Payer Data Requirements & Payers' Efforts to Narrow Lab Networks

What's New and How It's Different?
Everything said, expressed, or implied by me, Mark Erwin, should be interpreted as personal views and they do not represent the views of Prometheus Laboratories Inc.
The Importance of Diagnostic Medicine to the US Health Care System

- Clinical laboratory testing is integral to achieving evidence-based improvements in the US health care system that deliver greater care quality, patient outcomes, and cost efficiencies

- Over 7 billion laboratory tests are performed annually in the US

- Clinical laboratory testing plays a significant role in everyday medical practice contributing to over 70% of all clinical decision making

- With such extensive influence on medical care, lab testing intuitively delivers tremendous value since in accounts for only 2.3% of national healthcare spending and only 1.8% of all Medicare spending annually

- Clinical practice guidelines specify using diagnostic tests in the standard of care for 12 of the 15 most clinically and economically burdensome disease categories in the US

- Diagnostic testing objectively answers specific clinical hypotheses during patient work-up, and has a decisive role in health screening, diagnosing and setting treatment pathways

1. CDC Laboratory Medicine National Status Report 2008
2. Faulkner E. Journal of Managed Care Medicine 2009
4. Richardson S. The Process of Diagnosis 2002
The Role of Advanced Personalized Diagnostics in Patient Care

- Advanced molecular tests are a subset performed on cells, tissue and other body samples that represent 8% of clinical lab testing volume annually\(^1\)

- Molecular and genetic tests harness the advances of genetic medicine for the benefit of patient outcomes through improved care quality and safety

- Molecular and genetic tests have become a regular part of clinical practice with over 1,300 available to physicians today, and have the potential to bend the cost curve by improving diagnosis and treatment\(^2,3,4\)

- More than 60% of the US population may benefit from the use of genetic testing in the future\(^3\) through:
  1. Identifying patients predisposed for a given disease
  2. Diagnosing whether a patient has a disease
  3. Defining the severity of a disease, and
  4. Quantifying the effectiveness of a particular therapy

- Physicians across specialties overwhelmingly believe genetic testing will improve patient care and anticipate testing to impact 14% of patients in their own practice within five years\(^1\)

---

1. UnitedHealth Personalized Medicine Report 2012
Physicians and Patients Support Advanced Personalized Diagnostics

Genetic Testing Allows for More Personalized Medical Decisions

- Agree: 76.9%
- Neutral: 8.4%
- Not Sure: 9.2%
- Disagree: 5.4%

1,506 US Adults Surveyed January 2012\(^1\)

Genetic Testing Gives Me the Ability to Diagnose Conditions that Would Otherwise be Unknown

- Agree: 63.2%
- Neutral: 26.3%
- Not Sure: 6.8%
- Disagree: 3.7%

1,254 US Physicians Surveyed January 2012\(^1\)

---

1. UnitedHealth Personalized Medicine Report 2012
Promise of Personalized Medicine

Advanced Diagnostics Will Enable Better Health Outcomes and Increased Efficiency

Physicians & Patients
Seek better outcomes with decisions using patient-specific information

Payers
Seek more Evidence-Based Medicine (EBM)

Societies
Seek better resource allocation

Diagnostic Test Evolution/Revolution

• **Single analyte tests**
  – E.g., glucose, sodium, troponin
  – Measuring a single marker of interest to a treating physician for us in the management of a patient?

• **Panel tests**
  – E.g., chemistry panel, hepatitis panel
  – Provide measures of several individual analytes each of which has independent clinical relevance in patient management

• **Multianalyte tests**
  – E.g., Oncotype DX, Afierna, AlloMap, VeriStrat
  – Combine values from multiple markers to determines risk score or interpretive score that is the true analyte of interest to the treating physician
  – MAAA result is different from the underlying markers
  – Underlying markers may or may not have any independent clinical relevance
  – Now well established; many have been covered and paid by Medicare contractors for several years
Advanced Personalized Diagnostics Provide Data Across the Spectrum of Care

