Webinar 1: Understanding Reimbursement Implications For 2013

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

February 12, 2013

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Background and Learning Objectives

Molecular Pathology Coding and Reimbursement Webinar Series:

- This is the first in a series of four webinars intended to educate laboratory providers on the new molecular pathology (MoPath) codes for 2013, and how labs can influence sustainable reimbursement for molecular diagnostic services moving forward.

Learning Objectives For Today's Webinar:

- Be familiar with Tier 1 and Tier 2 MoPath codes
- Understand Medicare's rate-setting process for MoPath codes in 2013, and the implications for Medicaid and private payer reimbursements
- Understand how physicians will bill for interpretation and written report for a molecular diagnostic test

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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Introduction to MoPath CPT® Codes

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What are Molecular Pathology (MoPath) Codes?

- The American Medical Association (AMA) Current Procedural Terminology (CPT[1]) established new molecular pathology (MoPath) codes to:
  - Address payer concerns about the transparency of provider billing for molecular diagnostic tests
  - Replace the methodology-based CPT codes (CPT 83890-83914; 88384-88386) that previously allowed labs to bill different coding combinations (also known as “code stacks”) for the same test

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.

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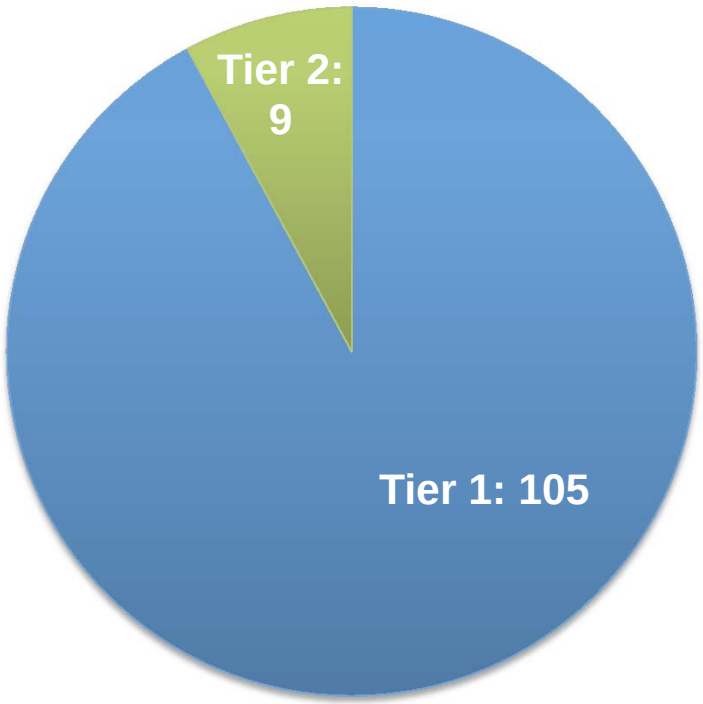
MoPath Codes are Categorized Into Tier 1 & Tier 2 Codes

A Total Of 114 Tier 1 & Tier 2 Codes Are Effective In 2013



Tier 1

- The majority of commonly performed single-analyte molecular tests (e.g., KRAS, BRAF)

Tier 2

- Procedures that are generally performed in lower volumes than Tier 1 procedures
- Arranged by 9 levels of technical resources and interpretive work by the physician or other qualified health care professional

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Tier 1 Codes for Cystic Fibrosis Genetic Testing

- The Tier 1 codes for CFTR gene analysis are segmented by the types of genetic variants interrogated

CPT Code	Descriptor
81220	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; common variants (e.g., ACMG/ACOG guidelines)
81221	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; Known familial variants
81222	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; Duplication/deletion variants
81223	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; Full gene sequence
81224	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; Intron 8 poly-T analysis (eg, male infertility)

Tier 1 Codes for Molecular Cytogenomics

- These Tier 1 codes describe whole-genome microarray analyses that test for (a) copy number variants (CNVs); or (b) CNVs and single nucleotide polymorphisms (SNPs)
- Note that CPT 81228 and 81229 are mutually exclusive and cannot be billed together for the same patient encounter

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

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Different Types of Molecular Cytogenomic Testing

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

CPT 81228	CPT 81229
• Using Oligonucleotide Probe Hybridization to Detect Copy Number Variants (CNVs)[1]	• Using Oligonucleotide Probes to Detect CNVs; **AND** • Using Single Nucleotide Polymorphism (SNP) Probes to Determine Zygosity Status[1]

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

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Tier 1 Codes For Somatic Cancer Mutations

- The Tier 1 codes for somatic cancer mutation analysis correspond to the type of gene mutations being analyzed
- These codes can be billed in combination when indicated
  - E.g., CPT 81235 and CPT 81275 can be billed together when both EGFR and KRAS testing is performed on the same patient specimen

