Reimbursement for Molecular Diagnostics

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Overview of Changes to Molecular Diagnostic Test Reimbursement

• Molecular pathology (MoPath) codes provide a consistent framework for laboratories to label molecular diagnostics tests, enabling payers (i.e., Medicare, private insurance companies) to properly identify and bill for services.

• Until recently, these codes were based on the type of test being performed and not the analyte being analyzed. This made it difficult for payers to identify and properly reimburse molecular diagnostics tests.

• The new MoPath codes set out by the American Medical Association (AMA) Current Procedural Terminology (CPT) replace the previous methodology-based "stacking" MoPath codes with analyte-specific codes.

http://www.illumina.com/clinical/diagnostics/reimbursement/
Overview of Changes to Molecular Diagnostic Test Reimbursement

MoPath codes are categorized into Tier 1 and Tier 2 codes:

• **Tier 1 codes** represent the majority of commonly performed single-analyte molecular tests.

• **Tier 2 codes** represent procedures that are generally performed in lower volumes than Tier 1 procedures (e.g., when the incidence of the disease being tested is rare), and correspond to nine ascending levels of technical resources and interpretive work performed by the physician or other qualified healthcare professional.

• On January 1, 2013, the “stacking” codes (CPT 83890-83914; 88384-88386) were retired and are no longer available for provider billing. Therefore, *laboratories are now required to use the new MoPath codes when billing for molecular diagnostic services.*

http://www.illumina.com/clinical/diagnostics/reimbursement/
Previous “Stacking” Codes

• Molecular pathology code “stacks” (83890 – 83914)
  – Series of CPT codes that represent steps/techniques used in performing test
    • Multiple technique CPT codes may be needed to represent one test /analyte
    • Multiple quantities may be needed for each CPT code.
      – Example: KRAS (codon 12, 13, 61)
      – 83898 X 2 amplification, single exon
      – 83904 X 2 sequencing / primer ext.
      – 83912 X 1 Interp & Rpt PCR

• Array codes 88384 – 88386 (for 10 – 500 probes)
Previous Billing System

Overview of Changes in Reimbursement and Coding for Molecular Pathology Testing, May 30, 2012; Michelle Ruben, MD

Anderson Cancer Center
Previous Billing System

- Different providers may “stack” differently
  
  **Provider A**
  Test: TP53
  
  - LIS converts to Stacked Codes & sends to Billing System
  - Sends out codes to bill
  - 6 x 83898
  - 6 x 83904
  - 1 x 83912

  **Provider B**
  Test: TP53
  
  - LIS converts to Stacked Codes & sends to Billing System
  - Sends out codes to bill
  - 5 x 83898
  - 5 x 83904
  - 1 x 83912
Previous Reimbursement Methodology

<table>
<thead>
<tr>
<th>Molecular “Stacked” Codes</th>
<th>CPTs</th>
<th>CLFS</th>
<th>OPPS</th>
<th>PFS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular techniques/steps</td>
<td>83890 – 83911, 83913 – 83914</td>
<td>✔</td>
<td>☒</td>
<td>☒</td>
</tr>
<tr>
<td>Molecular Interp &amp; Report</td>
<td>83912</td>
<td>✔</td>
<td>☒</td>
<td>✔ (w/ mod 26)</td>
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<tr>
<td>Molecular Array Codes</td>
<td>88384 – 88386</td>
<td>☒</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

- Mostly paid under CLFS, with Interpretation & Report also paid under the Professional Fee Schedule.
- Allows for separate payment for PhDs (or even techs) for Interpretation & Report on the technical side.
- Current Array codes are paid under OPPS instead of CLFS.
Issues with the Previous System

• Payers and other stakeholders could not readily determine what test was being run from billing data
• Medical Record Review Necessary to determine appropriateness of the test
• System allowed for significant differences between labs
• Everyone was confused
• Wide-spread agreement that an overhaul was needed.
AMA CPT Editorial Panel
Molecular Pathology Coding Workgroup

• December 2009 - convened to create new guidelines, definitions, and CPT codes
• Representation: Medicare carriers, CMS, private payers, related medical specialties, and industry
• Focus: molecular assays in cancer, genetics and histocompatibility (HLA – molecular based, not serology based).
• Working toward transparency: New coding scheme is more specific to allow for identification of tests being performed.
New Coding Scheme – Part 1
(Published in 2012 CPT)

Two-tiered system (within Category 1) published in 2012 code set:

**Tier 1:** High volume tests that will be identified with a unique, specific CPT code

Example: 81275 - KRAS gene analysis, variants in codons 12 and 13

**Tier 2:** Lower volume tests, grouped into one of 9 levels, with general descriptions.

Note: Reported analyte must be specifically included in the examples provided in the CPT book. (cannot self-assign)

Example: 81400 - Molecular pathology procedure, Level 1 (eg, identification of single germline variant [eg, SNP] by techniques such as restriction enzyme digestion or melt curve analysis)
### Tier 2 Example: Full Test Description for 81400

Molecular pathology procedure, Level 1 (e.g., identification of single germline variant [e.g., SNP] by techniques such as restriction enzyme digestion or melt curve analysis)

