ACOs and Integrated Delivery Networks Change the Value Proposition for Molecular and Genetic Tests

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President & CEO
Objectives

Understand the current coverage, coding and payment landscape for these lab services

Learn how ACOs, IDNs, and new collaborations in health care delivery align clinical, quality and economic outcomes

Identify opportunities to demonstrate value and play a larger role in health care delivery in the future
Reimbursement Landscape for Molecular Diagnostics (MoIDx)
The Reimbursement Framework

What is the clinical value of the technology to payers and purchasers?

- Coverage
- Payment
- Coding

What is the specific payment amount that providers will receive?

How will providers identify the service on claim forms?
Molecular Pathology (MoPath) Codes were Established and Gapfilled for Medicare Payment

2012
- The AMA created analyte-specific MoPath CPT codes to replace the methodology-based “stacking” codes
- The MoPath codes were implemented effective Jan 1, 2013

2013
- The MoPath codes were gapfilled by regional Medicare Administrative Contractors (MACs) for Medicare payment under the Clinical Laboratory Fee Schedule (CLFS)

2014
- CMS has calculated a National Limitation Amount (NLA), a.k.a. national fee schedule, for each code based on the median of local MAC fee schedule amounts
- The final 2014 CLFS does not include several Tier 1 codes and all of the Tier 2 codes
## Sample of 2014 National Payment Rates

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Descriptor</th>
<th>2014 NLA</th>
<th>LabCorp 2012 Code Stack Payment</th>
<th>Quest 2012 Code Stack Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>81235</td>
<td>EGFR (epidermal growth factor receptor) (e.g. non-small cell lung cancer) gene analysis, common variants (e.g. exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)</td>
<td>$330.01</td>
<td>$533.48</td>
<td>$301.92</td>
</tr>
<tr>
<td>81292</td>
<td>MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g. hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis</td>
<td>$646.24</td>
<td>$2,147.96</td>
<td>$930.52</td>
</tr>
<tr>
<td>81243</td>
<td>FMR1 (Fragile X mental retardation 1) (e.g. fragile X mental retardation) gene analysis; evaluation to detect abnormal (e.g. expanded) alleles</td>
<td>-</td>
<td>$637.49</td>
<td>$348.50</td>
</tr>
</tbody>
</table>
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
Definitions of Clinical Utility for Diagnostics

**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.
Sample Payer Criteria for Coverage of Diagnostic Tests

1. Technical feasibility is demonstrated, including reproducibility and precision. For comparison among studies, a common standardized protocol for the new diagnostic technology is established.

2. For accurate interpretation of study results, sensitivities, specificities, and positive and negative predictive values compared to standards are established.

3. The clinical utility of a diagnostic technique, i.e., how the results of the study can be used to benefit patient management, is established. The clinical utility of both positive and negative tests must be established.

Regence Blue Cross Blue Shield (UT, ID, OR, WA)

Source: http://blue.regence.com/trgmedpol/intro/
Case Study: OncoType Dx’s Long-Term Coverage Strategy

- For OncoType Dx, Genomic Health billed with an unlisted code at launch (2004), slow sales uptake for 2+ years

Genomic Health launched three-prong battle for expanded coverage:

- Developed a publication plan to fill in the evidence gaps that were hindering payer coverage
- Promoted grassroots support for OncoType Dx among the oncology community
- Appealed denied claims to fight negative coverage policies by Medicare and commercial payers on the basis of medical necessity

Source:
Future Considerations for Molecular Diagnostics Reimbursement
AMA/McKesson Partnership to Crosswalk CPT Codes to Z-code™ Identifiers

- As a way to provide more clarity around the existing CPT codes, the AMA and McKesson have partnered to develop a reference product, CPT CodeBridge™, that maps McKesson Z-Code™ Identifiers to AMA CPT codes in the hopes to:
  - Provide the healthcare industry with a standardized way to track and identify molecular diagnostic tests
  - Allow greater specificity to the use, identification, reporting and tracking of diagnostic tests
  - Connect clinical and financial data across claims systems, electronic health records (EHRs) and other systems
  - Enable informed molecular diagnostic test selection, coverage and payment decisions

- This product will be available to providers and payers through licensing agreements with the AMA beginning in early 2014
How the AMA/McKesson Reference Product Will Work

1. Test information is submitted to the McKesson Diagnostics Exchange and assigned a Z-Code Identifier.

2. The submitter can “opt-in” to share data with the AMA and participate in the mapped CPT Code process.

3. Once the “opt-in” option is selected, the AMA is sent test information and related data.

4. The AMA staff reviews data and makes mapping recommendations, which are reviewed by an advisory board consisting of MoPath subject matter experts.

5. The AMA will update the map three times a year to keep pace with the continuous addition of new diagnostic tests.
Implications of the AMA/McKesson Partnership

- Increased billing transparency
  - Provides further granularity to the existing MoPath codes

- Potentially increased coverage scrutiny
  - Payers will be able to link patient outcomes with the specific test being performed
  - With the ability to link outcomes to unique tests, payers may develop test-specific coverage guidelines

- Potential payment variations
  - Potential for differential payments for tests that may be billed with the same CPT code (e.g., FDA approved IVD kits vs. non-FDA approved LDTs)
March 2013:
The Association for Molecular Pathology (AMP) submitted an NGS coding proposal to the AMA

February 2014:
The NGS codes were accepted by the AMA CPT Editorial Panel for addition in 2015

April 23, 2013:
The AMA held a meeting with stakeholders to discuss an NGS coding framework based on AMP’s proposal

January 2015:
The date for implementation of the new NGS code set
Key Elements of NGS Code Set

- Codes categorized as:
  - Targeted multiple gene sequencing
  - Whole mitochondrial sequencing
  - Whole exome/genome sequencing