Description
- Prognostic tests to complement traditional risk factors
- Applied to high-risk patients to identify disease early
- Used for definitive diagnosis and general cancer typing
- Assess severity and/or risk of recurrence
- Inform adjuvant chemo decision
- Used to predict efficacy or safety response to specific treatments
- Recurrence, status change monitoring
- Monitoring for treatment efficacy

Test Examples
- BRACAnalysis®
- Breast Cancer IndexSM
- COLARIS®
- MELARIS®
- PANEXIA®
- AlloMap®
- Corus® CAD
- PreDx® Diabetes Risk Score
- Afiema®
- CancerTYPE ID®
- ConfirmMDx
- PathFinderTG®
- Prometheus IBD sgi
- DecisionDx-UM, LGG, GBM tests
- InformMDx
- Oncotype DX® Breast and Colon
- PredictMDx
- PREZEON™
- Prolaris®
- VeriStrat®
- OnDose™
- ChemoFx®
- PRACISSM
- TheraGuide® 5-FU
- Isonostics™
- Vectra™ DA
- Prometheus Thiopurine Metabolites

Adapted from Gustavsen G. The Reimbursement Landscape for Novel Diagnostics 2010
**Coding Evolution**

- **1990s-2000s** Molecular markers reported using *code stack* reporting *methodological steps* to perform the test

- **Mid-late 2000s** Advances in clinical diagnostics and computer analysis allow for many more molecular markers and for multianalyte markers (molecular and non-molecular multianalyte markers)—stacking codes became unwieldy

- **2009** AMA established the Molecular Pathology Work Group to develop *analyte-based coding* for molecular tests similar to established codes elsewhere in Pathology

- **2011** AMA established MAAA Work Group in 2011 as an outgrowth of the Molecular Pathology Work Group
  - MoPath codes limited to DNA/RNA analyses and generally not more than 1 or 2 markers
  - Needed different approach for MAAAs
Most Recent Coding Advancements

• Molecular Pathology – Tier 1
  – Most commonly performed
  – Gene target specific

• Molecular Pathology – Tier 2
  – Less commonly performed
  – Grouped by complexity levels
  – Gene target specific tests assigned by AMA/CPT

• MAAAs
  – Category I: Meet criteria for Category I codes
  – Administrative: Available in the US but may not meet criteria for Category I codes
  – Appendix O: Identifies test with proprietary name and laboratory (if applicable)
MAAA Definition

• Multianalyte Assays with Algorithmic Analyses (MAAA) are procedures that utilize multiple results derived from assays of various types, including molecular pathology assays, [FISH] and non-nucleic acid-based assays. Algorithmic analysis using the results of these assays as well as other patient information (if used) is then performed, and reported typically as a numeric score(s) or as a probability.

• MAAAs are typically unique to a single clinical laboratory or manufacturer.

• The result of individual component procedure(s) that are inputs to the MAAAs may be provided on the associated laboratory report, however, these assays are not ordered, reported, or billed separately using additional codes.

CPT 2013
Strong Clinical Foundation + Reimbursement Fundamentals = Reimbursement Success

Coverage
National & Local Decisions; Medicare & Private Payers

Coding
CPT Codes
HCPCS Codes
ICD-9-CM Codes

Payment
CLFS, MPFS and Other Fee Schedules

Peer Review Publications of Randomized Controlled Trials

Clinical Enthusiasm & Physician Specialty Society Support

U.S. Food and Drug Administration
The limitations of the current system reduce patient access to novel diagnostics. Uncertainty around coverage keeps some physicians from ordering a novel diagnostic that could improve patient care.

