Reimbursement in Molecular Pathology: Bringing Genomic Medicine to Patients

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In 2008, the Association for Molecular Pathology (AMP)2 Economic Affairs Committee (EAC), under the leadership of the late Dr. Jeffrey Kant, embarked on a project to design new Current Procedural Terminology (CPT) codes for identification and billing of molecular pathology services. At that time, payers were confronted with a dizzying array of highly technical method-based CPT codes that described the various steps used in performing molecular assays. Examples included “83890 isolation or extraction, each nucleic acid type (i.e., DNA or RNA)”; “83898 amplification, target, each nucleic acid sequence”; “83904 mutation identification by sequencing, single segment, each segment”; and “83912 interpretation and report.”

Laboratories “stacked” these codes on claim forms along with numerals that specified the number of times each step was performed. Payers could only guess at what the particular test was or why it was performed. Use of the CPT stacking codes was not uniform, and there was no way to ensure that tests were properly coded. Moreover, if more than one test was performed on a sample, Medicare Administrative Contractors (MACs) were unable to allocate CPT codes between tests. Finally, this coding structure left open the possibility that reimbursement rates for individual steps could influence assay design.

Despite their shortcomings, the stacking codes had a powerful redeeming feature. Molecular pathology was characterized by both rapid growth and continual technological change. The stacking code format offered great flexibility and an ability to readily accommodate new tests and assay designs, benefitting patients and helping to advance the field.

AMP’s Coding Solution

The AMP EAC’s efforts culminated in production of a whitepaper that proposed an innovative approach to coding molecular pathology procedures in genetics, oncology, and histocompatibility. This document was submitted to the American Medical Association (AMA) CPT Editorial Panel for consideration (1). In response, the AMA convened a workgroup “to propose solutions to issues for coding molecular assays in cancer, genetics, and histocompatibility.” The workgroup, which included input and participation from a wide range of stakeholders, was charged with constructing “a new subsection of the CPT Pathology and Laboratory subsection, guidelines, definitions and new CPT codes” (2).

AMP recommended a 2-tiered, volume-based coding format. According to relative volume data obtained from large reference laboratories and academic medical centers, a small number of procedures appeared to account for the majority of molecular testing. For example, at one large laboratory the top 12 tests comprised 85% of the total volume. Three tests (cystic fibrosis, factor V Leiden, and prothrombin G20210A) accounted for approximately 80% of all procedures. This concentration of volumes in a relatively small number of tests, combined with limitations on the number of available CPT codes, encouraged the AMA to adopt AMP’s proposed coding structure for most molecular pathology tests. The AMA’s new system accomplishes the dual goals of increasing transparency while preserving some of the flexibility of the stacking codes. The Tier 1 Molecular Pathology Procedures section of CPT contains the highest-volume tests. Each Tier 1 test has its own CPT code. As of this writing, 120 analytes and procedures had been assigned Tier 1 codes, and 599 tests had been placed in Tier 2. Tier 2 consists of 9 levels, each of which has a CPT code that is used for all analytes or procedures included within the level. Tests are assigned to levels based on the typical resources used to perform them (2–4).

Later additions included sections for Multianalyte Assays with Algorithmic Analyses (MAAs), and for Genomic Sequencing Procedures (GSPs) and Other Molecular Multianalyte Assays. This latter section was primarily created to meet the coding needs of next generation sequencing procedures (5).

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3 Nonstandard abbreviations: AMP, Association for Molecular Pathology; EAC, Economic Affairs Committee; CPT, Current Procedural Terminology; MAC, Medicare Administrative Contractor; AMA, American Medical Association; CLFS, clinical laboratory fee schedule; RUC, Specialty Society Relative Value Scale Update Committee; PAMA, Protecting Access to Medicare Act of 2014.
Physician Fee Schedule or Clinical Laboratory Fee Schedule?

Because most molecular pathology procedures are complex tests that require professional interpretation, the College of American Pathologists, AMP, and other professional societies argued that the new Molecular Pathology CPT codes should be paid under Medicare’s physician fee schedule. By contrast, commercial reference laboratories argued for placement on the clinical laboratory fee schedule (CLFS) (6, 7).

In anticipation of inclusion of the new Molecular Pathology CPT Codes on the Physician Fee Schedule, the Editorial Panel referred the codes to the AMA Specialty Society Relative Value Scale Update Committee (RUC) for relative valuation. The RUC evaluated the codes and provided CMS with direct practice expense inputs reflecting test costs and relative value unit recommendations for test interpretation. CMS published calculated direct practice expense amounts, representing total test costs less indirect costs, as well as work relative value units for many of the tests, but ultimately placed the new codes on the CLFS (8, 9).

CMS Pricing, to “Crosswalk” or to “Gapfill”?

CMS regulations specify 2 ways to price new CLFS tests, “crosswalking” and “gapfilling” (10). Tests that are similar to previously priced tests, or a portion of such tests, can be crosswalked to established payment levels. If no comparable assays are available for crosswalking, the gapfill methodology is employed.

During the gapfill process, MACs individually price tests for the first year. In the second year, CMS adopts the median of the contractor-specific prices to establish the National Limitation Amount, at which tests will be paid. MACs are required to take into account, if available, actual charges and routine discounts; required resources; payment by other payers; and charges, payment amounts, and resources required for comparable or otherwise relevant tests (10).

