Webinar 3: Genetic Testing For Cystic Fibrosis

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

February 19, 2013

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Learning Objectives

Molecular Pathology Reimbursement Webinar Series:

- This is the third in a series of four webinars 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 cystic fibrosis (CF) genetic testing

Learning Objectives:

- Understand the coverage landscape for CF genetic testing
- Explore the coding options for CF 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 your test that will 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.

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Coverage Landscape for CF Genetic Testing

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Cystic Fibrosis Coverage Landscape

- This coverage analysis focuses on private payer and state Medicaid program coverage for cystic fibrosis (CF) genetic testing
  - CF is a life-threatening genetic disease with a median life-span of 37 years
  - Testing is generally performed on children and individuals planning to conceive[1]

- CF genetic testing is **largely covered by private payers** for both carrier screening and confirmatory diagnostic testing
  - However, patients must meet specific eligibility criteria for coverage

[1] The American College of Obstetricians and Gynecologists. Committee Opinion: Update on Carrier Screening for Cystic Fibrosis. April 2011

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Common Private Payer Coverage Criteria for CF Carrier Screening

CF carrier screening is covered for individuals who meet any of the following criteria:

- Couples seeking prenatal care
- Couples who are planning a pregnancy
- Persons with a family history of cystic fibrosis
- Persons with a 1st degree relative identified as a cystic fibrosis carrier
- Reproductive partners of persons with cystic fibrosis

Source: Quorum Analysis of Payer Coverage Policies

Common Private Payer Coverage Criteria for CF Diagnostic Testing

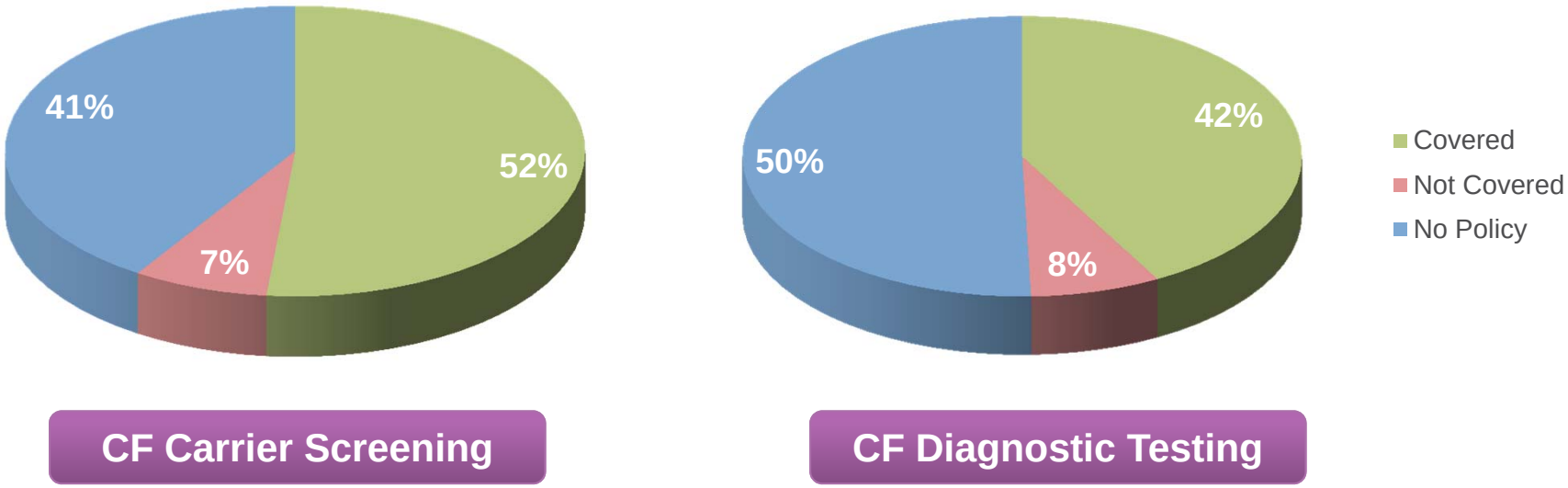
CF diagnostic testing is covered for individuals who meet any of the following criteria:

- Individual who exhibits symptoms of CF but has a negative sweat chloride test
- Infant with meconium ileus or other symptoms indicative of CF who is too young to produce adequate volumes of sweat for a sweat chloride test
- Male infertility from **either** of the following:
  - Congenital bilateral absence of vas deferens (CBAVD)
  - Azoospermia or severe oligospermia (i.e., < 5 million sperm/milliliter) with palpable vas deferens

Source: Quorum Analysis of Payer Coverage Policies

Private Payer Coverage Landscape for CF Genetic Testing

Private Payer Coverage by Number of Covered Lives*



CF Carrier Screening

CF Diagnostic Testing

- In the absence of a policy for CF genetic testing, the service will generally be covered as long as medical necessity can be justified

*As of December 2012

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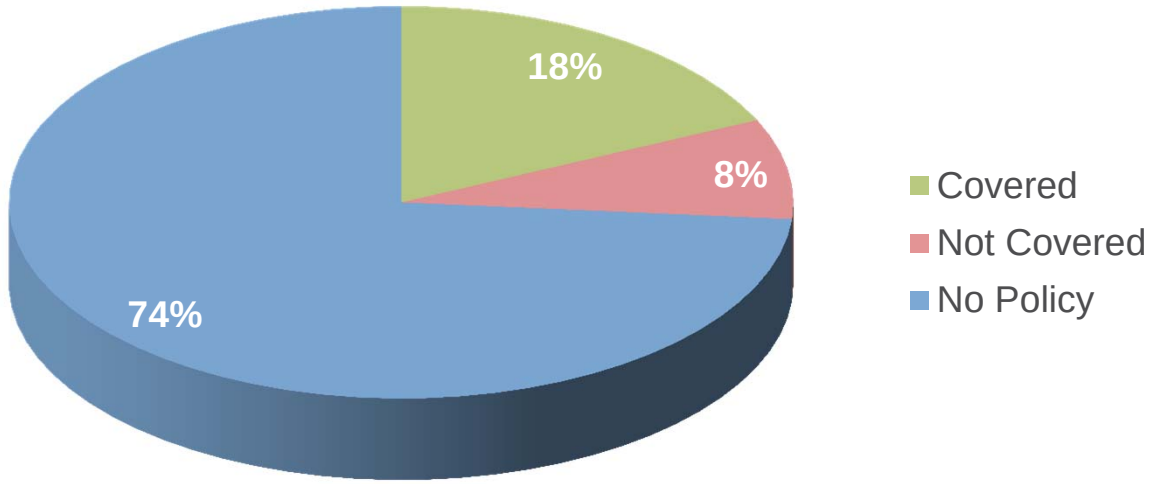
Medicaid Coverage Landscape for CF Genetic Testing

- The majority of state Medicaid agencies do not have any policies that specifically address coverage for CF genetic testing (carrier screening or diagnostic testing)
- Instead, most have general policies that cover laboratory services performed by CLIA-certified clinical labs