Source: Health Advances.
Which Stakeholder Influence Evidence Requirements & Access to New Diagnostics?
In developing new and revised Category I codes the CPT Advisory Committee and the CPT Editorial Panel require:

- that the service/procedure has received approval from the Food and Drug Administration (FDA) for the specific use of devices or drugs (if required);

- that the suggested procedure/service is a distinct service performed (or ordered) by many physicians/practitioners across the United States;

- that the clinical efficacy of the service/procedure is well established and documented in U.S. peer review literature;

- that the suggested service/procedure is neither a fragmentation of an existing procedure/service nor currently reportable by one or more existing codes; and

- that the suggested service/procedure is not requested as a means to report extraordinary circumstances related to the performance of a procedure/service already having a specific CPT code.
In the case of Mendelian and somatic disorders, there is a demonstrated relationship between biomarker and phenotype (i.e., clinical validity).

Biomarkers (e.g., SNPs) that have an association but not a proven causative effect to a known clinical phenotype(s) should have demonstrated clinical usefulness (e.g., high positive predictive value, high negative predictive value, directing therapy/management).

At least two U.S. laboratories are performing the analysis, unless proprietary (e.g., intellectual property) issues exist.

The analysis involves ≥ 10 variants identified in unrelated families. Multiple reports of the same variant may be included.

For dup/del assessment for Tier 2 code assignment the following guidelines will be used:

- Search GeneTests database. If ≥ 10% of disease alleles are associated with dup/del and ≥ 2 dup/dels are documented, place dup/del for analyte on Tier 2 list or,
- If BIOBASE HGMD® Professional database search identifies ≥ 10% of variants that are associated with dup/del (gross deletion or insertion variants/total number of BIOBASE® variants reported), place dup/del for analyte on Tier 2 list.

Evidence criteria are applied and access to new diagnostics is impacted even prior to payer consideration.
“I don’t think its fair that only one company makes the game Monopoly” – Steven Wright
3 Levels of Evidence Drive Coverage for Diagnostics

**Analytic Validity**
- Accuracy, precision, and reproducibility

**Clinical Validity**
- Association of the test result with clinical outcomes of interest

**Clinical Utility**
- Evidence that test use influences physician decision-making and/or improves patient outcomes
Clinical utility can refer to the ability of diagnostic test results to influence physician decision-making in treating a patient.

1. Patient evaluated for disease
2. Patient’s disease diagnosed
3. Physician selects the appropriate treatment
4. Patient has improved clinical outcomes

Clinical utility can refer to the ability of diagnostic test results to improve health outcomes downstream of treatment selection.
# Commercial Payer Criteria for Coverage

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Utility(^1)</td>
<td>▪ Is the test useful in patient management</td>
</tr>
<tr>
<td>Clinical and Analytical Validity(^1)</td>
<td>▪ How accurate (sensitivity and specificity)</td>
</tr>
<tr>
<td></td>
<td>▪ How well does the test perform in the lab</td>
</tr>
<tr>
<td></td>
<td>▪ How reproducible are results</td>
</tr>
<tr>
<td>Meets Regulatory Requirements</td>
<td>▪ CLIA is the current standard for lab services</td>
</tr>
<tr>
<td>Economic Assessment</td>
<td>▪ How cost effective is the diagnostic</td>
</tr>
<tr>
<td><strong>Other Factors</strong></td>
<td></td>
</tr>
<tr>
<td>Political Support for Decision</td>
<td>▪ National guidelines, medical society endorsements and regional/local physician key opinion leaders.</td>
</tr>
</tbody>
</table>

Clinical Validation

• Algorithms are extensively tested and evaluated to confirm accuracy and meaningfulness of results

• Peer-review literature informs the review of the algorithms
  – E.g., Oncotype DX has dozens of peer reviewed publications

• *Exponentially* more costly to develop and validate a MAAA
## Coverage

*FDA Approval ≠ Coverage*

### Innovative Test Examples

<table>
<thead>
<tr>
<th>Innovative Test Examples</th>
<th>FDA Cleared</th>
<th>Positive Coverage Policies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Aetna</td>
</tr>
<tr>
<td>AlloMap</td>
<td>Yes</td>
<td>✓</td>
</tr>
<tr>
<td>Oncotype DX (breast cancer)</td>
<td>No</td>
<td>✓</td>
</tr>
<tr>
<td>MammaPrint</td>
<td>Yes</td>
<td>✓</td>
</tr>
<tr>
<td>Pathworks CUP</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>BRACAnalysis</td>
<td>No</td>
<td>✓</td>
</tr>
<tr>
<td>OVA1</td>
<td>Yes</td>
<td>✓</td>
</tr>
<tr>
<td>KRAS (colorectal cancer)</td>
<td>No</td>
<td>✓</td>
</tr>
</tbody>
</table>

