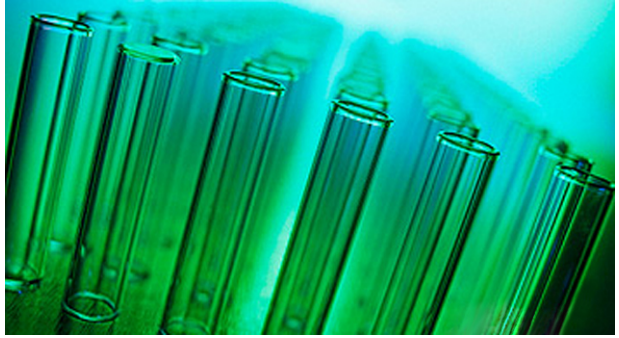

Reimbursement Considerations for Molecular Diagnostic Testing

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Quorum Consulting

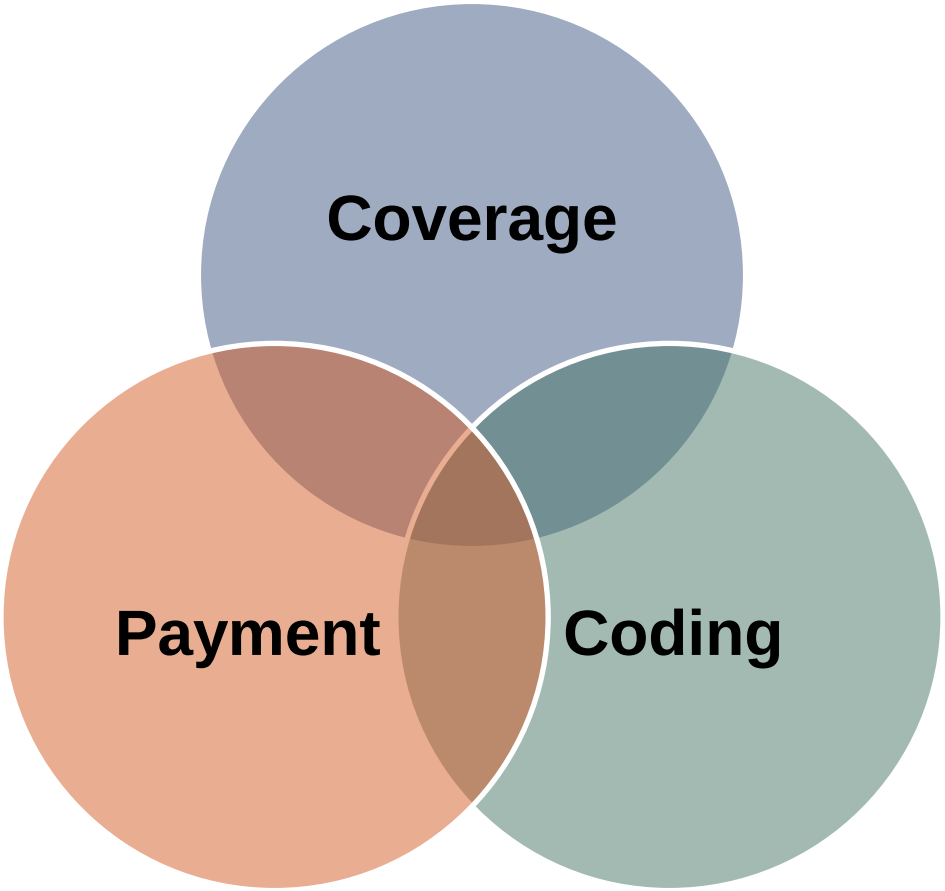
Learning Objectives

After this presentation, you should be able to:

- Describe the current coverage, coding and payment landscape for molecular diagnostics tests
- Explain how recent policy developments will affect future reimbursement for clinical laboratory testing
- Develop a high-level reimbursement plan for your molecular diagnostic test offerings

The Reimbursement Framework

Will payers pay for the service, and under what conditions?