Medicaid Coverage by Number of Covered Lives*



*As of December 2012

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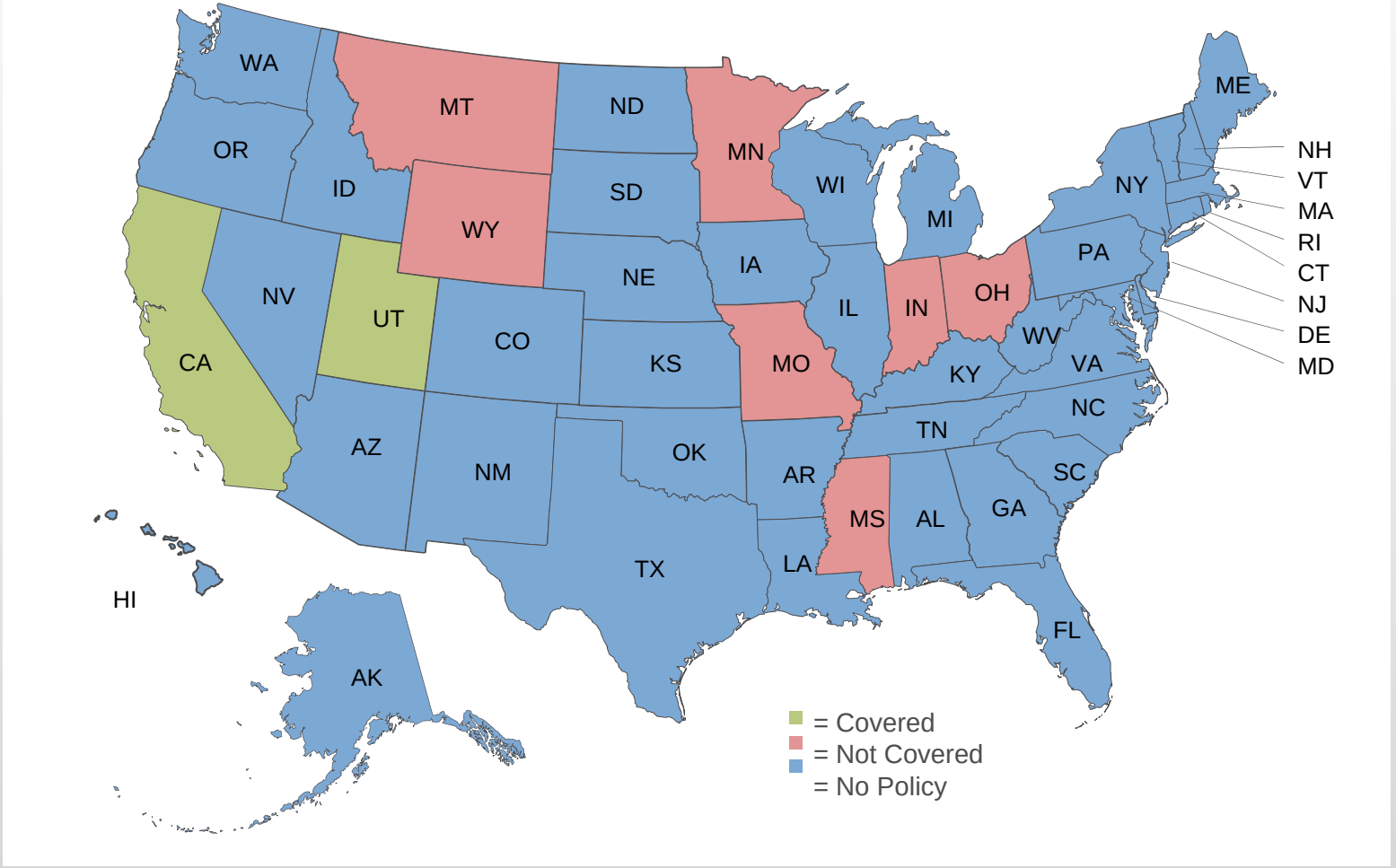
Medicaid Coverage Map for CF Genetic Testing



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2013 Coding Options for CF Genetic Testing

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Coding for CF Genetic Testing: Past and Present

- Prior to 2013, laboratories commonly used molecular diagnostic CPT[1] "code stacks" to bill for cystic fibrosis genetic 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 x 1*
- *CPT 83900 x 91*
- *CPT 83901 x 30*
- *CPT 83909 x 1*
- *CPT 83912 x 1*
- *CPT 83914 x 32*

2013 and Beyond

CPT 81220

CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) genetic analysis; common variants (eg, ACMG/ACOG guidelines)

**Example only*

[1] CPT is a registered trademark of the American Medical Association. ©2012 American Medical Association. All rights reserved.
[2] Athena Diagnostics. Test Catalog: Cystic Fibrosis Carrier Screen.

