Update on Reimbursement for Molecular Tests

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Premier Source Snapshot

Business focus	Strategic consulting, comprehensive reimbursement, billing, patient / physician access and commercial support services
Target markets	Labs utilizing lab developed test (LDT) model with an emphasis on molecular diagnostics
Employees	120 employees
Founded	January, 2004
Headquarters	San Mateo, CA and Charlotte, NC

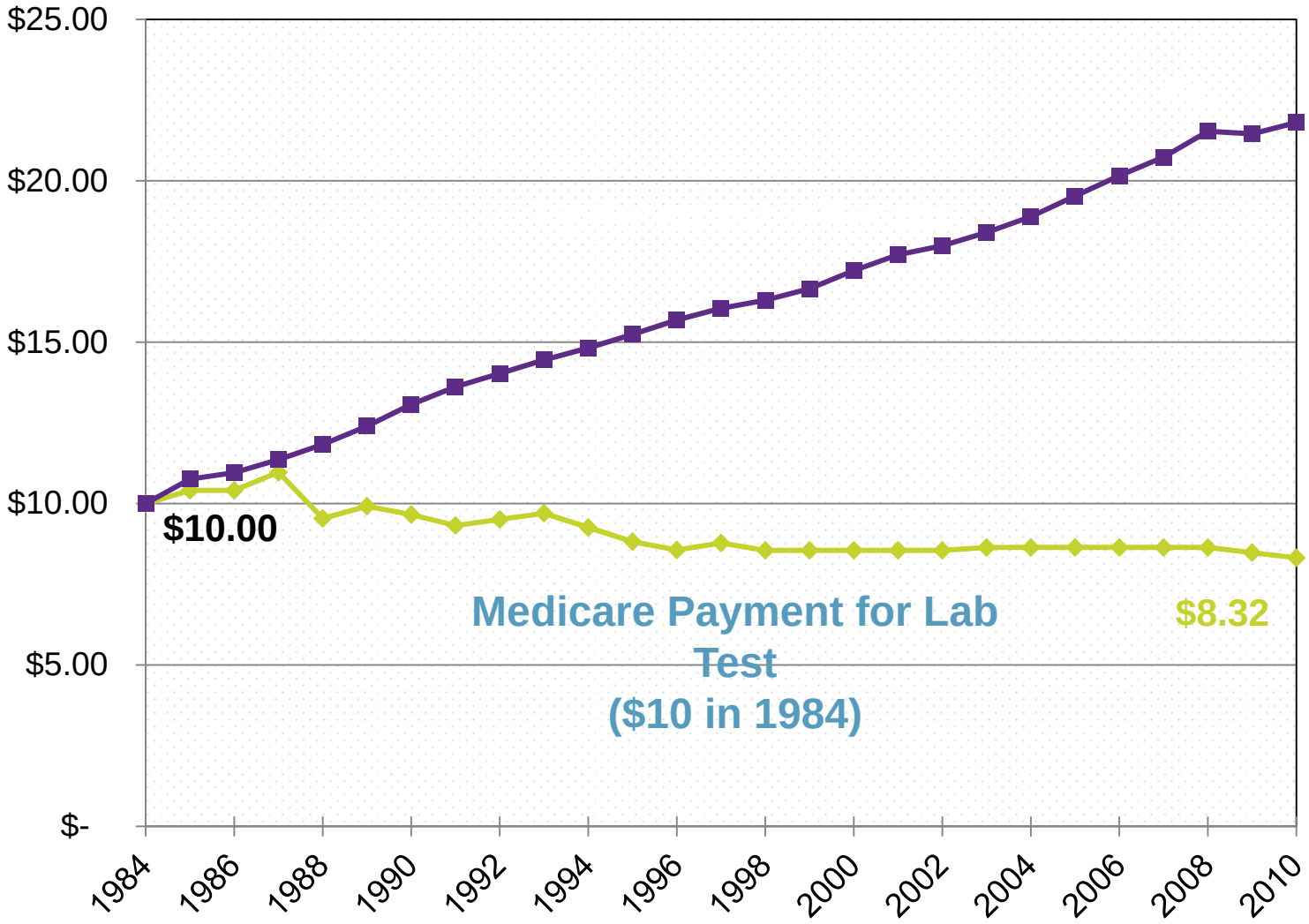
Premier Source Has Experience Across Several Technologies & Therapeutic Areas

	Technology Category		
	Diagnostics	**Biotech/Pharma**	**Medical Devices**
Oncology	✓	✓	
Cardiovascular	✓	✓	✓
Endocrine/ Metabolic	✓	✓	
Rare Diseases/ Orphan Drugs		✓	
Neurology/ Psychiatry	✓	✓	✓
Orthopedics			✓
Women's Health	✓		✓
Rheumatology	✓		

Changes impacting Molecular Tests

- Understand key changes in the market for Molecular tests
  - Clinical Laboratory Fee Schedule (CLFS)
  - Physician Fee Schedule (PFS)
  - Coding
  - MolDx Program
  - Payment Rates
  - Blue Card Network
- FDA Oversight

CLFS Created in 1984 with Annual Update for Inflation… But Payments Have Increased Only 7 Times in Past 30 Years



1984 **2010**

CMS Proposes Deep Cuts for 39 Pathology Codes (PFS)

- Capping PFS Pathology Codes Technical Component to Hospital Outpatient PPS (HOPPS)
  - Major Codes Include Flow, IHC, FISH
  - Overall 26% Cut, Some Codes Cut 75%
  - Many Codes, Reimbursement Below Direct Costs
  - Advocacy Campaign to Stop Proposal is One of Largest Ever for Lab Community
  - Deadline: Final Rule November 2013, Would Take Effect January 2014