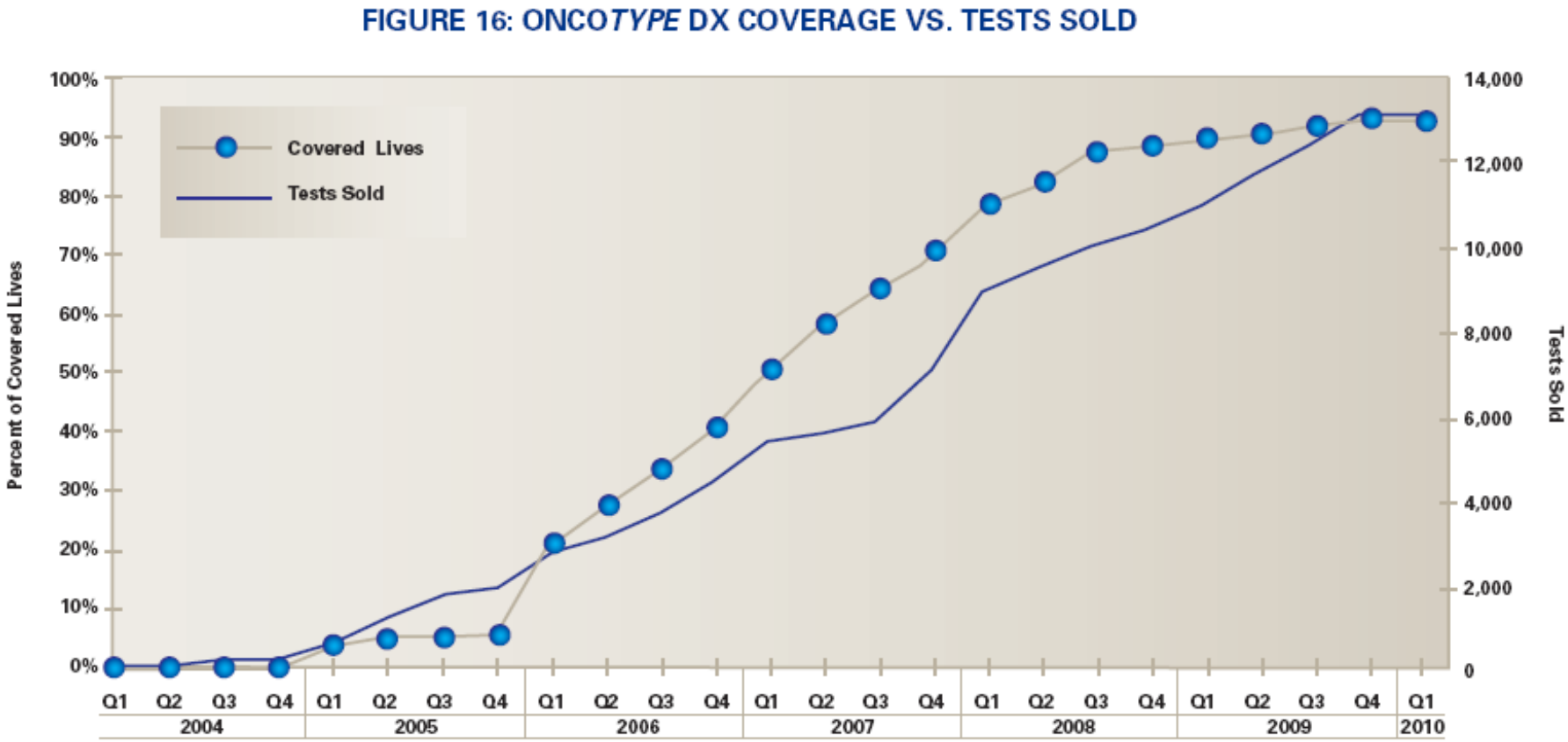


What is the specific payment amount that providers will receive?

How will providers identify the service on claim forms?

Keys to Coverage for Molecular Diagnostics

Payer Coverage Drives Test Volume/Sales



Source: BIO and Health Advances Report: The Reimbursement Landscape for Novel Diagnostics: Current Limitations, Real-World Impact, and Proposed Solutions. 2010.

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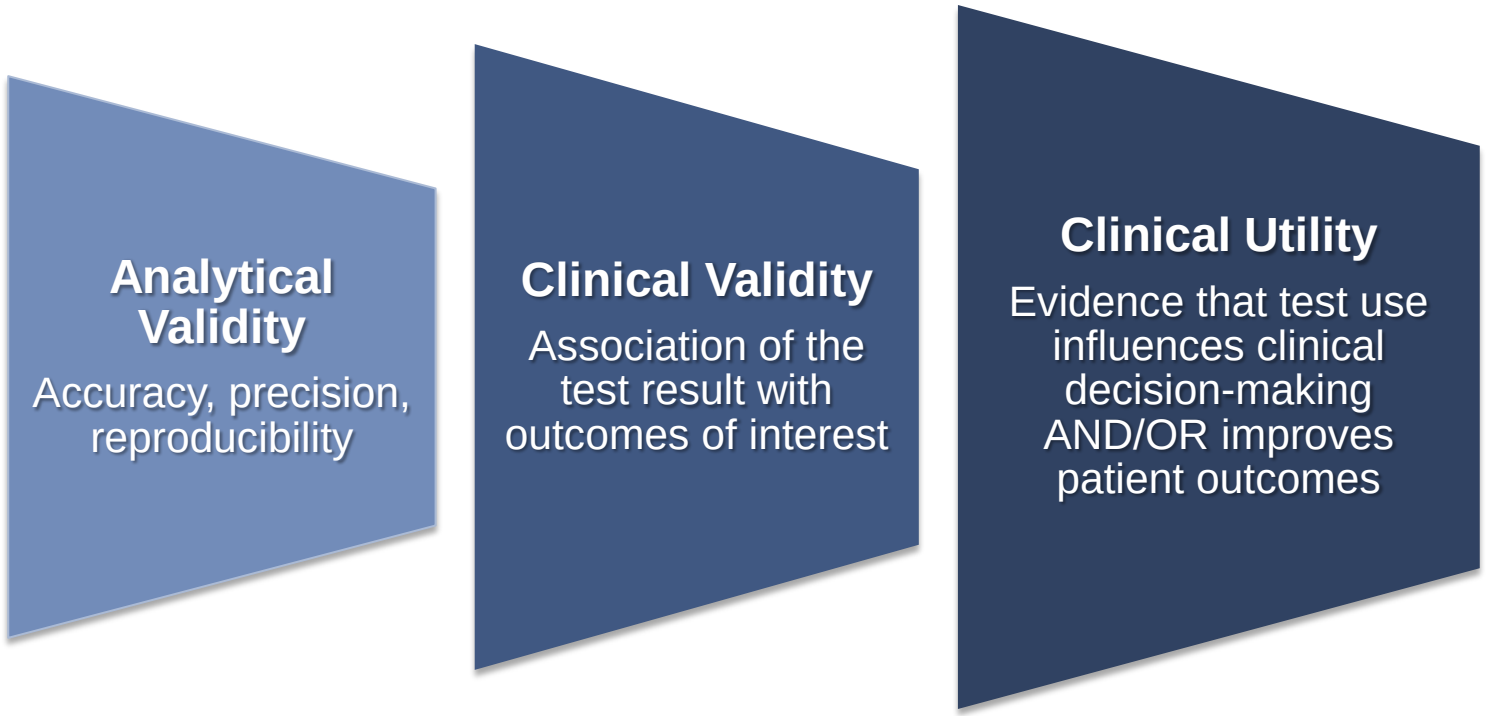
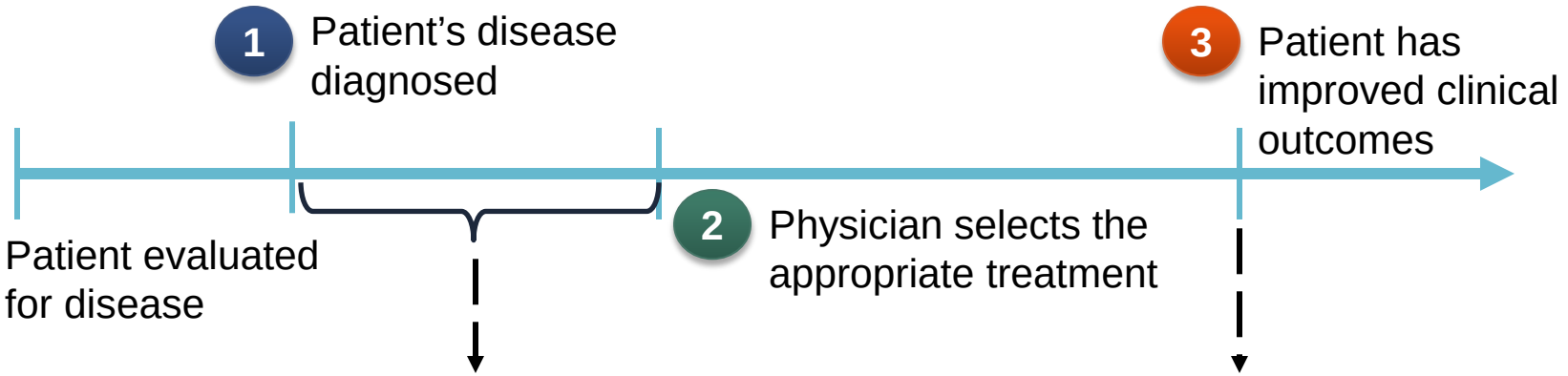
Evidence of Clinical Utility Drives Coverage for Diagnostic Tests