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Coding Options for CF Genetic Testing in 2013

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

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

CPT Code	Descriptor
81220	*CFTR* (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) genetic analysis; common variants (eg, ACMG/ACOG guidelines)
81221	known familial variants
81222	duplication/deletion variants
81223	full gene sequence
81224	intron 8 poly-T analysis (eg, male infertility)

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Coding *CFTR* Analysis for Different Indications

- The Tier 1 codes for *CFTR* analysis are segmented by the types of genetic variants interrogated, and can be billed for carrier screening or diagnostic testing

- The specific codes billed will depend on the type of testing performed in each case, and labs may use more than one code to report their services if indicated

It is the responsibility of each laboratory to bill the CPT code(s) that accurately describe the CF testing services provided based on the genetic analysis performed in each case

AMA CPT Clinical Vignette: CPT 81220[1]

- *CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) genetic analysis;* ***common variants (e.g., ACMG/ACOG guidelines)***

CPT 81220	A 26-year–old Caucasian female, approximately eight weeks pregnant and otherwise in good health, visits her obstetrician for a first prenatal visit. After discussing advantages and limitations of prenatal cystic fibrosis carrier screening with her obstetrician an anticoagulated peripheral whole blood sample is sent to the laboratory to be tested for common mutations and variants associated with cystic fibrosis.

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

AMA CPT Clinical Vignette: CPT 81221[1]

- *CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) genetic analysis;* ***known familial variants***

CPT 81221	A 1-year–old Caucasian male, whose 6-year–old brother was previously diagnosed with cystic fibrosis, is brought by his mother to the pediatrician for genetic testing. The brother was previously demonstrated to be a compound heterozygote carrying one copy each of the common *CFTR* DeltaF508 mutation as well as a rare variant not included in assays which test for common variants of *CFTR* but known to cause cystic fibrosis. An anticoagulated peripheral whole blood sample is sent to the laboratory for testing of these known mutations.

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

AMA CPT Clinical Vignette: CPT 81222[1]

- *CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) genetic analysis;* ***duplication/deletion variants***

CPT 81222	A 17-year–old Caucasian female, previously diagnosed with cystic fibrosis based on convincing clinical criteria and two elevated sweat chloride results, visits her pediatrician with her father to discuss potential additional genetic testing. Previous tests with a screening assay for common mutations and variants followed by *CFTR* full gene sequence analysis revealed only heterozygosity for the DeltaF508 mutation. An anticoagulated peripheral whole blood sample is forwarded to a reference laboratory for deletion/duplication analysis for an uncommon *CFTR* mutation.

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

AMA CPT Clinical Vignette: CPT 81223[1]

- *CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis;* ***full gene sequence***

CPT 81223	A 17-year–old Caucasian female with chronic rhino-sinusitis, idiopathic bronchiectasis, and two sweat chloride measurements in the intermediate range (40-60meq/L) is suspected by her pediatrician of having an atypical form of cystic fibrosis. A tube of anticoagulated peripheral whole blood is submitted to the laboratory for full CFTR gene sequence analysis.

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

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AMA CPT Clinical Vignette: CPT 81224[1]

- *CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis;* ***intron 8 poly-T analysis (e.g., male infertility)***

CPT 81224	Following recent consultation with his family physician regarding his wife's difficulty in conceiving a child, a 34-year–old Caucasian male is referred to a urologist for infertility workup. Physical further examination and testing reveals bilateral absence of the vas deferens. The urologist recommends genetic analysis of the CFTR gene to look for common CFTR mutations and assess the intron 8 poly-T region frequently associated with male infertility. An anticoagulated peripheral whole blood sample is forwarded to the laboratory for testing.

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

Payments and Rate Setting for CF Genetic Testing

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Uncertainty Around 2013 Payments for CF Genetic 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 CFTR gene analysis, are uncertain at this time

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

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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 gapfilling to develop their MoPath fee schedules

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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)

[1]Code 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.

