Webinar 3:
Genetic Testing For Cystic Fibrosis

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

February 19, 2013
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
Coverage Landscape for CF Genetic Testing
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
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 1\textsuperscript{st} 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
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*
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 Landscape for CF Genetic Testing

- Covered: 74%
- Not Covered: 18%
- No Policy: 8%

*As of December 2012
Medicaid Coverage Map for CF Genetic Testing

= Covered
= Not Covered
= No Policy

MAP TEXT:
- AL
- AZ
- AR
- CA
- CO
- CT
- DE
- DC
- FL
- GA
- ID
- IL
- IN
- IA
- KS
- KY
- LA
- ME
- MA
- MI
- MN
- MO
- MS
- MT
- NE
- NV
- NH
- NJ
- NM
- NY
- NC
- ND
- OH
- OK
- OR
- PA
- PR
- RI
- SC
- SD
- TN
- TX
- UT
- VA
- VT
- WI
- WV
- WY
- AK
- HI
2013 Coding Options for CF Genetic Testing
CPT is a registered trademark of the American Medical Association. ©2012 American Medical Association. All rights reserved.

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.
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)
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 81220¹

- 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.

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.
### AMA CPT Clinical Vignette: 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.

**CPT 81222**

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AMA CPT Clinical Vignette: CPT 81223

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

A 17-year-old Caucasian female with chronic rhinosinusitis, 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.

AMA CPT Clinical Vignette: CPT 81224

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

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.

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Payments and Rate Setting for CF Genetic Testing
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.
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
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.
Gapfilling Timeline For Tier 1 And Tier 2 Codes

- Nov 6, 2012: CMS released final 2013 CLFS payment determinations
- Apr 1, 2013: Deadline for MACs to propose gapfill payment rates, followed by a 60-day comment period
- Sep 30, 2013: Final gapfill rates will be issued by this date, followed by a 30-day reconsideration
- Jan 1, 2014: NLAs for each gapfilled code are implemented
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:
  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
# Detailed Cost Analysis Inputs for CF Genetic Testing

<table>
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<th><strong>Testing Volume</strong></th>
<th>Annual number of tests performed</th>
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<td>Average number of tests per run</td>
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### 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
The objective of a cost analysis is to calculate the cost of performing the test for a single specimen.

**Steps To Calculating Your Lab’s 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:
   \[ \text{Time spent (in hours)} \times \text{staff salary \\& benefits per hour (for each staff member)} \]
3. Calculate total variable cost per run:
   \[ 1 + 2 \]
4. Calculate total variable cost per test:
   \[ \frac{3}{\text{average number of tests per run}} \]

**How to Calculate Fixed Cost Per Test**

1. Calculate annual overhead cost allocated to CF testing:
   \[ \text{Total overhead cost} \times \% \text{ allocated to CF testing} \]
2. Calculate annual capital equipment cost allocated to CF testing:
   \[ \frac{\text{Equipment cost}}{\text{avg useful life in years}} \times \% \text{ allocated to CF testing} \]
3. Calculate total annual fixed cost for CF testing:
   \[ 1 + 2 \]
4. Calculate total fixed cost per test:
   \[ \frac{3}{\text{annual number of tests performed}} \]

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

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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
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
Questions?

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