- **Analytical validity**, or how a diagnostic test compares to a gold standard (clinical truth), is typically the only requirement for FDA approval
- **Clinical utility**, or the ability of the test to alter the way patients are managed and/or improve net health outcomes, is **key to securing payer coverage**



Payers Have Varying Definitions of Clinical Utility

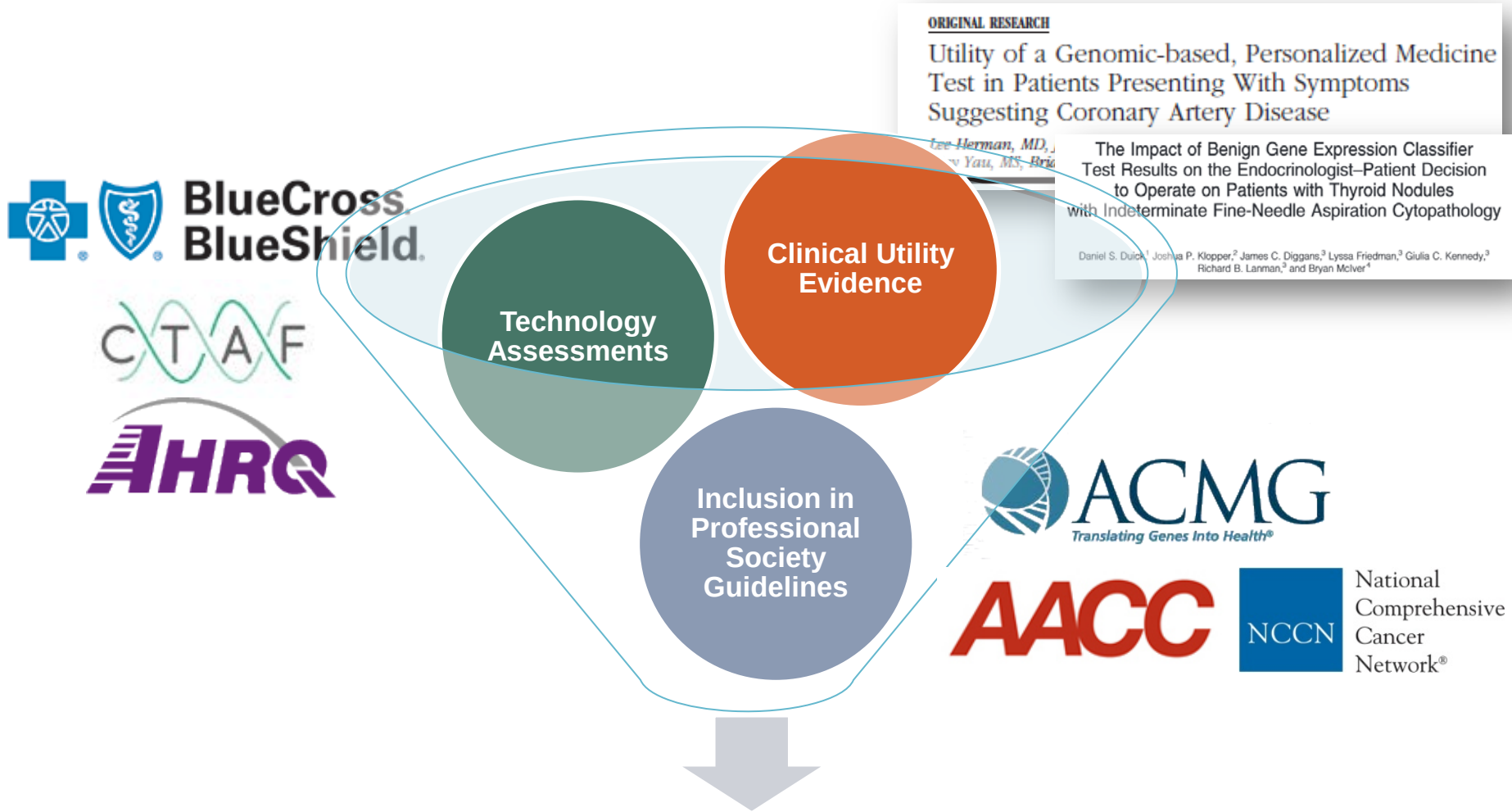


Clinical Utility Definition #1:
Refers to the ability of the diagnostic test results to influence physician decision-making when treating a patient

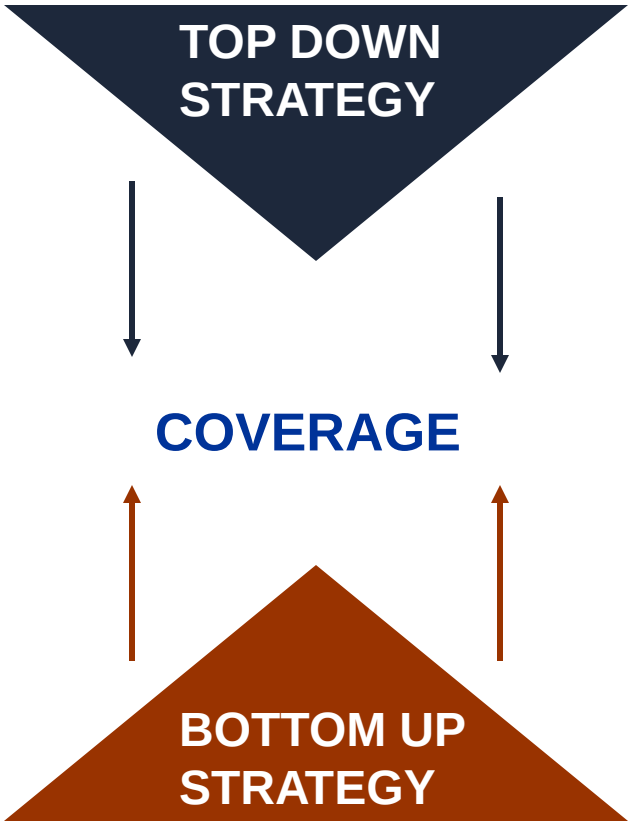
Clinical Utility Definition #2:
Improved health outcomes downstream of treatment selection may also be a requirement to demonstrate clinical utility for some payers