✓ Denotes Positive Coverage Policy

Source: Health Advances analysis
New Medicare Molecular Diagnostics Program ("MolDx" Program)

Palmetto GBA, the Medicare Contractor for J1 implemented new requirements for certain test submitted by labs in the J1 area as of June, 2012.

The purpose is to give transparency to the tests being performed and evaluation of coverage by Palmetto

• Test impacted:
  • Genomic & proteomic assays
    • Gene tests
    • Pharmacogenomic assays
    • Tumor markers
  • Multi-variant tests
    • Predictive
    • Prognostics
“MoIDx” Process for New Tests

Technical Assessment
• Register for Z code in the McKesson Exchange System or PTI
• Clinical evidence Review
  • Clinical validity, analytical validity, clinical Utility
• SME evaluation
• GRADE Scoring System Applied
• Published: ?

Coverage Process
• Published LCD or Article
• Debate regarding non coverage publication and public comment on Tech Assessments
• Determination not posted on website
• Reapply after 180 days with new evidence
• Coverage limited to specific disease organ, etc.

Reimbursement
• Crosswalk/Gap-fill determination
• Value-based determination
• Market-based determination
• Private & gov’t rates
• Discounted rates
• Health Economic studies
• Resources
“MoIDx” Process

Expanding

• Palmetto has indicated at the direction of CMS that they will be expanding the MoIDx program nationally. No details have been announced, but range of involvement could include:

  • Palmetto identification and evaluation of new tests with recommendations for coverage, but left to the discretion of the MAC

  • Palmetto identification and evaluation of new tests with coverage decisions that will be applied to all MACs

  • The above plus Palmetto processing of MoIDx claims
Technology Assessment Criteria

- The technology must have final approval from appropriate regulatory bodies
- The scientific evidence must allow conclusions concerning the effect of the technology on health outcomes
- The technology must improve the net health outcome
- The technology must be as beneficial as any established alternatives
- The improvement must be attainable outside the investigational setting

Source: Blue Cross Blue Shield Association Technology Evaluation Center Criteria

Traditional tech assessment criteria don’t fit the paradigm of innovative diagnostics very well
APPENDIX: Guidelines for Evaluating Diagnostic Tests

– ...direct proof of effectiveness of diagnostic tests is usually unavailable. Typical studies that evaluate the effectiveness of tests focus either on technical characteristics...or effects on accuracy... The MCAC can sometimes, but not always, draw conclusions about the effectiveness of a test from such information.

– The recommended approach for evaluating diagnostic tests is, therefore, as follows:
  • Review, when available, high quality studies that provide direct evidence that test results improve health outcomes.
  • If there is no high quality direct evidence, determine the extent to which there are changes in patient management, particularly when the management strategy is effective in patients with the disease and does not benefit or even harms those without the disease.
Addressing Clinical Utility Can Expedite Adoption

