



Webinar 4: Molecular Cytogenomic Testing

A Molecular Pathology Coding
and Reimbursement Webinar
Series in partnership with Quorum
Consulting

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Learning Objectives

Molecular Pathology Reimbursement Webinar Series:

- ▶ This is the final installment of our four part webinar series intended to educate laboratory providers on the new molecular pathology (MoPath) codes that have replaced code stacking in 2013
- ▶ In this webinar, we will review coverage, coding, and payment for molecular cytogenomic testing

Learning Objectives:

- ▶ Understand the coverage landscape for molecular cytogenomic testing
- ▶ Explore the coding options for molecular cytogenomic testing in 2013 and beyond
- ▶ Be familiar with the inputs that payers may use for rate-setting in 2013, and how to develop a detailed costing analysis for the tests your laboratory is offering to support accurate rate-setting

illumina is providing this review of the molecular pathology reimbursement landscape in collaboration with Quorum Consulting for educational purposes only. The content should not be considered legal advice. For official ruling on the MoPath codes readers should consult CMS, the AMA, and other sources as appropriate.

Molecular Cytogenomic Coverage Landscape

- ▶ This coverage analysis focuses on private payer and state Medicaid program coverage for postnatal molecular cytogenomic testing to diagnose unexplained developmental delay, congenital anomalies, intellectual disability (ID), and autism spectrum disorders (ASDs)¹
 - Molecular cytogenomic testing can reveal underlying chromosomal abnormalities that are linked to these disorders
 - Testing is generally performed on children
- ▶ Private payer coverage of postnatal molecular cytogenomic testing is growing, but not yet widespread
 - The number of positive coverage policies has been increasing over the last year



¹ Manning, Hudgins, Professional Practice and Guidelines Committee. Array-based technology and recommendations for utilization in medical genetics practice for detection of chromosomal abnormalities. ACMG Practice Guidelines, 2010

Common Private Payer Coverage Guidelines for Postnatal Molecular Cytogenomic Testing

- ▶ Postnatal molecular cytogenomic testing may be covered to diagnose unexplained developmental delay, congenital anomalies, intellectual disability (ID), and autism spectrum disorders (ASDs) in individuals who meet all of the following criteria:

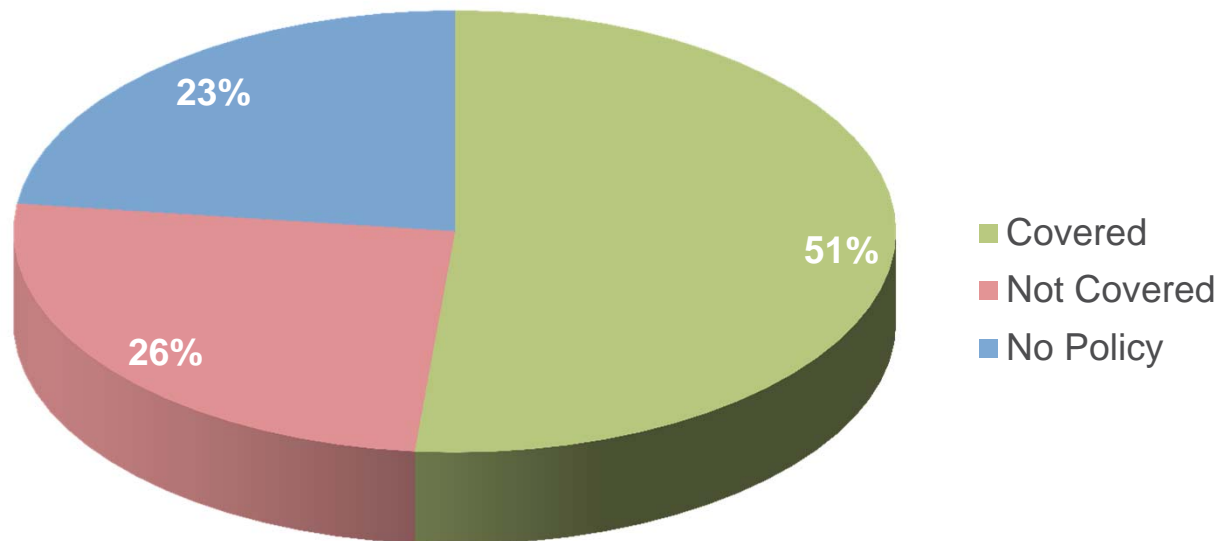
- Children with apparent non-syndromic cognitive delay
- Persons who have had inconclusive biochemical tests for metabolic disease
- *FMR1* genetic analysis, when clinically indicated, is negative
- Child has certain malformations
- Results of the test will impact clinical management of the patient