Payers are increasingly requiring evidence of improved health outcomes as a condition for coverage

Keys to Coverage



Top-Down vs. Bottom-Up Strategies to Secure Coverage



- ✓ Developing and publishing strong clinical utility evidence
- ✓ Engaging payer medical directors to advocate for publication of favorable coverage policies

- ✓ Developing a robust appeals program to overturn medical necessity claim denials
- ✓ Leveraging successful appeals to make a case for formal coverage

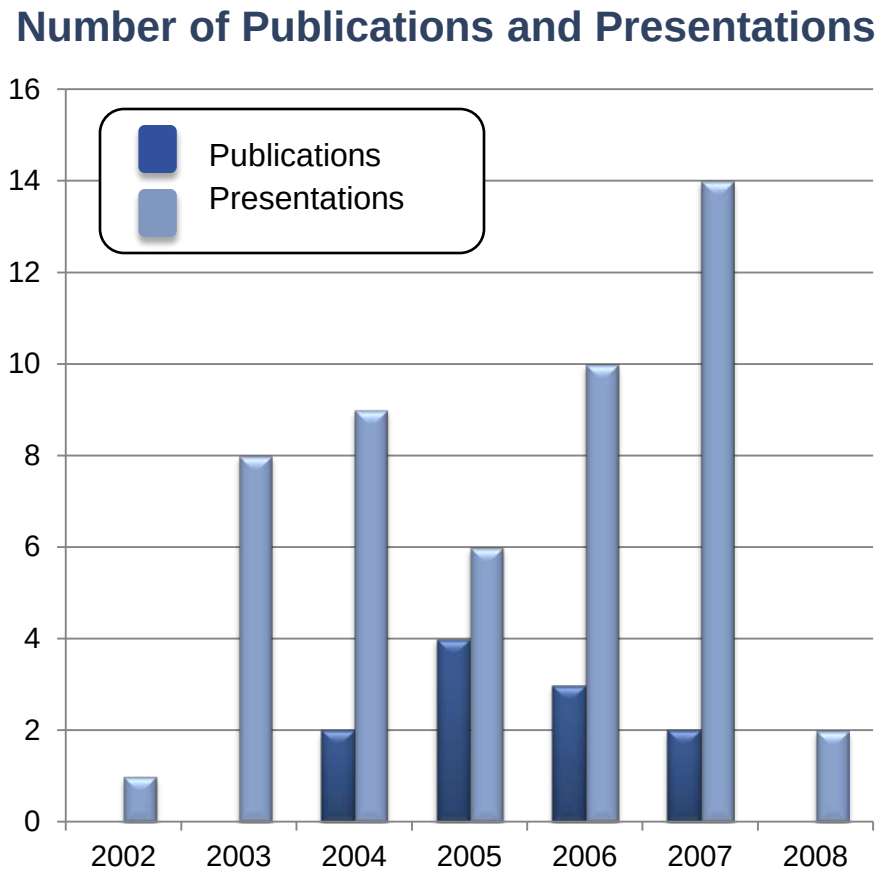
In the absence of strong clinical utility evidence, a robust appeals program can be an effective tool to secure coverage

Case Study: Genomic Health Launched a Three-Prong Plan to Expand Coverage for OncoType Dx

1. Develop a publication plan to address evidence gaps that were hindering payer coverage

2. Promote grassroots support for OncoType Dx among the oncology and patient advocate communities

3. Appeal denied claims on the basis of medical necessity to fight negative payer coverage policies



Source: BIO and Health Advances Report: The Reimbursement Landscape for Novel Diagnostics: Current Limitations, Real-World Impact, and Proposed Solutions. 2010.

Coding for Molecular Diagnostics

New Molecular Pathology (MoPath) Codes Were Introduced in 2013

Before 2013

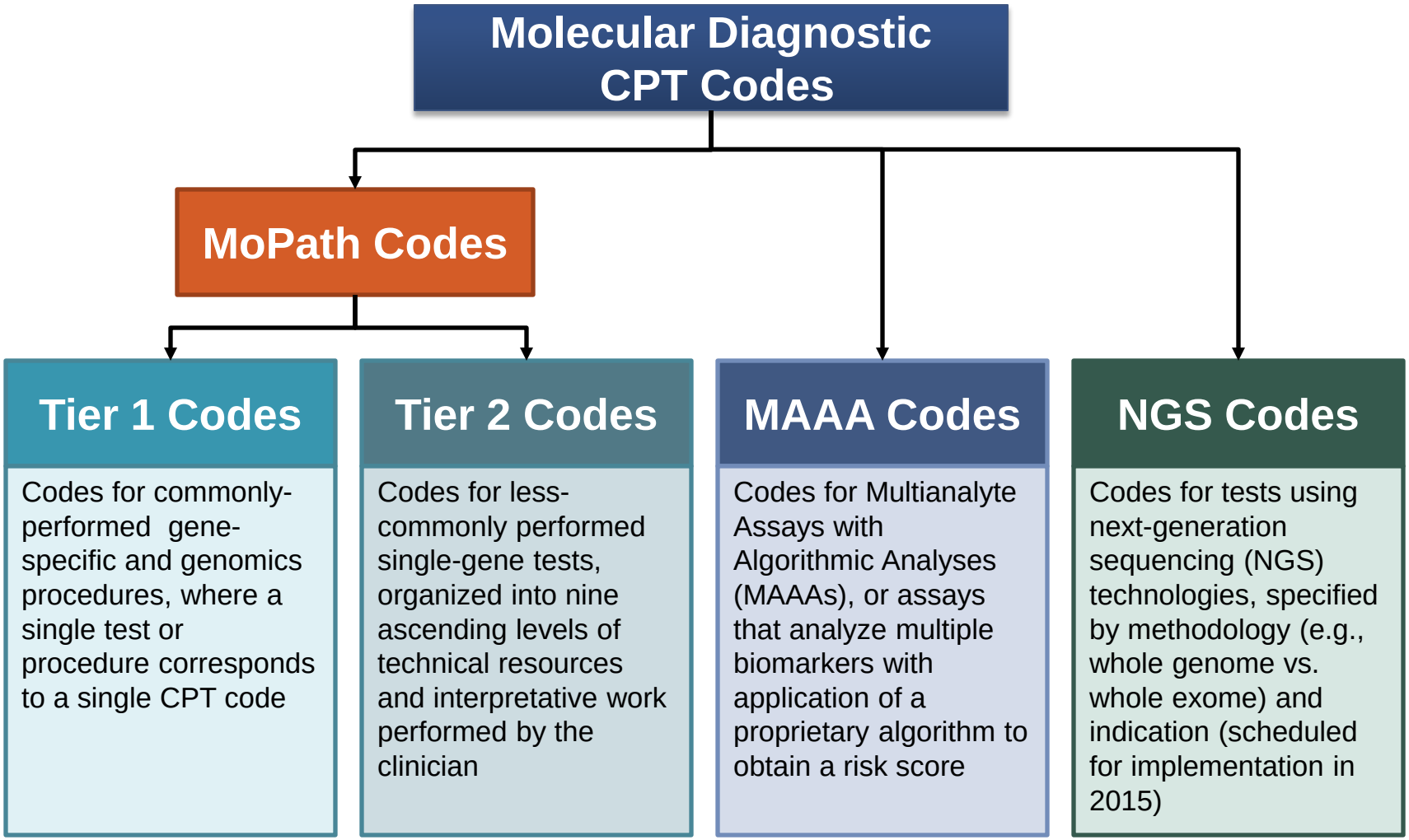
83907	*Lysis of cells prior to nucleic acid extraction, each specimen*
83891	*Isolation or extraction of highly purified nucleic acid, each nucleic acid type*
83892	*Enzymatic digestion, each enzyme treatment*
83912	*Interpretation and report*
83896	*Nucleic acid probe, each*

