Reimbursement for Advanced Diagnostics: Challenges and Opportunities

Institute of Medicine
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Brian Carey
Topics

1. Reimbursement challenges for Advanced Diagnostics
2. PAMA Clinical Laboratory Fee Schedule (CLFS) reform overview
3. Timeline and key open issues for PAMA implementation
4. Potential Innovative Models
Venture Capital Assessment of Risk

Last Fall at the Harvard Personalized Medicine Conference a prominent VC stated the risks for personalized medicine investing are:

- Clinical (VCs believe they can control this)
- Intellectual Property (increasingly harder to obtain)
- Regulatory (uncertainty and fear)
- Reimbursement (completely unpredictable)
Reimbursement Challenges

- Advanced diagnostics are typically single laboratory performs test, often early stage companies
  - Resource intensive development costs (cost of clinical trials, publications, guidelines)

- Reimbursement hurdles are high
  - Demonstrate analytical validity, clinical validity and clinical utility, physician utilization
  - Lack of granular coding
  - Complex billing rules

- Private payers and Medicare undertake lengthy coverage reviews
  - Pre-emptive non-coverage policies for new tests
PAMA CLFS Reform

- Protecting Access to Medicare Act of 2014 (PAMA) included landmark CLFS payment reform
  - First major reform to the CLFS since 1984

- Establishes new transparent market-based payment methodology
  - Lab reported private payor rates will set benchmark for Medicare prices

- Legislation designed to encourage continued advanced diagnostic innovation
  - Advanced Diagnostic Laboratory Tests (ADLTs)

- Many details left to agency rulemaking
Market-Based CLFS Payment Rates

- Starting on January 1, 2017, most rates on the CLFS will be derived from private payor rates for laboratory services

- CMS will establish a “weighted median” for each test by volume for each lab and payor
  - Reduction for an individual laboratory test that exceeds 10% phased in 2017 - 2022

- Advanced diagnostics paid at Actual List Charge for 3 quarters
  - Subject to recoupment if market price proves substantially lower

- Private payor reporting is every three years
  - Lab must certify accuracy and completeness of data
  - ADLTs will report annually
<table>
<thead>
<tr>
<th>Date</th>
<th>Rule</th>
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<tbody>
<tr>
<td>January 1, 2015</td>
<td>CMS precluded from price adjustments to the CLFS under prior “technology change” statute</td>
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<td>MACs must make lab test coverage policy through LCDs</td>
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<tr>
<td>June 30, 2015</td>
<td>CMS will publish final rule for CLFS market price reporting</td>
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<tr>
<td>July 1, 2015</td>
<td>CMS will establish expert outside advisory panel</td>
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<tr>
<td>January 1, 2016</td>
<td>Laboratories must begin price reporting at some point in 2016</td>
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<td></td>
<td>CMS must assign HCPCS code to existing ADLTs that were paid in April, 2014 by miscellaneous codes</td>
</tr>
<tr>
<td>January 1, 2017</td>
<td>Market based pricing for all CLFS tests; Actual List Charge pricing for new ADLT tests</td>
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Open PAMA Implementation Issues

1. Data Elements
   - How will CMS define data elements for price reporting?

2. Reporting Requirements
   - Which labs have to report data?

3. ADLT Classification
   - What process will designate tests that are eligible for ADLT classification?

4. Coding
   - Who will assign new HCPCS codes and unique identifiers for new ADLT and new FDA cleared or approved tests?

5. Coverage LCD Rules
   - MAC consolidation
Price Reporting: Who will report and When

Data for CY2017 Payment rates

Who will report?
Labs with over half of Medicare revenue from Part B Physician and Part B CLFS fee schedule
- Hospital outreach testing?
- Exemptions for physician and small labs?

When will reporting period be?
Rates must be effective by 1/1/2017, so reporting period will probably close by early 2016
What period will be reported?
(E.g. 6 months of data)

Rules for the reported price
Market price includes both insurance payment and copay
Issues related to timing of payment, in-network and out-of-network labs
PAMA creates a new test category called Advanced Diagnostic Laboratory Test (ADLT)

Payment methodology

- Under PAMA new ADLTs in 2017 will be paid for three quarters at “Actual List Charge”
- Recoupment if list charge exceeds 130% of market rate
- Annual reporting obligation

Granular Coding

- Existing ADLTs are entitled to unique codes as of January 1, 2016
- New ADLTs will be assigned “temporary HCPCS codes”
Advanced diagnostic laboratory test is defined as:
- a clinical diagnostic laboratory test that is
- offered and furnished by a single laboratory and
- not sold for use by a laboratory other than the original developing laboratory (or a successor owner).

In addition, the test must also meet at least one of the following three criteria:
- analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result; or
- FDA cleared or approved; or
- other similar criteria established by CMS

Who will determine whether a test is an ADLT?
PAMA requires CMS to assign “**temporary HCPCS**” codes to identify new ADLTs and/or any FDA approved or cleared tests on a rolling basis

- Statute allows CMS codes to assign “**permanent**” codes

**AMA CPT** proposed a new category of “PAMA codes” consistent with Statutory requirements

- Codes would be assigned quarterly basis
- No utilization or literature requirements

**McKesson** has developed Z-Code Identifiers

- Used by MolDX program
- Limited adoption by private payers
Granular Coding Is Critical

- Unique and timely coding of ADLTs is essential to lab’s ability to collect private payer data
- The lack of unique codes will hinder CMS ability to collect meaningful data and its ability to determine accurate market rates for ADLTs
- Codes must be assigned in a timely fashion so that data collection and submission is not impeded
- **All payers, including private payors must be able to accept, process and make payment for codes**
Local Coverage Determination Reform

- PAMA includes new requirements for the LCD process for clinical lab tests
- CMS has proposed:
  - All new lab test coverage policies must be done through LCD
  - Draft LCD can be released at any time (not on a CAC schedule)
    - CAC meeting is optional
  - Public comment period shortened to 30 days
  - Final LCD becomes effective on the issue date
- Statute effective January 1, 2015
  - CMS has not finalized rulemaking
Medicare Contractor Consolidation

- PAMA allows CMS to consolidate lab tests into one-to-four regional special Medicare Administrative Contractors
  - Analogous to the four DME MACs
- Will the Palmetto MolDX program serve as a model for MAC consolidation?
  - Currently operates in 23 states
Potential Innovative Models

- Premium payment for FDA approved Companion Diagnostics
  - BRAF, KRAS, EGFR

- Coverage with Data Collection
  - MolDX Coverage of ConfirmMDx for Prostate Cancer
  - MolDX coverage of Comprehensive Genomic Profiling tests

- FDA/CMS Parallel Review
  - Exact Sciences Cologuard

- Risk Sharing Arrangements
  - Treatment of discounts under PAMA
Contact information

Brian Carey, Partner
Foley Hoag LLP
1717K Street, NW
Washington, DC 20036
bcarey@foleyhoag.com
202.261.7398