Source: Quorum Analysis of Payer Coverage Policies

Private Payer Coverage Landscape for Molecular Cytogenomic Testing

- ▶ Postnatal molecular cytogenomic testing is currently covered for approximately 51% of private payer covered lives
- ▶ The number of positive coverage policies has been increasing in the last year, driven in part by favorable recommendations from specialty societies such as the American College of Medical Genetics (ACMG)

Private Payer Coverage by Number of Covered Lives*

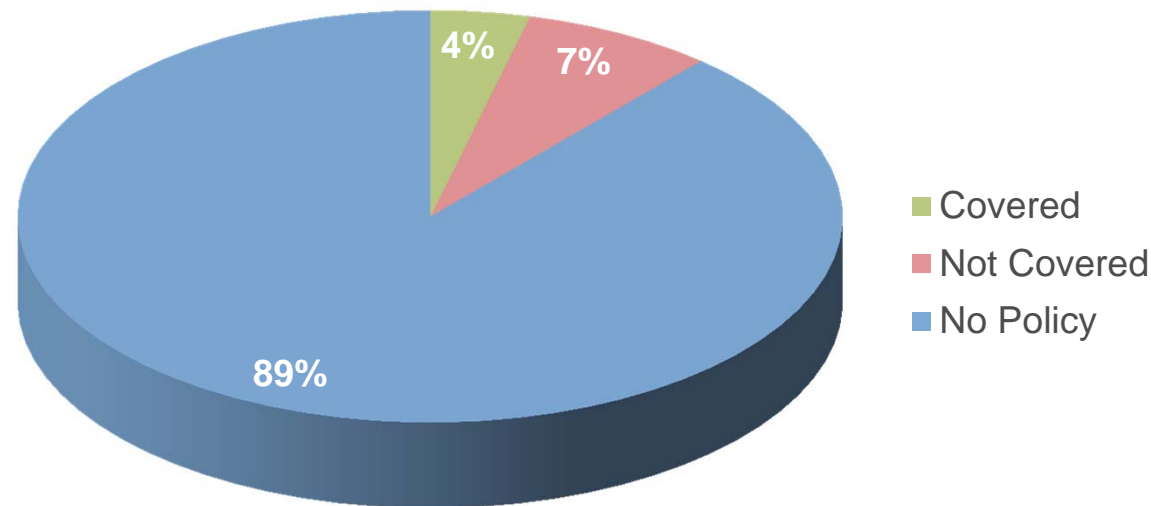


*As of December 2012

Medicaid Coverage Landscape for Molecular Cytogenomic Testing

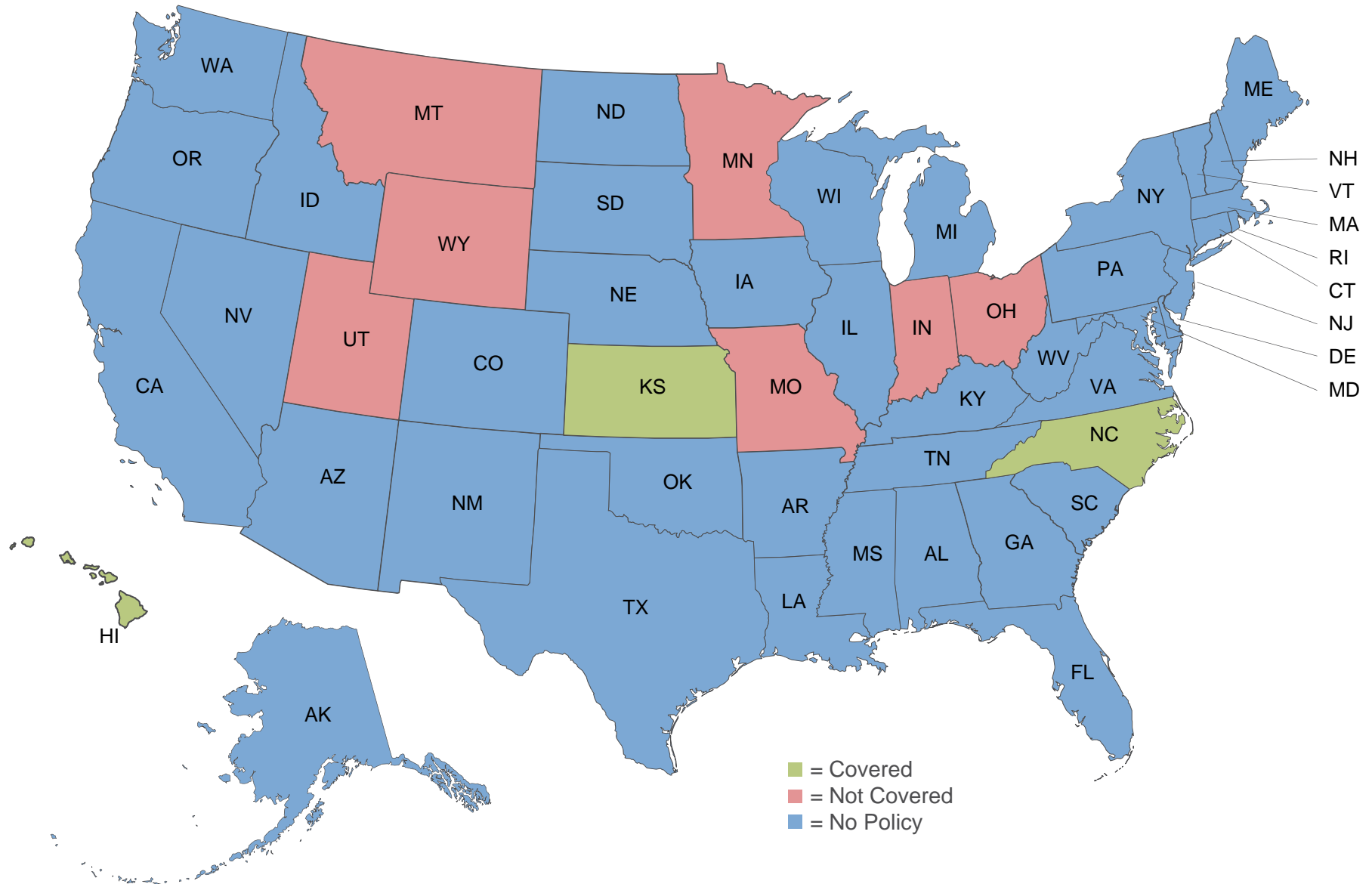
- ▶ The majority of state Medicaid agencies do not have any policies that specifically address coverage for molecular cytogenomic testing (postnatal or prenatal)
- ▶ Instead, most have general policies that cover laboratory services performed by CLIA-certified labs

Medicaid Coverage by Number of Covered Lives*



*As of December 2012

Medicaid Coverage Map for Molecular Cytogenomic Testing



Coding for Molecular Cytogenomic Testing: Past and Present

- ▶ Prior to 2013, laboratories commonly used molecular diagnostic CPT¹ “code stacks” to bill for molecular cytogenomic testing
 - These codes have been retired as of January 1, 2013
- ▶ Starting in 2013, molecular diagnostic code stacking has been replaced with analyte-specific molecular pathology (MoPath) codes

Before 2013^{2*}

CPT 83891
CPT 88386
CPT 83892
CPT 83898



2013 and Beyond

CPT 81229

Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities

**Example only*

¹ CPT is a registered trademark of the American Medical Association. ©2012 American Medical Association. All rights reserved.

² Quest Diagnostics. 2012 AMA Changes in CPT Coding. 10/9/2012.

Coding Options for Molecular Cytogenomic Testing in 2013

Effective January 1, 2013, laboratories must use the following Tier 1 MoPath codes to bill for molecular cytogenomic analysis

- ▶ Tier 1 codes represent the majority of commonly performed molecular tests

CPT Code	Descriptor
81228	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (eg, Bacterial Artificial Chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)
81229	Interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities

Differences in Coding: CPT 81228 vs. 81229¹

The codes for molecular cytogenomic analysis are segmented by the types of genetic variants interrogated.