After 2013

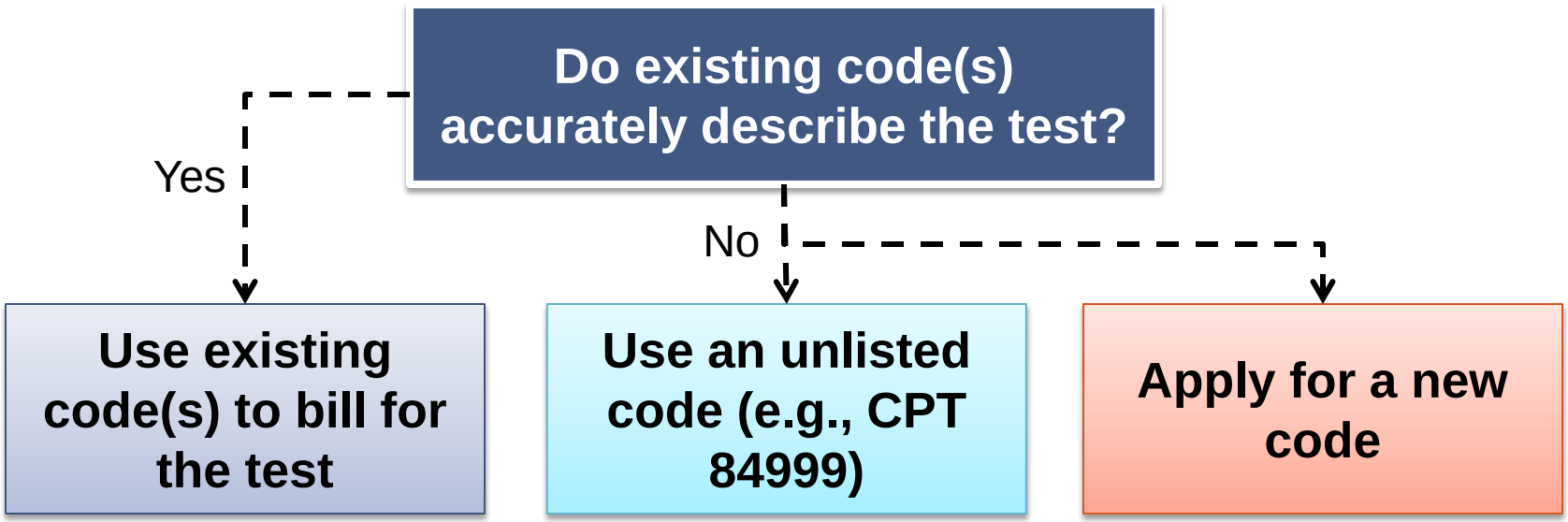
CPT 81210

BRAF (v-raf murine sarcoma viral oncogene homolog B1) (eg, colon cancer), gene analysis, V600E variant

The AMA Has Established Several CPT Code Sets for Molecular Diagnostic Tests



Determining Coding Options for Your Test



- Considered the path of least resistance
- Corresponding payment rate, if any, may not be ideal

- Often requires extra documentation
- Claims will likely be flagged by payers for manual review, delaying time to payment
- No set payment rate

- Ultimately facilitates claims processing
- Application process is time- and resource-intensive
- Opportunity or challenge for rate-setting

Applying For a New MoPath/MAAA CPT code

- **Criteria for a new Category I MoPath or MAAA CPT code[1]:**
  - Published evidence of clinical validity and clinical utility
  - Test is offered by at least 2 US labs, unless proprietary
  - Evidence of widespread use within the relevant clinical community
  - Support from the relevant specialty societies

CPT Application Process for Lab Codes

Draft and submit CPT coding application

↓

Present at Pathology Coding Caucus (PCC) meeting

↓

Present at CPT Editorial Panel Meeting

Securing a new Category I CPT code can take anywhere from 12 to 18 months

[1] American Medical Association. Molecular Pathology Procedures/Multianalyte Assays with Algorithmic Analyses (MAAA): Coding Change Application. http://www.ama-assn.org/resources/doc/cpt/cpt-code-change-request-maaa.doc

McKesson Z-code™ Identifiers Are An Additional Way to Identify Molecular Diagnostic Tests

- A McKesson Z-code™ Identifier is a 5 character alpha-numeric identifier that provides further granularity for billing a molecular diagnostic test
- The AMA and McKesson have partnered to develop a reference product, CPT CodeBridge™, that maps McKesson Z-code™ Identifiers to AMA MoPath CPT codes
- This product is currently available to providers and payers through licensing agreements with the AMA

Implications of CPT CodeBridge™ for Labs

- ***Increased billing transparency to payers***
- ***Potentially increased coverage scrutiny***
- ***Potential payment variations for tests billed with the same CPT code***