MAC pricing was established in early 2013 for many of the new molecular pathology CPT codes, with what appears to have been significant declines in reimbursement for some tests. Pricing was incomplete and inconsistent, and MACs were criticized for failing to provide a specific basis for most payment amounts or coverage decisions. Several MACs adopted prices from a single contractor. Conversely, MACs argued that laboratories were unwilling to provide them with cost data to assess (11, 12).

On May 9, 2013, CMS published each MAC’s interim prices on its website, with a 60-day comment period. CMS posted “final” national limitation amounts on September 30, 2013, which were released as the final CLFS after a 30-day reconsideration period. Throughout this process some upward adjustments in pricing occurred in response to provider complaints, but laboratories have continued to complain about low pricing levels as well as perceived errors in coverage decisions. Moreover, in addition to pricing issues, a prolonged period of nonpayment occurred during 2013, adversely impacting labs (13).

The Protecting Access to Medicare Act of 2014

On April 1, 2014, the President signed the Protecting Access to Medicare Act of 2014 (PAMA), commonly known as the “doc fix,” into law (14). Included as an offset within PAMA was Section 1834A, “Improving Medicare Policies for Clinical Diagnostic Laboratory Tests.” This legislation enacted the first major change in CLFS pricing methods since the fee schedule was established in 1984.

PAMA ostensibly moves the CLFS to market-based pricing. The law requires “applicable laboratories” to report to CMS each price received from every payer for all nonbundled tests, together with price-specific volumes. CLFS payments will be derived from a weighted median of these data. The law threatens potentially draconian civil monetary penalties for mistakes, up to $10,000.00 per misrepresentation or omission per day.

Because Medicare continues to pay the new molecular pathology CPT codes on a fee-for-service basis for outpatients, payer-specific prices and volumes for molecular pathology tests will generally be reportable. Many hospitals and smaller laboratories may be unable to satisfy the new reporting requirements with their current information technology systems (15, 16). Therefore, if these entities are required to report test prices and volumes, many may abandon reportable testing to avoid the risk of penalties.

Hospitals clearly have individual interests in avoiding test reporting. However, their not-for-profit status, multiple missions, and provision of uncompensated laboratory technical and professional consultative services contribute to cost structures and payment rates that are typically increased relative to large commercial reference laboratories. Therefore, if the accompanying PAMA regulations are written so that hospital prices are excluded from the reported data, the volume-weighted median will be further skewed toward contracts between the largest laboratories and the largest insurers. This could have the effect of pricing many hospitals and smaller labs, and the more comprehensive services they may provide, out of the market.

Capturing the Value

Optimally, pricing for molecular pathology procedures would reflect the value these essential services bring to patients. Molecular pathology procedures are used to diagnose
and guide the use of targeted therapies to treat cancer. They end the diagnostic odysseys of parents seeking explanations for children’s illnesses and assist in family planning. They enable individuals who are predisposed to developing cancer to take prophylactic measures that can prevent the disease, thereby saving lives.

Molecular pathology tests constitute a small fraction of aggregate US healthcare expenditures. Given their enormous contribution to patient care, they are a bargain by any conventional standard.

The AMA RUC provided direct input recommendations to CMS for many of the new molecular pathology CPT codes. These recommendations were based on rigorous scrutiny of data that were supplied with assurances of anonymity by laboratories of varying types and sizes and reviewed by technical experts in molecular pathology. The RUC process produced fair and accurate pricing for the molecular codes, and its recommendations should have been accepted. For services that contain physician work, RUC valuation continues to be the most fair, reliable, and accurate method of price determination. The CLFS system would benefit from the incorporation of a similar peer-based valuation system.

However, if market-based pricing data are to be used for price determination, such data should come from insurance companies that purchase laboratory services, rather than laboratories themselves. This approach would place the burdens of data collection and reporting on the stakeholders who are best able to bear them. Moreover, ultimate payment levels should take into account the range of settings and comprehensiveness of molecular services provided. Finally, pricing should be generated in a nondiscriminatory manner that attempts to preserve the richness of the field and fosters its growth and advancement. Only in this way can our enormous investments in genomic sciences achieve maximum benefits for our patients.

Author Contributions: All authors confirmed they have contributed to the intellectual content of this paper and have met the following 3 requirements: (a) significant contributions to the conception and design, acquisition of data, or analysis and interpretation of data; (b) drafting or revising the article for intellectual content; and (c) final approval of the published article.

Authors’ Disclosures or Potential Conflicts of Interest: Upon manuscript submission, all authors completed the author disclosure form. Disclosures and/or potential conflicts of interest:

Employment or Leadership: R.D. Klein, Association for Molecular Pathology’s (AMP) Professional Relations Committee, American Medical Association CPT Molecular Pathology Workgroup, AMA CPT Molecular Pathology Advisory Group (MPAG), AMA CodeBridge Mapping Panel, and College of American Pathologists Economic Affairs Committee.

Consultant or Advisory Role: None declared.

Stock Ownership: None declared.

Honoraria: R.D. Klein, Speaker, Cambridge Healthtech Institute, Molecular Medicine TriCon.

Research Funding: None declared.

Expert Testimony: None declared.

Patents: None declared.

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