CPT 81228

- Using Oligonucleotide Probe Hybridization to Detect Copy Number Variants (CNVs)¹

CPT 81229

- Using Oligonucleotide Probes to Detect CNVs; **AND**
- Using Single Nucleotide Polymorphism (SNP) Probes to Determine Zygosity Status¹

¹American Medical Association. 2012 Current Procedural Terminology: Changes, An Insider's View.

Billing Guidelines for Molecular Cytogenomic Testing

- ▶ Note that CPT 81228 and 81229 are mutually exclusive, and cannot be billed together for the same patient encounter

It is the responsibility of each laboratory to bill the CPT code that most accurately describes the type of molecular cytogenomic testing performed in each case.

AMA CPT Clinical Vignette: CPT 81228¹

- ▶ *Cytogenomic constitutional (genome-wide) microarray analysis; **interrogation of genomic regions for copy number variants (eg, Bacterial Artificial Chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)***

CPT 81228

An 18 month old male presents to his physician with unexplained developmental delay.

The patient has a normal karyotype, and his diagnostic evaluation is otherwise unrevealing. A sample of anticoagulated peripheral whole blood is submitted to the laboratory for cytogenomic constitutional (genome-wide) microarray analysis.

¹ American Medical Association. Current Procedural Terminology: 2012 Changes, An Insider's View.

AMA CPT Clinical Vignette: CPT 81229¹

- ▶ *Cytogenomic constitutional (genome-wide) microarray analysis; **interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities***

CPT 81229

A newborn female is determined to have multiple congenital anomalies by the attending physician.

The patient has a normal karyotype, and her diagnostic evaluation is otherwise unrevealing. The parents indicate they are both from the same ethnic background.

A sample of anticoagulated peripheral whole blood is submitted to the laboratory for cytogenomic constitutional (genome-wide) microarray analysis.

¹ American Medical Association. Current Procedural Terminology: 2012 Changes, An Insider's View.

Uncertainty Around 2013 Payments for Molecular Cytogenomic Testing

- ▶ With implementation of the new MoPath codes in 2013, many payers are still in the process of establishing their fee schedules
- ▶ As a result, 2013 payment rates for the MoPath codes, including those for molecular cytogenomic analysis, are uncertain at this time

During this time of uncertainty, engage your payers to ensure that your input is considered in the rate setting process

How are Payers Setting Payment Rates For The MoPath Codes in 2013?

Medicare

- Tier 1 and Tier 2 MoPath codes will be **gapfilled** for Medicare payment in 2013
- Local Medicare Administrative Contractors (MACs) will be responsible for setting regional fee schedule amounts in 2013

Medicaid and Private Payers

- Medicaid and private payers may use a variety of methods to set payment rates, but often use Medicare as a benchmark
- Some payers may also undertake activities similar to gap-filling to develop their MoPath fee schedules

What Does the Medicare Gapfilling Process Entail?

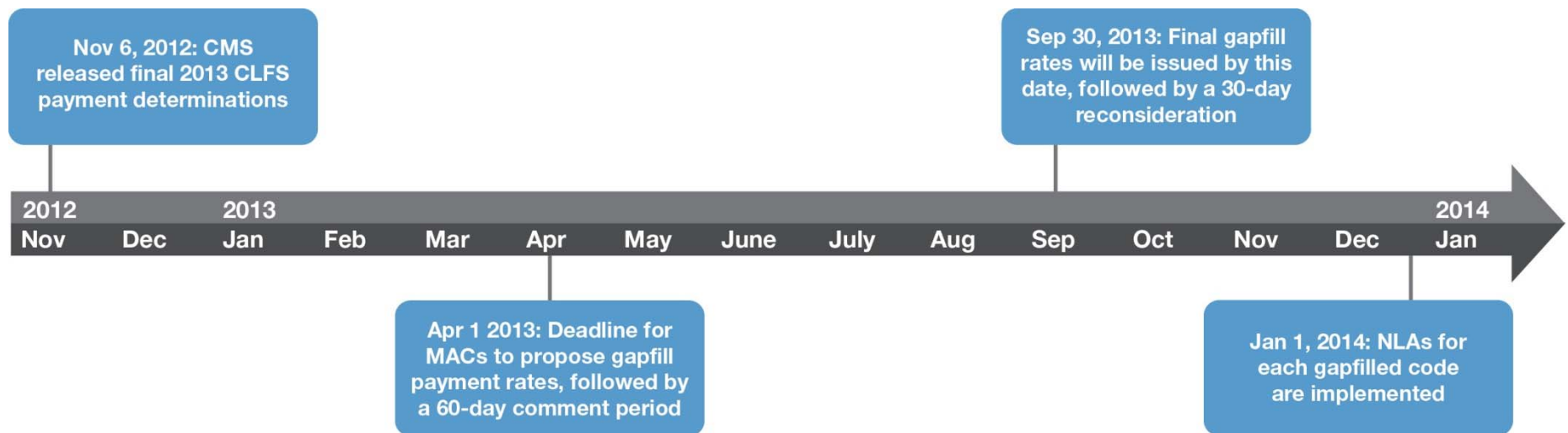
- ▶ In 2013, local MACs will set regional fee schedule amounts for each Tier 1 and Tier 2 code based on any combination of the following information:

- Charges for the test and routine discounts to charges
- Resources required to perform the test
- Payment amounts determined by other payers
- Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.¹

- ▶ In 2014, the national payment rate for each code is calculated as the median of the local fee schedule amounts set by the MACs in 2013
 - This median payment rate is referred to as the National Limitation Amount (NLA)

¹Code of Federal Regulations (CFR) Title 42 - Public Health, Part 414 – Payment for Part B Medical and Other Health Services, Section 414.508 – Payment for a new clinical diagnostic laboratory test.

Gapfilling Timeline for Tier 1 and Tier 2 Codes



The Laboratory Provider's Role in Rate Setting

- ▶ Laboratory providers can play a key role in the rate setting process by ensuring that payers have access to the proper data inputs required to set accurate payment rates

Charges for the test and routine discounts to charges

Cost analysis of resources required to perform the test

Payment amounts determined by other payers

Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant

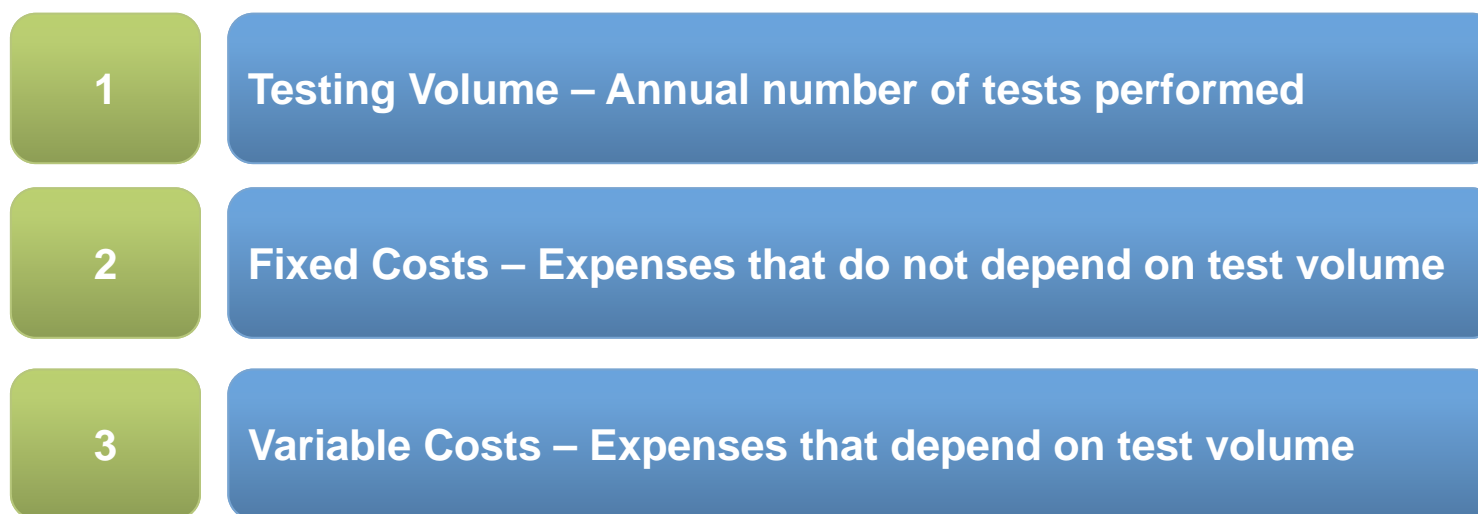
Clinical background information on the test