Molecular Diagnostics Payment Systems

Reimbursement Rate-Setting for Clinical Laboratory Services

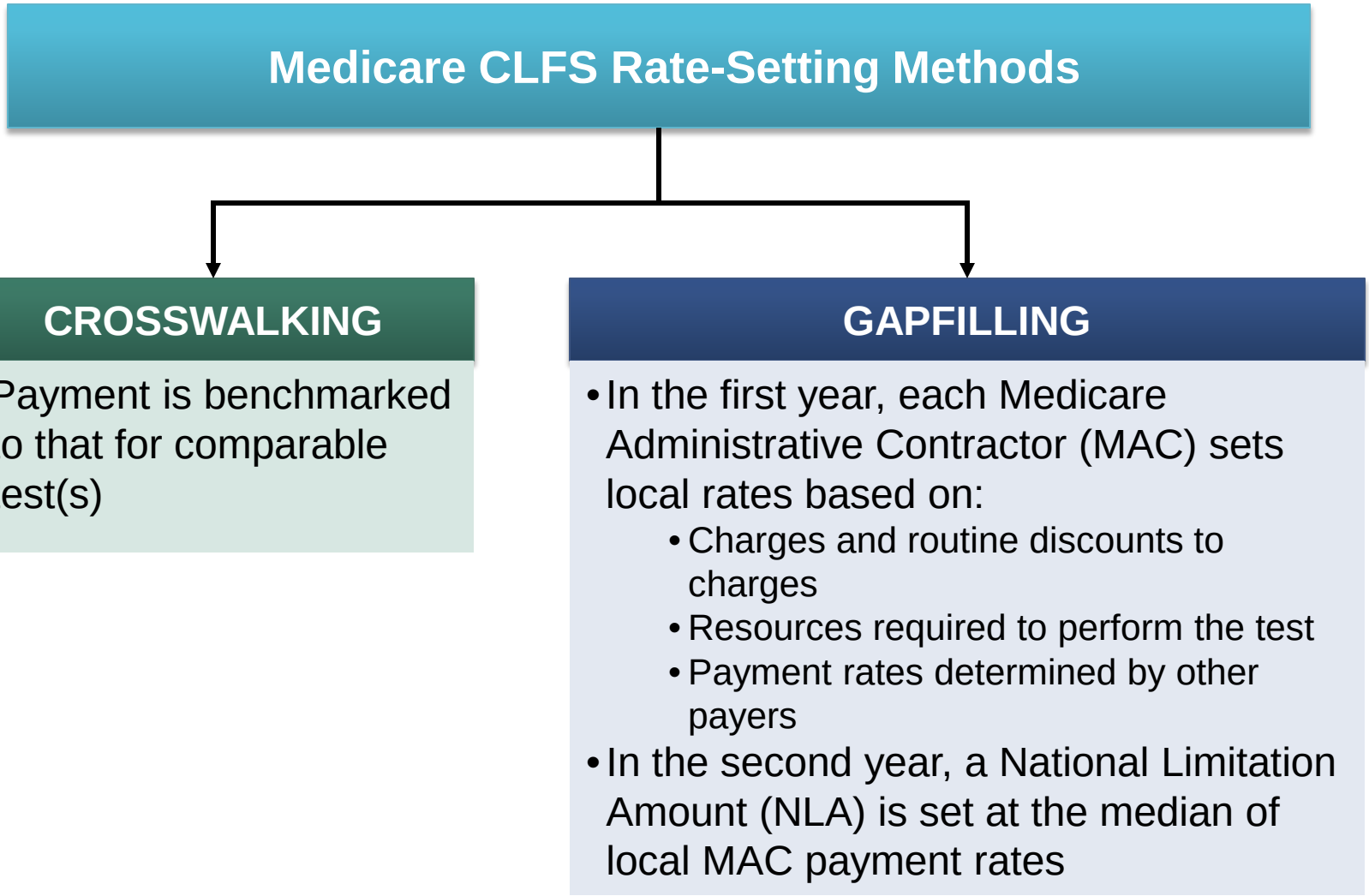
Medicare reimburses diagnostic laboratory services under one of two payment systems, depending on whether the test is performed by a lab technician or by a physician:

1. Clinical Laboratory Fee Schedule (CLFS)
2. Medicare Physician Fee Schedule (MPFS)

Private payers may utilize a variety of methodologies to determine payment rates for diagnostic laboratory services, which typically also varies based on contracting status ("in-network" vs. "out-of-network").

However, private payers often benchmark their payment rates to Medicare's (e.g., Medicare +20%).

Medicare CLFS Payment Rates Are Set By Either Crosswalking or Gapfilling



CMS Decided to Gapfill Payment Rates for the New MoPath Codes in 2013

2012

- The AMA approved the creation of analyte-specific Tier 1/Tier 2 MoPath CPT codes to replace the methodology-based "stacking" codes

2013

- The new MoPath codes were implemented, and the old "stacking" codes retired
- The MoPath codes were gapfilled for Medicare payment under the CLFS

2014

- CMS released NLAs for the MoPath codes, but excluded many Tier 1 codes and all of the Tier 2 codes

Sample 2014 Medicare NLA Payment Rates for MoPath Codes

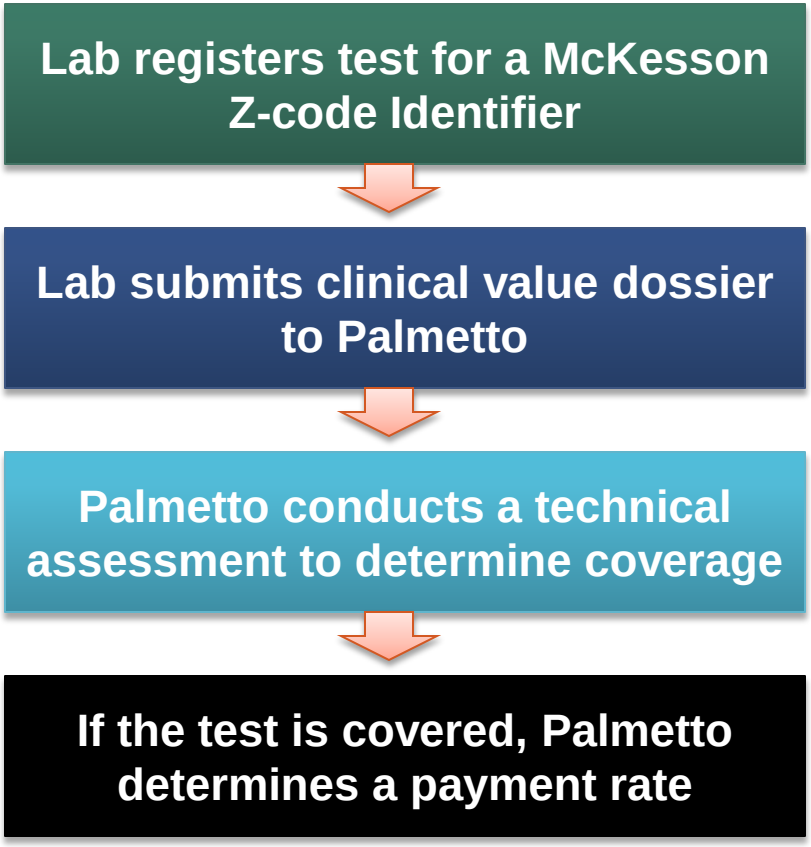
CPT Code	Descriptor	2014 NLA	LabCorp 2012 Code Stack Payment*	Quest 2012 Code Stack Payment*
81210	BRAF (v-raf murine sarcoma viral oncogene homolog B1) (eg, colon cancer), gene analysis, V600E variant)	**$179.25**	$53.00	$259.10
81235	EGFR (epidermal growth factor receptor) (e.g. non-small cell lung cancer) gene analysis, common variants (e.g. exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)	**$330.01**	$533.48	$301.92
81275	KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, variants in codons 12 and 13	**$197.48**	$265.64	$212.64
81292	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g. hereditary non-polyposis colorectal can-cer, Lynch syndrome) gene analysis; full sequence analysis	**$646.24**	$2,147.96	$930.52