CPT Code	Descriptor
81210	BRAF (v-raf murine sarcoma viral oncogene homolog B1) (e.g., colon cancer), gene analysis, V600E variant
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)
81275	KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (e.g., carcinoma) gene analysis, variants in codons 12 and 13

Billing for Physician Interpretation and Reporting Services

- In some cases, it may be medically necessary for physicians to provide interpretation and a written report for a molecular diagnostic test, beyond the technical reporting of test results
- To allow physician billing and reimbursement for these services when performed, CMS created new Healthcare Common Procedure Coding System (HCPCS) code G0452 *(Molecular pathology procedure; physician interpretation and report)*[1]
- HCPCS G0452 is not billable by non-physician geneticists and other lab personnel
  - Any interpretation and reporting services performed by these individuals would be included in the payment rate for the associated MoPath code

[1] Centers for Medicare and Medicaid Services. Calendar Year 2013 New and Reconsidered Clinical Laboratory Fee Schedule (CLFS) Test Codes And Final Payment Determinations. Accessed November 6, 2012, at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-CY2013-Final-Payment-Determinations-11052012.pdf

Coding for Molecular Diagnostic Services in 2013 (and Beyond)

- The “stacking” CPT codes that laboratories previously used to bill for molecular diagnostic services were retired on January 1, 2013

- Effective January 1, 2013, laboratories must use the new MoPath codes to bill for molecular diagnostic services

How will payers reimburse the MoPath codes in 2013 and beyond?

Reimbursement Methodologies for Molecular Diagnostic Services

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Payer Rate-Setting for Molecular Diagnostic Procedures

- Medicare reimburses molecular pathology/diagnostic services under one of two payment systems, depending on whether the test is performed by lab technicians or physicians:
  - Clinical Laboratory Fee Schedule (CLFS)
  - Medicare Physician Fee Schedule (MPFS)

- Private payers may utilize a variety of methodologies to determine payment rates for molecular diagnostic services
- However, they often look to Medicare as a benchmark or reference point for setting their own payment rates

Rate-Setting Under CLFS: Gapfilling vs. Crosswalking

When a new CPT code is reimbursed under the CLFS, CMS determines the payment rate using one of two methods:

Gapfilling

No comparable test exists.

CMS instructs each Medicare Administrative Contractor (MAC) to independently set rates for the first year of use based on :

- Charges and routine discounts to charges
- Resources required to perform the test
- Payment rates determined by other payers

Crosswalking

New test is comparable to existing test(s) based on factors such as:

- Analyte
- Assay process
- Technology employed

New test code is assigned the same payment rate as that for an existing code or combination of codes

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Medicare Payment for Tier 1 & 2 MoPath Codes in 2013

- On November 6, 2012, CMS announced that the Tier 1 and Tier 2 MoPath codes will be **gapfilled** under the CLFS for Medicare payment in 2013[1]

- Therefore, the local MACs will be responsible for setting regional fee schedule amounts in 2013 for the labs in their jurisdiction

How will the MACs establish payment rates for the Tier 1 and Tier 2 codes under the gapfilling process?

[1] Centers for Medicare and Medicaid Services. Calendar Year 2013 New and Reconsidered Clinical Laboratory Fee Schedule (CLFS) Test Codes And Final Payment Determinations. Accessed November 6, 2012, at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-CY2013-Final-Payment-Determinations-11052012.pdf

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Overview of the Medicare Gapfilling Process

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What Does the Gapfilling Process Entail?

- It will be up to the discretion of local MACs to set regional fee schedule amounts in 2013 for each Tier 1 and Tier 2 code based on information such as:

  - Charges for the test and routine discounts to charges;
  - Resources required to perform the test;
  - Payment amounts determined by other payers; and
  - 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 will be 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

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Implications of Medicare Gapfilling for Other Payer Reimbursements

- Because Medicaid and private payers often use Medicare as a benchmark when developing their own payment policies, the outcomes of the Medicare gapfilling process could influence the payment rates set by other payers

- Some private payers may also undertake activities similar to gapfilling to develop their own MoPath fee schedules

Key Takeaways

Effective January 1, 2013, laboratories must use the new MoPath codes to bill for molecular diagnostic services

HCPCS G0452 can be billed for interpretation and reporting services provided by ***physicians*** only

Tier 1 and Tier 2 MoPath codes will be gapfilled under the CLFS for Medicare payment in 2013

Medicare gapfilling outcomes can influence Medicaid and private payer reimbursements as well

Laboratories are encouraged to engage Medicare and other payers *as early as possible* in 2013 to ensure that they have the necessary information to set accurate payment rates

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Coming Up Next:
Influencing the Rate Setting Process

- You are invited to attend the next webinar on **Thursday, February 14 at 9:00 a.m. PT** to learn about:
  - The role that laboratories can play in ensuring accurate and sustainable reimbursement for the MoPath codes in 2013 and beyond
  - The timeline of critical communication periods with payers during the rate setting process in 2013
  - Best practices for engaging payers during the rate-setting process

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