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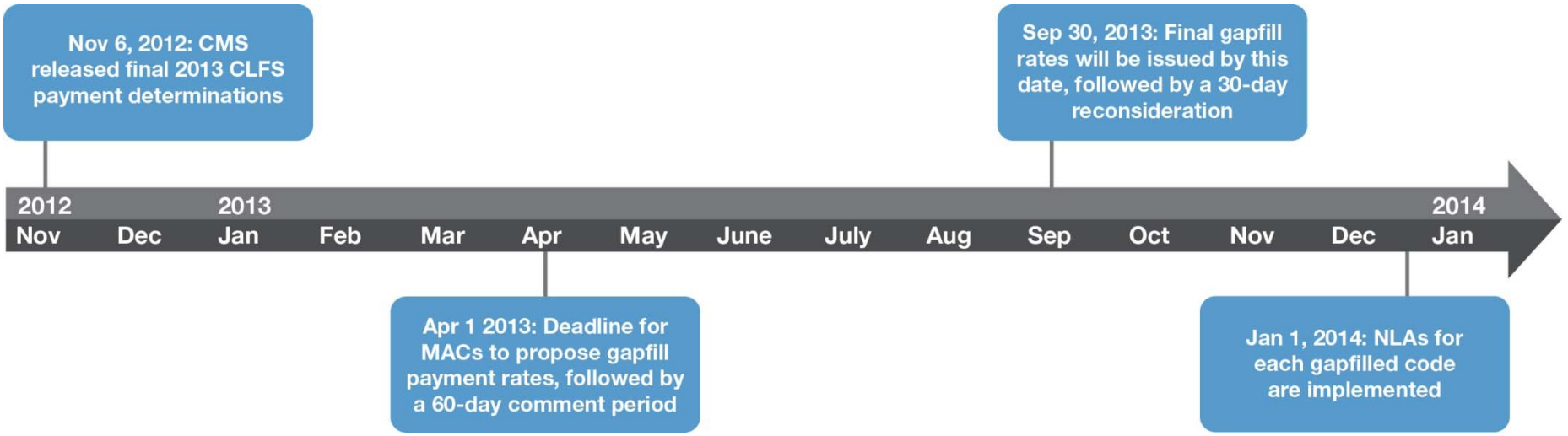
Gapfilling Timeline For Tier 1 And Tier 2 Codes



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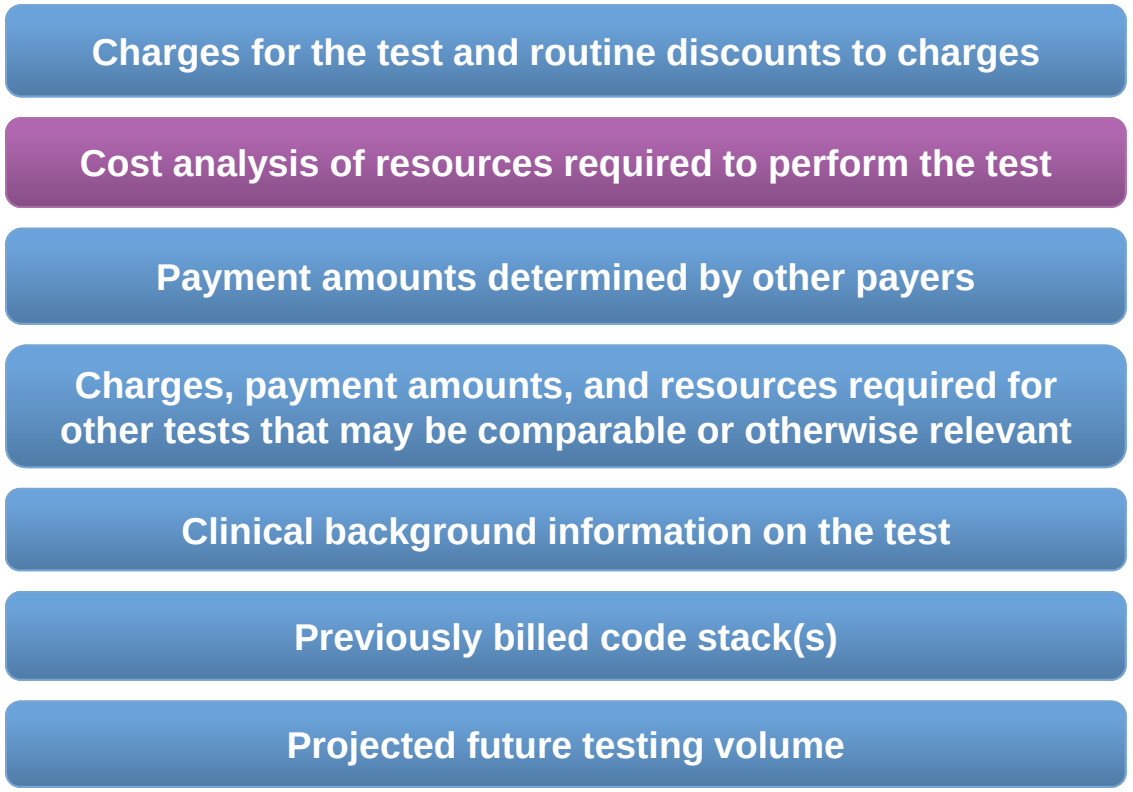
The Laboratory Provider's Role In Rate Setting