*Quorum estimates based on code stacks published by Quest and LabCorp in 2012 and the 2012 Medicare CLFS.

Recent Developments in Molecular Diagnostics Reimbursement

The Palmetto MolDx Program Aims to Standardize Coverage and Payment of Molecular Diagnostics

The MolDx Program



- Launched in 2012, the MolDx Program was designed to address Palmetto's concerns around lack of transparency in billing and payment for molecular testing
- The program currently applies to Palmetto's Jurisdiction 11 (WV, VA, NC, SC) and Noridian's Jurisdiction E (CA, NV, HI)
- All labs submitting Medicare claims in these jurisdictions must participate in the MolDx program in order for their claims to be paid

Source: http://www.palmettogba.com/palmetto/MolDX.nsf/DocsCatHome/MolDx

The Protecting Access to Medicare Act (PAMA) of 2014 Affects Reimbursement for ALL Clinical Lab Services

- **Starting January 1, 2016**, all labs for which the majority of revenue comes from Medicare must **submit information to CMS on their private payer reimbursements**, including:
  - Payment amounts, reflecting all discounts and price concessions, for each test and each unique private payer
  - The volume of tests paid by each unique private payer

- This law applies to **all** clinical laboratory services paid under the CLFS or MPFS, including molecular diagnostics, chemistry, and cytopathology tests

Date	Major Milestone
January 1, 2016	Submission of laboratory private payer reimbursement data begins
January 1, 2017	CLFS payment rates determined through private payer reimbursement data take effect

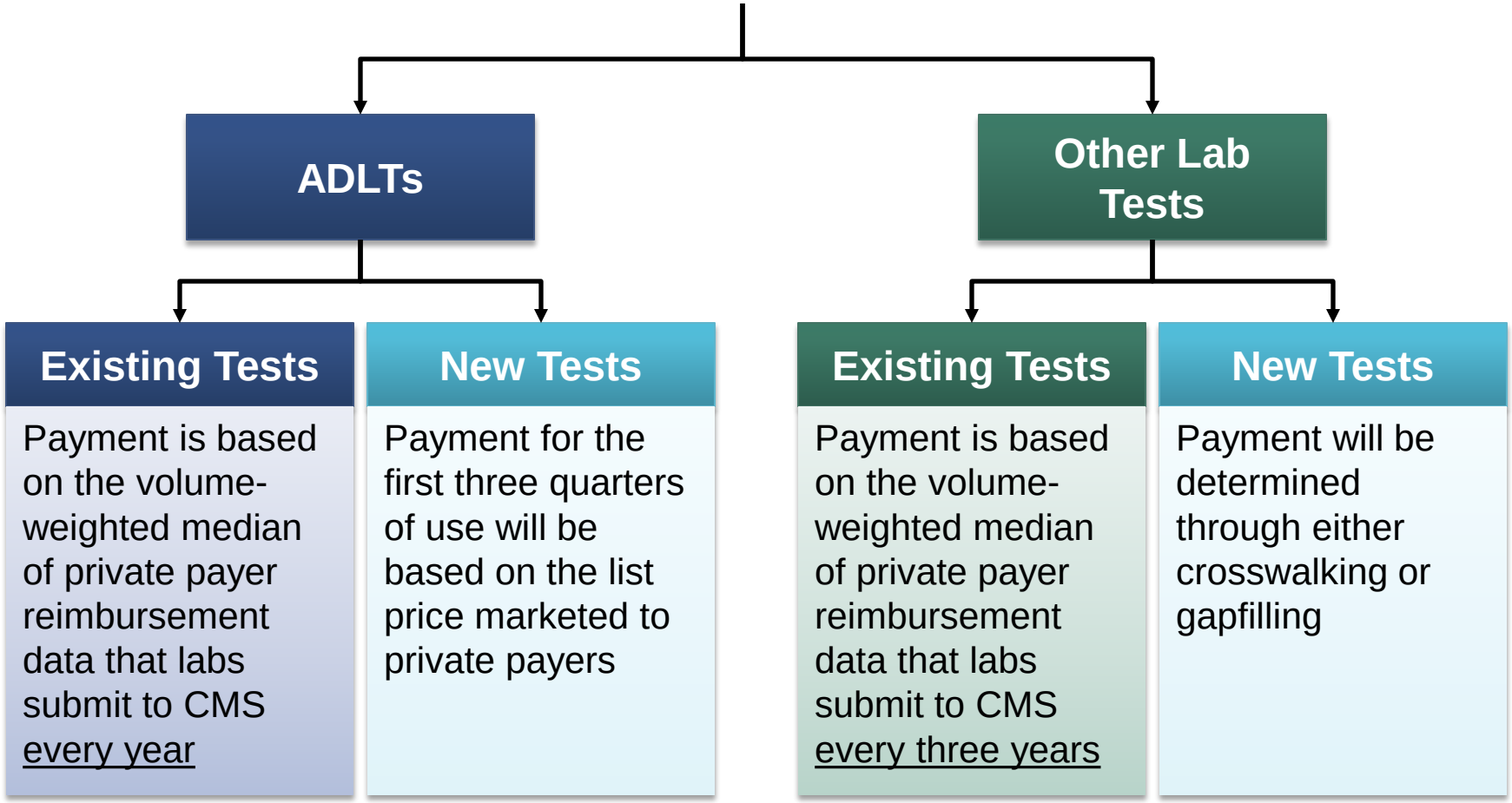
Source: http://beta.congress.gov/113/bills/hr4302/BILLS-113hr4302enr.pdf