- **ACADM** (acyl-CoA dehydrogenase, C-4 to C-12 straight chain, MCAD) (e.g., medium chain acyl dehydrogenase deficiency), K304E variant
- **ACE** (angiotensin converting enzyme) (e.g., hereditary blood pressure regulation), insertion/deletion variant
- **AGTR1** (angiotensin II receptor, type 1) (e.g., essential hypertension), 1166A>C variant
- **CCR5** (chemokine C-C motif receptor 5) (e.g., HIV resistance), 32-bp deletion mutation/794 825del32 deletion
- **DPYD** (dihydropyrimidine dehydrogenase) (e.g., 5-fluorouracil/5-FU and capecitabine drug metabolism), IVS14+1G>A variant
- **F2** (coagulation factor 2) (e.g., hereditary hypercoagulability), 1199G>A variant
- **F5** (coagulation factor V) (e.g., hereditary hypercoagulability), HR2 variant
- **F7** (coagulation factor VII [serum prothrombin conversion accelerator]) (e.g., hereditary hypercoagulability), R353Q variant F13B (coagulation factor XIII, B polypeptide) (e.g., hereditary hypercoagulability), V34L variant
- **FGF** (fibrinogen beta chain) (e.g., hereditary ischemic heart disease), -455G>A variant
- **Human Platelet Antigen 1 genotyping (HPA-1)**, ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura),
  - **HPA-1a/b (L33P)** Human Platelet Antigen 2 genotyping (HPA-2), GP1BA (glycoprotein Ib [platelet], alpha polypeptide [GPIba]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura),
  - **HPA-2a/b (T145M)** Human Platelet Antigen 3 genotyping (HPA-3), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex], antigen CD41 [GPIIib]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura),
  - **HPA-3a/b (I843S)** Human Platelet Antigen 4 genotyping (HPA-4), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura),
  - **HPA-4a/b (R143Q)** Human Platelet Antigen 5 genotyping (HPA-5), ITGA2 (integrin, alpha 2 [CD49B, alpha 2 subunit of VLA-2 receptor] [GPIa]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura),
  - **HPA-5a/b (K505E)** Human Platelet Antigen 6 genotyping (HPA-6w), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa, antigen CD61 [GPIIIa]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura),
  - **HPA-6a/b (R489Q)** Human Platelet Antigen 9 genotyping (HPA-9w), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex, antigen CD41] [GPIIib]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura),
  - **HPA-9a/b (V837M)** Human Platelet Antigen 15 genotyping (HPA-15), CD109 (CD109 molecule) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura),
  - **HPA-15a/b (S682Y)**
  - **SERPINE1** (serpine peptidase inhibitor clade E, member 1, plasminogen activator inhibitor -1, PAI-1) (e.g., thrombophilia), 4G variant
New Coding Scheme – Part 2
Phase 2: MAAAs (in 2013)

Multianalyte Assays with Algorithmic Analysis (MAAA)

– Definition: Procedures that utilize multiple results derived from molecular pathology and other lab tests, which are then used in proprietary algorithmic analyses to derive a single result, reported typically as a numeric score or probability. They are typically proprietary or unique to a single vendor.

– Examples: Oncotype DX, Mammaprint

Tier 1 Codes for MAAAs – function just like traditional CPTs and are part of molecular pathology Tier 1.

Administrative Code List – also maintained by CPT, but not screened for clinical utility. Minimum standard is that they are available for patient care.
New Coding Scheme

Deletions: Mol Path stacked codes (83890 – 83914)
  – Mol Path array codes (88384 – 88386)
  – Genetic modifiers (Appendix I)

Additions: 8XX99 – New Unlisted code for Mol Path

New codes administered by:
  – AMA CPT Editorial Research & Development
  – Work through professional organizations (CAP, AMP, etc.)

Will continue to add new codes and descriptions; updates are expected ~ three times a year.

Creating a permanent “Molecular Pathology Advisory Group”
  – Panel of experts to advise CPT Editorial Panel
Setting Payment Rates

• Gapfilling is one of two methodologies that the Centers for Medicare and Medicaid Services (CMS) can employ to set the Medicare payment rate for a new CPT code that is reimbursed under the Clinical Laboratory Fee Schedule (CLFS).

• The second is crosswalking, which involves benchmarking payment for the new code to the same rate for comparable, existing test(s) or code(s).

• When CMS decides to gapfill payment for a new code, the local Medicare Administrative Contractors (MACs) are responsible for determining the appropriate fee schedule amounts in the first year. In the second year, CMS calculates a national payment rate based on the median of these local fee schedule amounts. This median payment rate is referred to as the National Limitation Amount (NLA).
Medicare Administrative Contractors (MACs)

http://www.illumina.com/clinical/diagnostics/reimbursement/
Physicians’ Professional Fees

• 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), which will go into effect in 2013.

• 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 CPT code.
Coding Challenges

• Descriptions are highly technical and specific
• Descriptions lack any flexibility in approach
• Descriptions, as currently written, will force the use of supplemental, unlisted codes
• The number of codes and tests is in the 100s, and growing rapidly
• Management and maintenance of descriptions will be difficult
Early Adopter Payer Example

Palmetto LCDs / MolDx Program

• Palmetto – MAC for jurisdiction J1 and J11. Implementing first in J1 (CA, NV, HA), then J11 (SC, NC, VA, WV)

• Creating their own molecular diagnostic evaluation program with “Z codes” to identify tests

• Laboratory provider is required to identify and provide scientific data (analytical and clinical validity, and clinical utility) to establish the CMS (Centers for Medicare & Medicaid Services) requirement of “reasonable and necessary.”

• Tests not paid without this data submitted and a Z-code assigned
Implications for the Diagnostic Test Industry

• Previous system was an impediment to innovation in diagnostic testing
• New tests can now be priced at the value of the information the test provides
• Need to undertake economic evaluation of the value of the test to support pricing
• Need to develop internal expertise in health economic research
• Need to allow for the extra time (and cost) for the payers to assess the economic evaluation