- Analytical and clinical validity are established during the approval process for a device or diagnostic.
- Evidence of clinical utility often is not currently required for regulatory approval.
- Post approval, clinical utility questions can hinder market adoption:
  - Clinicians unsure of how to integrate the new technology into practice,
  - Payers unsure about the impact of the technology on patient care (process) and on health (outcomes).
<table>
<thead>
<tr>
<th>Application of test</th>
<th>Clinical validity</th>
<th>Clinical utility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis (symptomatic patient)</td>
<td>Association of marker with disorder</td>
<td>Improved clinical outcomes—a health outcomes based on diagnosis and subsequent intervention or treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Availability of information useful for personal or clinical decision-making</td>
</tr>
<tr>
<td></td>
<td></td>
<td>End of diagnostic odyssey</td>
</tr>
<tr>
<td>Disease screening (asymptomatic patient)</td>
<td>Association of marker with disorder</td>
<td>Improved health outcome based on early intervention for screen positive individuals to identify a disorder for which there is intervention or treatment, or provision of information useful for personal or clinical decision making</td>
</tr>
<tr>
<td>Risk assessment/susceptibility</td>
<td>Association of marker with future disorder (consider possible effect of penetrance)</td>
<td>Improved health outcomes based on prevention or early detection strategies</td>
</tr>
<tr>
<td>Prognosis of diagnosed disease</td>
<td>Association of marker with natural history benchmarks of the disorder</td>
<td>Improved health outcomes, or outcomes of value to patients, based on changes in patient management</td>
</tr>
<tr>
<td>Predicting treatment response or adverse events (pharmacogenomics)</td>
<td>Association of marker with a phenotype/metabolic state that relates to drug efficacy or adverse drug reactions</td>
<td>Improved health outcomes or adherence based on drug selection or dosage</td>
</tr>
</tbody>
</table>

*Clinical outcomes are the net health benefit (benefits and harms) for the patients and/or population in which the test is used.*
Have Evidence Requirements for Personalized Diagnostics Gotten Any Clearer?

Donning his new canine decoder, Professor Schwartzman becomes the first human being on Earth to hear what barking dogs are actually saying.
Reimbursement Challenges for Advanced Personalized Diagnostics

Traditional reimbursement methods only consider the cost to perform the test, while Advanced Personalized Diagnostics provide significantly more value and are held to much higher clinical and analytic standards than traditional pathology testing.

Value Provided to Patients can be Quantitatively Measured

i. Accurate and timely diagnoses improve patient health outcomes (e.g. fewer hospital bed days, longer survival, etc.)

ii. Surgery avoidance (e.g. organ resection and resulting life-long pharmacotherapy)

iii. Appropriate therapy selection (e.g. pharmacogenomics to optimize therapy selection and treatment response monitoring)

iv. Ineffective therapy avoidance (e.g. toxic and costly side effects of chemotherapy)

Costs to Develop and Validate Far Exceed Traditional Pathology Tests

i. Establish the analytic validity of all test components

ii. Demonstrate high clinical validity of the test through prospective randomized clinical trials

iii. Demonstrate in clinical studies that physicians recognize the utility of the test and act on its results in real-world medical practice
R&D expenditures prior to product launch have risen dramatically in response to market demands for robust clinical, analytic and utility data.

R&D Expenditures of Recently Launched Novel Diagnostics

Average: $9MM

Average: $30MM

1. Gustavsen G. The Reimbursement Landscape for Novel Diagnostics 2010
Coverage Inconsistencies: Oncotype DX

Another way to illustrate coverage inconsistency is over time, examining the gap between early and late coverage policies.

Oncotype DX Coverage Timeline
Positive coverage as percent of total US covered lives over time

Source: Health Advances interviews and analysis, Genomic Health quarterly reports and earnings call transcripts.
Coverage with evidence development (CED)

- CED provides temporary coverage for a technology on the condition that additional clinical evidence continues to be collected
  - Additional long-term evidence is collected through the patients’ participation in an organized, registry-type program
  - The goal is to develop evidence that will support more informed long-term decision-making
- Both Medicare and private payers have used CED to provide access to potentially beneficial, yet unproven, medical technologies
  - Medicare first applied the CED concept in 1995 with lung volume reduction surgery (LVRS)
  - A few private payers have established similar programs (e.g., Aetna, HealthNet, regional Blues)

CED may provide an opportunity to obtain reimbursement while collecting additional evidence for a favorable long-term coverage decision
CED allows Medicare to develop evidence about how a medical technology is used in clinical practice so that Medicare can do the following:

a) Clarify the impact of these items and services on the health of Medicare beneficiaries;

b) Consider future changes in coverage for the technology; and

c) Generate clinical information that will improve the evidence base upon which providers base their recommendations to Medicare beneficiaries regarding the technology.