How PAMA Defines Advanced Diagnostic Laboratory Tests (ADLTs)

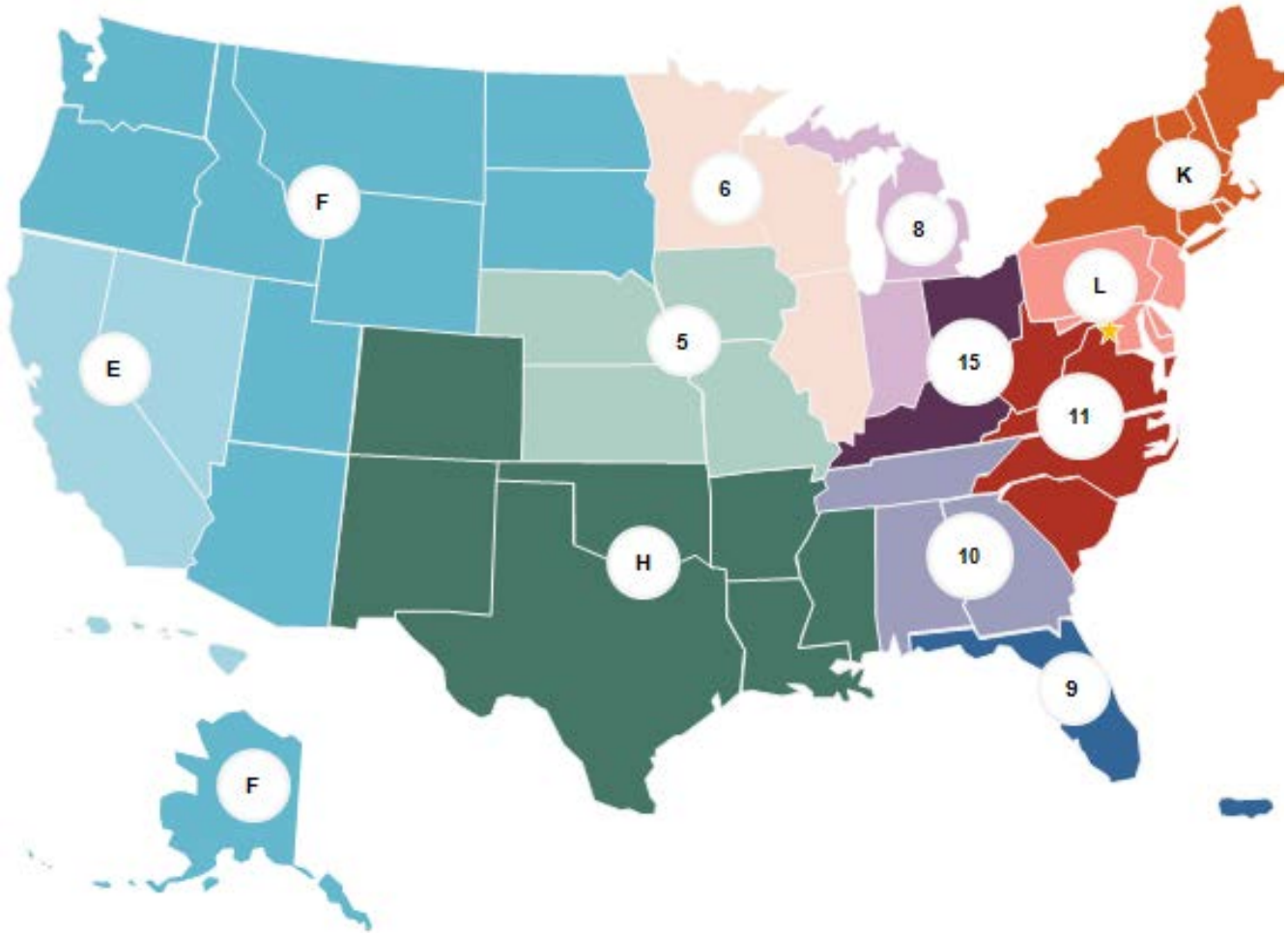
- Tests that are provided by a single source; **AND**
- Involve the analysis of multiple biomarkers combined with unique algorithms; **OR**
- Are FDA approved; **OR**
- Meet any other criteria established by CMS

PAMA Will Change the Rate-Setting Process for Clinical Laboratory Tests

Medicare rate-setting for clinical laboratory tests performed on or after January 1, 2017 will vary depending on the type of test



PAMA May Also Affect How Lab Claims Are Processed in the Future



- PAMA provides the HHS Secretary with the authority to designate up to four MACs to establish coverage policies and/or process claims for clinical laboratory tests for the entire Medicare program

Developing a Reimbursement Plan for Your Tests

Developing a Reimbursement Plan: Key Takeaways

Coverage

- If necessary, develop a publication plan to generate (clinical utility) evidence to support coverage
- Prepare materials and protocols to support appeals for denied claims

Coding

- Determine whether any existing CPT code(s) are appropriate for your test
- If not, consider using an unlisted code or applying for a new code

Payment

- Negotiate payment rates with your contracted private payers
- If applicable, work with your local MAC to determine payments for codes that are not on the CLFS

Self-Assessment

1. Which of the following types of evidence is most important to payers in evaluating coverage for a diagnostic test?
   a) Analytical validity
   b) Clinical validity
   c) Clinical utility
   d) All of the above

2. Which of the following code sets are organized into nine levels of increasing technical complexity and interpretive work?
   a) MoPath Tier 1 codes
   b) MoPath Tier 2 codes
   c) Multianalyte Assays with Algorithmic Analysis (MAAA) codes
   d) Next Generation Sequencing (NGS) codes

Self-Assessment (cont'd)

3. Which of these Medicare jurisdictions is/are currently subject to the requirements of the Palmetto MolDx program?
   a) J11 (NC, SC, VA, WV)
   b) JE (CA, HI, NV)
   c) J11 and JE
   d) None of the above

4. Under the Protecting Access to Medicare Act, starting in 2017, how would CMS set Medicare payment rates for new Advanced Diagnostic Laboratory Tests (ADLTs) in the first 3 quarters of availability?
   a) By crosswalking
   b) By gapfilling
   c) Based on the weighted median of private payer reimbursement amounts
   d) Based on the test's list price

Thank you for your attention!

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