- 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



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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:

1	**Testing Volume – Annual number of tests performed**
2	**Fixed Costs – Expenses that do not depend on test volume**
3	**Variable Costs – Expenses that depend on test volume**

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Detailed Cost Analysis Inputs for CF Genetic Testing

Testing Volume	Annual number of tests performed
	Average number of tests per run
Annual Fixed Costs	**Overhead:** • Rent • Utilities • Miscellaneous cost • % of total overhead allocated to CF testing
	Capital Equipment: • Equipment cost • Average useful life (in years) • % of total overhead allocated to CF testing
	Salaries & Benefits (for each staff member) • Average annual salary • Benefits as a % of annual salary
Variable Costs Per Run	**Disposable Equipment** • Product consumable cost (e.g., vendor consumables) • Disposable consumable cost (e.g., pipette tips)
	Staff Time Spent (for each staff member) • To perform the test • To interpret results and prepare the report

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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

Total Cost per Test = Variable Cost per Test + Fixed Cost per Test

How to Calculate Variable Cost Per Test	How to Calculate Fixed Cost Per Test
1. Calculate disposable equipment cost per run: ***Product consumable cost + disposable consumable cost***	1. Calculate annual overhead cost allocated to CF testing: ***Total overhead cost * % allocated to CF testing***
2. Calculate staff labor cost per run: ***Time spent (in hours) * staff salary & benefits per hour (for each staff member)***	2. Calculate annual capital equipment cost allocated to CF testing: ***(Equipment cost / avg useful life in years) * % allocated to CF testing***
3. Calculate total variable cost per run: ***1 + 2***	3. Calculate total annual fixed cost for CF testing: ***1 + 2***
4. Calculate total variable cost per test: ***3 / average number of tests per run***	4. Calculate total fixed cost per test: ***3 / annual number of tests performed***

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Key Takeaways: Coverage And Coding

- CF genetic testing is widely covered for both carrier screening and confirmatory diagnostic testing
  - Patients must meet specific eligibility criteria in order for these services to be covered

- Effective January 1, 2013, laboratories must use the following Tier 1 MoPath codes to bill for CFTR gene analysis:

CPT Code	Descriptor
81220	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; common variants (eg, ACMG/ACOG guidelines)
81221	known familial variants
81222	duplication/deletion variants
81223	full gene sequence
81224	intron 8 poly-T analysis (eg, male infertility)

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 gapfilling to develop their MoPath fee schedules

- A detailed cost analysis of the resources required to perform *CFTR* gene analysis will be an important input to support accurate rate-setting for CPT codes 81220-81224

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

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Coming Up Next: Coverage, Coding, and Payment for Molecular Cytogenomic Testing

- You are invited to attend the next webinar on Thursday, February 21 at 9:00 a.m. PT to learn about:
  - The coverage landscape for molecular cytogenomic testing
  - The coding options for molecular cytogenomic testing in 2013 and beyond
  - The inputs that payers may use for rate-setting in 2013, and how to develop a detailed costing analysis for your test that will support accurate rate-setting

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

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Questions?

- Please type your questions into the Webex Q&A box

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