- Targeted multi-gene panels address a clinical question or condition and are separated into code pairs:
  - One for genomic sequence analysis
  - One for duplication deletion gene analysis

Example:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSAX1</td>
<td>X-linked intellectual disability (XLID) (eg. syndromic and non-syndromic XLID); genomic sequence analysis panel, must include sequencing of at least 60 genes, including ARX, ATRX, CDKL5, FMR1, HUWE1, IL1RAPL, KDM5C, MECP2, MED12, MID1, RPS6KA3, OCRL, FGD1, L1CAM, and SLC16A2</td>
</tr>
<tr>
<td>GSAX2</td>
<td>duplication/deletion gene analysis, must include analysis of at least 60 genes, including ARX, ATRX, CDKL5, FMR1, HUWE1, IL1RAPL, KDM5C, MECP2, MED12, MID1, RPS6KA3, OCRL, FGD1, L1CAM, and SLC16A2</td>
</tr>
</tbody>
</table>

Section 216 of this law, “Improving Medicare Policies for Clinical Diagnostic Laboratory Tests”, heralds significant changes to how clinical laboratory tests will be paid.

**How it will affect payment:**

- Beginning January 1, 2016, all relevant diagnostic laboratories will be required to submit information on both the volume and payment for all diagnostic tests by each unique private payer.
  - CMS will use this information to calculate weighted median payment rates for these laboratory tests under the CLFS.

- Initial payment rates for new “advanced laboratory diagnostic tests,” which include any single-source, lab-developed tests that encompass tests that involve analysis of multiple biomarkers combined with a unique algorithmic analysis (a.k.a. MAAAs), will be benchmarked based on the test’s list price.

Source: [http://beta.congress.gov/113/bills/hr4302/BILLS-113hr4302enr.pdf](http://beta.congress.gov/113/bills/hr4302/BILLS-113hr4302enr.pdf)
How it will affect coverage:

- The law gives the HHS Secretary authority over designating up to four Medicare Administrative Contractors (MACs) to establish coverage policies and/or process claims for payment for laboratory tests for the entire Medicare program.

- This may align with a national expansion of Palmetto GBA’s MolDx program.

- Ultimately, clinical laboratory tests nationwide may come under the jurisdiction of only a handful of MACs or less.
Implications of the Affordable Care Act for Diagnostics Reimbursement
# Accountable Care Organizations

<table>
<thead>
<tr>
<th>Payment Structure</th>
<th>Accountable Care Organizations (ACOs)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Who</strong></td>
<td>Medicare/Private payers: ACOs are groups of doctors, hospitals, and other health care providers, who give coordinated high quality care to their patients. Medicare and private payers have various versions of ACO models and programs, all with similar goals of reducing cost while maintaining quality of care.</td>
</tr>
<tr>
<td><strong>What</strong></td>
<td>ACOs make providers jointly accountable for the health of their patients, giving <strong>them financial incentives to cooperate and save money</strong> by avoiding unnecessary tests and procedures. Those that save money while also meeting quality targets would keep a portion of the savings. Providers can choose to be at <strong>risk of losing money</strong> if they want to aim for a bigger reward, or they can enter the program with no risk at all.</td>
</tr>
<tr>
<td><strong>When</strong></td>
<td>ACO models under Medicare started January 2012</td>
</tr>
<tr>
<td><strong>Where</strong></td>
<td>Nationwide</td>
</tr>
<tr>
<td><strong>Why</strong></td>
<td>The goal of coordinated care is to ensure that patients, especially the chronically ill, get the right care at the right time, while <strong>avoiding unnecessary duplication of services</strong> and <strong>preventing medical errors</strong></td>
</tr>
</tbody>
</table>

Accountable Care Organizations (cont.)

- Promotes value of services over volume.
- Allows for providers, hospitals, and practice groups to coordinate together in facilitating high quality and efficient care.
- The following diagram shows the various relationships involved with an ACO.

Source: http://www.switchpointllc.com/images/casestudies/CS1_chart1.gif
Accountable Care Organizations (cont.)

- Allows for providers, hospitals, and practice groups to coordinate together in facilitating high quality and efficient care.

- Some Medicare models have risk sharing involved, while most models have profit sharing through incentives.

- Medicare released the Pioneer, Two-sided, and One-sided Risk Model ACO. The following diagram shows the two-sided risk model:

Source: [http://www.switchpointllc.com/images/casestudies/CS1_chart1.gif](http://www.switchpointllc.com/images/casestudies/CS1_chart1.gif)
Opportunities and Risks

Bundled Payment Models

• The Bundled Payment for Care Initiative (BPCI) program aims to predetermine payments for an entire episode of care, including laboratory testing.

Clinical Utility

• Stakeholders will have to make a strong clinical utility argument to include payments under the BPCI and with healthcare reform.
• As MoPath tests become more popular, payers will focus more attention on clinical utility in evaluating coverage for MoPath tests.
Opportunities and Risks

Evidence-Based Medicine (EBM)

• Legislation related to the Patient Centered Outcomes and Research Institute (PCORI) notes that primary research on molecularly-informed trials will be in the research agenda, and that research will take into account individual and subpopulation differences, including genetic and molecular subtypes.

New Payment and Delivery Models

• As part of the Accountable Care Organization (ACO) model, primary physicians are looking for more ways to care for patients. Molecular diagnostics fit well into this dynamic of enabling improved clinical decision-making by supporting and assisting in coordinated medical care.
Takeaways

✓ Participate in the shift from volume to value
✓ Develop metrics and tools that demonstrate cost shift and/or cost reductions
✓ Partner with primary care and referring physicians to affect system wide change
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