Coding

- CPT codes are used by insurance companies to identify the service that you have submitted a claim for.
- CPT codes are determined by the American Medical Association, but are priced by the Center for Medicare and Medicaid Services.
- For 2013, new CPT codes have been introduced to better fit the Molecular Diagnostics tests.
  - Tier 1 codes are for tests that have wide adoption and may be performed by multiple laboratories
    - 92 codes were introduced 1-1-2012, and additional 13 codes added on 1-1-2013
    - CMS did not price Tier 1 codes for 2012, for 2013 all 105 codes priced by the Gapfill method
  - Tier 2 codes are for tests that are performed at lower volumes but are medically useful
    - 10 codes were published 1-1-2012, and a Miscellaneous code 81479 added 1-1-2013
    - These codes are arranged by level of technical resources and physician interpretation needed and the gene or genes tested (a significant number of new genes were added to the 2012 codes for 2013.
    - CMS did not price Tier 2 codes for 2012, the Gapfill method used to price these codes for 2013.
    - The 2013 Tier 2 codes represent 288 tests.
  - MAAA codes are Multianalyte Assays with Algorithimic Analysis
    - Most codes in this category identify the laboratory that performs them
    - There are Adminstrative MAAA codes that identify Multianalyte Assays with Algorithimic Analysis that are not proprietary
    - A Miscellaneous code 81599 added for 2013
    - Must meet the following criteria
      - Well documented in published literature
      - Unique procedure(s)
      - Wide spread use
    - CMS will not price these codes for 2013

Coding continued

The stacked codes (83800 to 83914) that a number of laboratories used to bill their tests have been eliminated for 2013.

If a laboratory's test does not fit into one of the new codes that have been "priced," they will have to use a Miscellaneous code to bill tests.

- Miscellaneous codes have no set value
  - Using a miscellaneous code requires that you explain your test upfront
    - Miscellaneous code tests are best submitted on paper if possible
    - Include Test Requisition Form with a Medical Necessity Statement signed by ordering Physician, Test Results form and a description of the test
  - In most cases, tests coded with a miscellaneous code will need to be appealed
- Tier 2 (81479) and MAAA (81599) both have a new Miscellaneous code
  - Even though miscellaneous codes are not priced, the fact that CMS published that they would not price the MAAA codes for 2013 will limit the commercial adoption of the 81599 code
  - 81479 has received no CMS "approval" so commercial insurances may not adopt it either.
- Laboratories are still opting to use the Unlisted Chemistry procedure code (84999) to bill their tests

Medicare Pilot Program in Molecular Diagnostics

- CMS, in conjunction with Palmetto GBA, created a pilot program for molecular diagnostic tests
- Under the program, known as MolDx, Palmetto assigns a Z-code for each molecular diagnostic test billed to the contractor
  - Labs request a Z-code from McKesson Diagnostics Exchange
  - Palmetto will reject all claims that do not have a Z-code
  - The Z-code must be submitted along with the appropriate CPT codes; it does not replace the CPT codes
- In addition to the new Z-codes, Palmetto created a technology assessment process for tests
  - Labs must submit an executive summary of the evidence supporting the clinical utility of their test
  - New tests entering the market must go through the coverage review process before Palmetto will cover and pay for them

Current Coding Situation for diagnostics:

- Medicare fee schedules (CLFS or PFS) do not:
  - allow for patient value; diagnostics guide treatment decisions that save money
  - recognize R&D costs; which can total in the tens of millions of dollars
- Private payers often follow CMS lead so major administrative agency reform needed
- Palmetto Coding Initiative - ID misc tests
- AMA - CPT Molecular Pathology Workgroup
- McKesson - Z codes Pilot

Overview of Blue Cross Blue Shield

- There are 38 BCBS companies that cover all 50 states. Several companies cover multiple states and several states have multiple BCBS companies.
- All BCBS companies offer
    - Commercial plans
    - Medicare Advantage plans
    - Federal Employee plans
- BCBS companies have two processes that you need to be aware of:
    - As of October 2012, tests for BCBS members must be billed to the BCBS plan for the area where the sample was taken not the plan where your lab is located
    - Most BCBS plans will not pay a non-participating provider, but will pay the patient directly. Some plans will not even provide information regarding a claim to a non-participating provider.
        - The exception to this is payment for Medicare Advantage cases.

FDA and Laboratory Developed Tests (LDTs)

- Innovation in Molecular Testing Has Occurred Under "CLIA's Watch"
  - CLIA & Innovation
  - Perceived Gaps in CLIA
    - "Clinical Validity"
    - Companion Diagnostics
  - FDA Changed Course in 2010 – From "Enforcement Discretion" to Announcing Intention to "Regulate All LDTs"
    - Draft "Guidance" Anticipated for Three Years
    - Is OMB Currently Reviewing?
    - Will FDA Issue Guidance & What Will It Do?

Conclusion

- Molecular diagnostic tests are being hindered by the CLFS and PFS.
- Pricing for the tier 1 and 2 codes are still in progress or have yielded insufficient rates
- MolDx program delayed due to Palmetto losing CA jurisdiction. Palmetto initiating program in SC, NC, and VA jurisdiction
- Blue Card Network puts additional pressure on OON labs.
- Foundation Medicine gets “crazy” valuation

Thank you!

For follow-up, please contact:

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