Previously billed code stack(s)

Projected future testing volume

Components of a Cost Analysis

- ▶ A cost analysis of the resources required to perform a test is a significant data point that payers will likely consider in rate setting
 - This would likely lead to more accurate rate setting than if payers were to evaluate prior payment history with code stacking
- ▶ The output would be the estimated **cost of running a test for a single specimen**
- ▶ Key components of a cost analysis include:



Detailed Cost Analysis Inputs for CF Genetic Testing

Testing Volume	<p>Annual number of tests performed</p> <p>Average number of tests per run</p>
Annual Fixed Costs	<p>Overhead:</p> <ul style="list-style-type: none"> • Rent • Utilities • Miscellaneous cost • % of total overhead allocated to CF testing <p>Capital Equipment:</p> <ul style="list-style-type: none"> • Equipment cost • Average useful life (in years) • % of total overhead allocated to CF testing <p>Salaries & Benefits (for each staff member)</p> <ul style="list-style-type: none"> • Average annual salary • Benefits as a % of annual salary
Variable Costs Per Run	<p>Disposable Equipment</p> <ul style="list-style-type: none"> • Product consumable cost (e.g., vendor consumables) • Disposable consumable cost (e.g., pipette tips) <p>Staff Time Spent (for each staff member)</p> <ul style="list-style-type: none"> • To perform the test • To interpret results and prepare the report



Steps to Calculating Your Lab's Cost Per Test

- ▶ The objective of a cost analysis is to calculate the cost of performing the test for a single specimen

$$\text{Total Cost per Test} = \text{Variable Cost per Test} + \text{Fixed Cost per Test}$$

How to Calculate Variable Cost Per Test

1. Calculate disposable equipment cost per run:

$$\text{Product consumable cost} + \text{disposable consumable cost}$$

2. Calculate staff labor cost per run:

$$\text{Time spent (in hours)} * \text{staff salary \& benefits per hour (for each staff member)}$$

3. Calculate total variable cost per run:

$$1 + 2$$

4. Calculate total variable cost per test:

$$3 / \text{average number of tests per run}$$

How to Calculate Fixed Cost Per Test

1. Calculate annual overhead cost allocated to molecular cytogenomics:

$$\text{Total overhead cost} * \% \text{ allocated to molecular cytogenomics}$$

2. Calculate annual capital equipment cost allocated to molecular cytogenomics

$$(\text{Equipment cost} / \text{avg useful life in years}) * \% \text{ allocated to molecular cytogenomics}$$

3. Calculate total annual fixed cost for molecular cytogenomics:

$$1 + 2$$

4. Calculate total fixed cost per test:

$$3 / \text{annual number of tests performed}$$

Key Takeaways: Coverage and Coding

- ▶ Postnatal molecular cytogenomic testing for the diagnosis of unexplained developmental delay, congenital anomalies, intellectual disability (ID), and autism spectrum disorders (ASDs) is witnessing growing coverage by private payers
- ▶ Beginning January 1, 2013, laboratories must use the following Tier 1 MoPath codes to bill for molecular cytogenomic testing:

CPT Code	Descriptor
81228	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (eg, Bacterial Artificial Chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)
81229	interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities



Key Takeaways: Payment and Rate Setting

- ▶ Because Medicaid and private payers often use Medicare as a benchmark when developing their own payment policies, the outcomes of the Medicare rate-setting process could influence the payment rates set by other payers
 - Some private payers may also undertake activities similar to gap-filling to develop their MoPath fee schedules
- ▶ A detailed cost analysis of the resources required to perform molecular cytogenomic analysis will be an important input to support accurate rate-setting for CPT codes 81228-81229

Laboratories are encouraged to engage Medicare and other payers in Jan-Mar 2013 to ensure that they have the necessary information to make accurate payment determinations

Additional Resources Are Available Online

Please visit our website at
<https://www.illumina.com/reimbursement>
for additional resources
and background information on
molecular diagnostic coding and reimbursement in 2013