As a condition of payment, healthcare providers must submit additional patient data to supplement standard claims data.
"Well, heaven knows what it is or where it came from — just get rid of it. But save that cheese first."
Reimbursement Reform Proposal

• One concept proposes that CMS establish market-based reimbursement for advanced molecular diagnostics while maintaining the Clinical Laboratory Fee Schedule (CLFS) pricing for traditional pathology tests

• Market-based reimbursement would implement the concept of “Average Test Price” (ATP), similar to “Average Sales Price” (ASP) for pharmaceuticals
  • ATP = Average payment accepted by the lab from private payers
  • Like ASP, the innovator lab would report data to CMS periodically
  • CMS would publish the ATP and its corresponding ATP-related rate
  • Private payers would likely adopt ATP as the basis for negotiating reimbursement as they have with ASP for pharmaceuticals

• Market-based reimbursement unlocks CMS from fixed CLFS pricing and allows the government to enjoy free-market pricing effects

• This proposal leverages a well-established methodology used by CMS today, recognizes the value delivered by advanced diagnostic tests and allows CMS to maintain a degree of pricing flexibility should market conditions dramatically change for advanced molecular diagnostics
Payer Attempts to Narrowing Laboratory Providers & Networks

• Numerous large payers have recently implemented policies aimed at reducing the use of out-of-network lab services
  • Patient-focused strategies
    • Increased patient out-of-pocket for out-of-network lab services
      – Separate and larger out-of-network deductible
      – Larger co-pay / co-insurance
    • Non-coverage of out-of-network services
  • Educational campaign aimed at getting patients to request to their doctor the use of an in-network lab
  • Referring physician-focused strategies
    • Payer educational campaigns to network MD’s
    • Adherence / lack-of-adherence reports
    • Financial penalties
      – United Healthcare
Payer Attempts to Narrowing Laboratory Providers & Networks

If you need lab work done, stick with one of Cigna’s network labs. Not only will you get quality care, but you’ll also save more money. That’s because you will usually be charged a much lower rate when you use an in-network lab, rather than a lab that’s not part of the Cigna network.

**The importance of lab tests**
Your doctor may order tests to help find out more about your health – like to see if you have diabetes, or to find out if your thyroid medicine is working. For these tests and others, your doctor will need a sample of your blood, urine or tissue, which is then sent to a lab for analysis.

**Save money on lab tests**
Save money by having those lab tests done at a Cigna network lab. Here’s how to make it happen:

- Find network labs by going to myCigna.com or calling the number on your Cigna ID card.
- Tell your doctor you want to use a Cigna network lab.
- If your doctor takes a sample in the office, ask for it to be sent to a Cigna network lab.
- Make sure the lab is an in-network lab. Just because a lab accepts your Cigna ID card doesn’t necessarily mean it’s part of the Cigna network.

**Going out of network could cost you**
If you use a lab that’s not in the Cigna network, you’ll be responsible for paying the out-of-network rate. You may even have to pay the full cost of the service with no discount at all. This could end up costing you a lot more than what you’d pay at an in-network lab.

**Save even more**
If you go to a national lab such as Quest Diagnostics® or Laboratory Corporation of America® (LabCorp), you can get even bigger savings. Even though other labs may be part of the Cigna network, you can save up to 75% when you choose a national lab. And with hundreds of locations nationwide, it’s easy to get quality services at a lower cost.

Find an in-network lab near you on myCigna.com.
Payer Attempts to Narrowing Laboratory Providers & Networks

- Strategies used by specialty laboratories
  - Contract with payers
    - Clinician advocacy
    - Specialty society endorsement
    - Critical mass of claims
  - Contract with general reference labs
  - Support programs as an out-of-network provider for patients with large out-of-pocket requirements
“Say... What's a mountain goat doing way up here in a cloud bank?”
Thank you!