratory developed tests (LDTs, or***
 2. ***Are performed or marketed by a sole source, hospital or reference laboratory, or***
 3. ***Have not received a specific AMA CPT code, or***
 4. ***Have not obtained an NCD or a coverage determination from Palmetto GBA (LCD or article)***

Pending Draft Legislation

Modern Cures Act (Modernizing Our Drug & Diagnostics Evaluation and Regulatory Network Cures Act of 2011)

MODERN would help doctors find the patients most likely to be helped by a certain treatment by offering more tests to doctors and patients.

Right now, there is no clear pathway for getting new tests approved. Plus once approved, it can still take a year or more before a test is available for patients. MODERN will open a clear pathway for approving new tests.

Status: Not yet introduced

Pending Draft Legislation

Modern Cures Act (Modernizing Our Drug & Diagnostics Evaluation and Regulatory Network Cures Act of 2011)

Diagnostic Test Related Specifics of MODERN

- Creates a new council charged with creating materials to help improve understanding of key concepts of Dx
- ***Gap-fill payment determinations to include: impact on patient care, test technical characteristics, claims data, laboratory charges, private payer rates***
 - Advice from expert advisory panel – clinicians, patients, laboratories, HTA, genetic counselors, etc.
- ***Quarterly assignment of temporary HCPCS codes***
- Defines new clinical dx lab test: a clinical dx test to which a new or substantially revised HCPCS code is assigned on or after 1/1/2005
- ***Provisions for companion diagnostics***

Draft Legislation

BETTER Patient Act

- **The bill establishes a new category of regulated products, "In vitro Diagnostic Products (IVDP) distinct from a medical "device"**
- Creates a regulatory framework within FDA that divides IVDPs into high, moderate, and low risk tests and establishes a fast track process including accelerated approval and priority review
 - Permits LDTs and IVDP already on market to remain in clinical use provided cleared by state of New York CLEP
- **Defines competent and reliable scientific evidence as that evidence that substantiates intended use claims**
 - Established FDA Diagnostic Advisory Committee to provide advice on the development of guidelines for categorizing by risk of tests and criteria for evaluating the sufficiency of evidence to demonstrate a test is accurate and reliable
- Authorizes the establishment of registration fee and user fee for IVDP Sponsors

Status: Not yet introduced

Draft Legislation

Coalition For 21st Century Medicine Proposal

- **New reimbursement approach would be based upon a market price benchmark –i.e., the average test price (ATP) negotiated with and paid by all payors.** The ATP would be analogous to the average sales price used to set the payment for physician administered drugs and biologicals under Medicare part B
- New approach could fit within a gap-fill process in that developers of new laboratory tests would have the option to recommend that CMS cross-walk a new test to a substantially similar test or to gap-fill the test
- **If the test is an advanced personalized diagnostic, then an ATP-based rate would serve as the gap-fill amount.**

Status: Not yet introduced

Value-based Purchasing

Value-based Purchasing Inpatient Hospital Payments

Rewards performance relative to peers

Budget Neutral

Financial rewards are derived from poorly performing hospitals

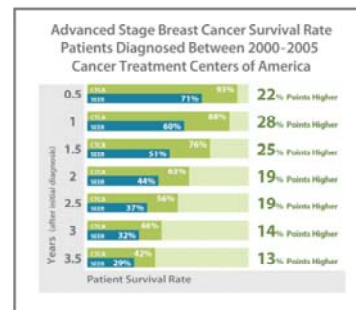
Applicable metrics

- Mortality Rates – AMI, PN, HF
- Readmission Rates – AMI, PN, HF
- Medicare spending per beneficiary
- Appropriate initial antibiotic selection

Estimated Savings through 2015

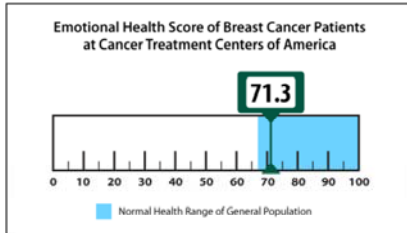
Rewarding Quality and efficiency - \$55 billion
Investing in patient safety – lowering readmissions and hospital-acquired conditions - \$10 billion through 2013

Cancer Quality Metrics



www.cancercenters.com

Cancer Quality Metrics



As illustrated in the graphs above, the average mean physical health score reported by breast cancer patients three months into treatment at Cancer Treatment Centers of America (CTCA) was about 76, while that of the majority of adults in the general population was somewhere between 67 and 100.

www.cancercenters.com

Cost of Cancer in US

National Cancer Institute

National Costs for Cancer Care in 2010 in **Billions of Dollars** by Cancer Site*

<u>Cancer Site</u>	<u>Direct Costs</u>
Breast (female)	\$16.50
All Sites	\$124.57

*<http://costprojections.cancer.gov/>

Where Do We Stand

Summary

- Successes on the Regulatory Front
- Looming Challenges with CPT Coding
- Adequate Payment Challenges Being Addressed, But Currently Not Solved
- Payment Reform (VBP) May Offer Opportunities

ISPOR Personalized Medicine Special Interest Group



Thank You!

For more information, please contact:

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