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Reimbursement for Molecular Cytogenomic Testing in the United States

A review of coverage, coding, and payment for molecular cytogenomic testing.

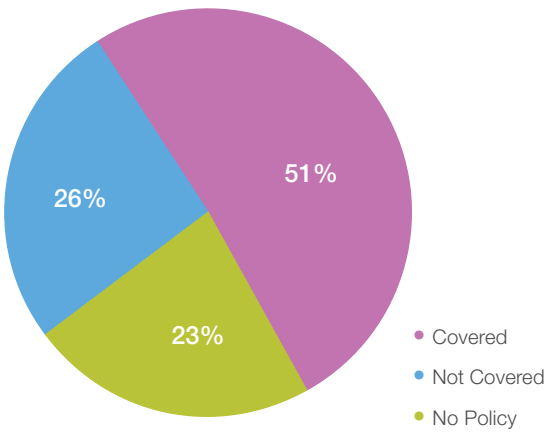
Introduction

In 2012 the American Medical Association (AMA) established a new set of analyte-specific molecular pathology (MoPath) codes for laboratories to use in billing. Here, we review the current coverage, coding, and payment landscape for molecular cytogenomic testing.

Coverage

Payer coverage of molecular cytogenomic testing is growing, but not yet widespread. A 2012 survey showed that 51% of private payer covered lives are associated with payers that have positive coverage policies for molecular cytogenomic testing, whereas 26% are insured by payers that have negative policies for this service (Figure 1). The remaining 23% are covered by payers that have not issued any formal policies for molecular cytogenomic testing. However, the absence of a coverage policy does not necessarily indicate non-coverage, but implies that the procedure may be covered if medical necessity can be justified.

Figure 1: Private Payer Coverage by Number of Covered Lives



Based on an analysis of n = 170,665,015 payers performed by Quorum Consulting in December 2012.

Based on private payer coverage guidelines, molecular cytogenomic testing to diagnose unexplained developmental delay, autism spectrum disorder (ASD), intellectual disability, or congenital anomalies, is generally covered for individuals who meet any of the following criteria:

- Children with apparent nonsyndromic cognitive delay
- Persons who have had inconclusive biochemical tests for metabolic disease
- *FMR1* gene analysis, when clinically indicated, is negative
- Children with certain malformations
- Results of the test will impact clinical management of the patients

The majority of state Medicaid agencies do not have policies specifically addressing coverage for molecular cytogenomic testing, but have general policies that cover laboratory services performed by CLIA-approved labs.

Local Medicare Administrative Contractors (MACs) have generally issued negative coverage policies for molecular cytogenomic testing, citing in their determination that it is statutorily excluded as a Medicare benefit.

Coding

There are two Current Procedural Terminology (CPT®)[1] codes for molecular cytogenomic testing, which are segmented by the types of genetic variants interrogated (Table 1). The following CPT codes are available for laboratories to use if they accurately describe the services performed for molecular cytogenomic testing. It is the responsibility of each laboratory to determine the most appropriate CPT codes to use when billing for their services.

Table 1: MoPath Codes for Molecular Cytogenomic Testing

CPT Code	Descriptor
81228	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (e.g., 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

AMA CPT Clinical Vignettes

The AMA provides clinical vignettes that describe common clinical scenarios in which each code may be billed[2,3]:

- **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 blood is submitted to the laboratory for cytogenomic constitutional (genome-wide) microarray analysis.
- **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 blood is submitted to the laboratory for cytogenomic constitutional (genome-wide) microarray analysis.

Payment

For 2013, the Centers for Medicare & Medicaid Services (CMS) assigned the local Medicare Administrative Contractors (MACs) the responsibility of setting regional fee schedule amounts for the new MoPath code set (including payment rates for molecular cytogenomic testing) via gapfilling.

Gapfilling is used when a comparable test does not exist. CMS instructs local MACs to establish payment rates in the first year based on charges and routine discounts to charges, resources required, and other payers' payment rates. For reimbursement in the second year and beyond, CMS calculates a national payment rate by using the median of the local MAC fee schedules.

On September 30, 2013, CMS released the 2014 national Medicare fee schedule amounts for the MoPath codes, which were based on the final gapfill rates determined by each MAC[4]. However, the national fee schedule did not include any payment rates for the molecular cytogenomic testing codes. Since payment rates will vary by payer (both private and public), laboratories are encouraged to contact individual payers directly to clarify the fee schedule amounts for these codes in 2014.

References

1. CPT is a registered trademark of the American Medical Association. ©2012 American Medical Association. All rights reserved.
2. American Medical Association. 2012 Current Procedural Terminology: Changes, an Insider's View
3. © American Medical Association 2011. All rights reserved.
4. Centers for Medicare & Medicaid Services. Gapfill Pricing Inquiries. Accessed on October 1, 2013 (www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Gapfill-Pricing-Inquiries.html)

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.

Illumina • 1.800.809.4566 toll-free (U.S.) • +1.858.202.4566 tel • techsupport@illumina.com • www.illumina.com

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