Overview of Changes in Reimbursement and Coding for Molecular Pathology Testing
May 30, 2012

Michelle Ruben
Project Manager, Revenue and Rate Setting Strategy
MD Anderson Cancer Center
Agenda

- Current State
- Molecular Pathology Coding Workgroup
- New Molecular Pathology Codes
- Coding Challenges
- Status of Implementation with Payers
- How will we get paid?
- Current Efforts
Current State
“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)
Example: Current Billing

**LIS**

- **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

- **Test: BRAF**
  - LIS converts to Stacked Codes & sends to Billing System
  - Sends out codes to bill:
    - 1 x 83898
    - 1 x 83904
    - 1 x 83912

- **Test: KRAS (12,13,61)**
  - LIS converts to Stacked Codes & sends to Billing System
  - Sends out codes to bill:
    - 2 x 83898
    - 2 x 83904
    - 1 x 83912
Current Billing

• Different providers may “stack” differently

Provider A
Test: TP53

• LIS converts to Stacked Codes & sends to Billing System

6 x 83898
6 x 83904
1 x 83912

• sends out codes to bill

Provider B
Test: TP53

• LIS converts to Stacked Codes & sends to Billing System

5 x 83898
5 x 83904
1 x 83912

• sends out codes to bill
# Current 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>X</td>
<td>X</td>
</tr>
<tr>
<td>Molecular Interp &amp; Report</td>
<td>83912</td>
<td>✓</td>
<td>X</td>
<td>✓</td>
</tr>
<tr>
<td>Molecular Array Codes</td>
<td>88384 – 88386</td>
<td>X</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 Current State

- Payers and other stakeholders cannot readily determine what test is being run from billing data
- Medical Record Review Necessary to determine appropriateness of the test
- System allows for significant differences between labs
- Everyone is CONFUSED!

Thus, wide-spread agreement that an overhaul is needed.
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.
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)
New Coding Scheme – Part 1
(Published in 2012 CPT)

Tier 2 Example: Full Test Description for 81400 *(yes this is just 1 code!!)*

Molecular pathology procedure, Level 1 (eg, identification of single germline variant [eg, SNP] by techniques such as restriction enzyme digestion or melt curve analysis)
* ACADM (acyl-CoA dehydrogenase, C-4 to C-12 straight chain, MCAD) (eg, medium chain acyl dehydrogenase deficiency), K304E variant
* ACE (angiotensin converting enzyme) (eg, hereditary blood pressure regulation), insertion/deletion variant
* AGTR1 (angiotensin II receptor, type 1) (eg, essential hypertension), 1166A>C variant
* CCR5 (chemokine C-C motif receptor 5) (eg, HIV resistance), 32-bp deletion mutation/794 825del32 deletion
* DPYD (dihydropyrimidine dehydrogenase) (eg, 5-fluorouracil/5-FU and capecitabine drug metabolism), IVS14+1G>A variant
* F2 (coagulation factor 2) (eg, hereditary hypercoagulability), 1199G>A variant
* F5 (coagulation factor V) (eg, hereditary hypercoagulability), HR2 variant
* F7 (coagulation factor VII [serum prothrombin conversion accelerator]) (eg, hereditary hypercoagulability), R353Q variant F13B (coagulation factor XIII, B polypeptide) (eg, hereditary hypercoagulability), V34L variant
* FGB (fibrinogen beta chain) (eg, hereditary ischemic heart disease), -455G>A variant
* Human Platelet Antigen 1 genotyping (HPA-1), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), 10
* HPA-1a/b (L33P) Human Platelet Antigen 2 genotyping (HPA-2), GP1BA (glycoprotein Ib [platelet], alpha polypeptide [GPIba]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), 10
* 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]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), 10
* HPA-3a/b (I843S) Human Platelet Antigen 4 genotyping (HPA-4), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), 10
* HPA-4a/b (R143Q) Human Platelet Antigen 5 genotyping (HPA-5), ITGA2 (integrin, alpha 2 [CD49B, alpha 2 subunit of VLA-2 receptor] [GPla]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), 10
* HPA-5a/b (K505E) Human Platelet Antigen 6 genotyping (HPA-6w), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa, antigen CD61 [GPIIIa]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), 10
* 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]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), 10
* HPA-9a/b (V837M)Human Platelet Antigen 15 genotyping (HPA-15), CD109 (CD109 molecule) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), 10
* HPA-15a/b(S682Y)
* SERPINE1 (serpine peptidase inhibitor clade E, member 1, plasminogen activator inhibitor -1, PAI-1) (eg, thrombophilia), 4G variant
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.

**Recommended action:** If your facility performs any of these either in-house, or bills for services sent out, request a CPT code to allow for billing.
2013 –The following changes are expected:

- **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 needed?**

- AMA CPT Editorial Research & Development 312-464-5486
  or mopath@ama-assn.org
  See CPT Process on www.ama-assn.org

- Work through professional organizations (CAP, AMP, etc.)

**Work will continue throughout the year 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
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.
Example 1: KRAS

Option 1: 81275 – KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, variants in codons 12 and 13

Option 2: 81403 – KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma), gene analysis, variant(s) in exon 2

But at MD Anderson - KRAS is performed using codons 12, 13, and 61.

Under the new system, how do we charge appropriately for full performance of the work associated with KRAS? How is codon 61 to be reported?
Current “Stacked” Charging Approach

KRAS (Codons 12,13,61)

<table>
<thead>
<tr>
<th>Current</th>
<th>TECHNICAL</th>
<th>T E C H N I C A L</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>Description</td>
<td>Qty</td>
</tr>
<tr>
<td>83898</td>
<td>Amplification, single exon <em>(12&amp;13, 61)</em></td>
<td>2</td>
</tr>
<tr>
<td>83904</td>
<td>Sequencing / primer ext. <em>(12&amp;13, 61)</em></td>
<td>2</td>
</tr>
<tr>
<td>83912</td>
<td>Interpretation &amp; Report</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PROFESSIONAL</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>Description</td>
</tr>
<tr>
<td>83912</td>
<td>Interpretation &amp; Report</td>
</tr>
</tbody>
</table>
Comparison of Approaches
Current vs. 2013

 KRAS (Codons 12,13,61)

<table>
<thead>
<tr>
<th>Current</th>
<th>Future 2013 (After Unlisted code provided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T E C H N I C A L</td>
<td></td>
</tr>
<tr>
<td>CPT</td>
<td>Description</td>
</tr>
<tr>
<td>83898</td>
<td>Amplification, single exon</td>
</tr>
<tr>
<td></td>
<td>(codons 12&amp;13, codon 61)</td>
</tr>
<tr>
<td>83904</td>
<td>Sequencing / primer ext.</td>
</tr>
<tr>
<td></td>
<td>(codons 12&amp;13, codon 61)</td>
</tr>
<tr>
<td>83912</td>
<td>Interp &amp; Report</td>
</tr>
<tr>
<td>P R O F E S S I O N A L</td>
<td></td>
</tr>
<tr>
<td>CPT</td>
<td>Description</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>83912</td>
<td>Interp &amp; Report</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Or, do we just use 81403?

(KRAS, gene analysis, variant(s) in exon 2)
81404 - Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)

*PDGFRA* (*platelet-derived growth factor receptor alpha polypeptide*) (eg, *gastrointestinal stromal tumor*), targeted sequence analysis (eg, *exons 12, 18*)

But at MD Anderson - PDGFRa is run first on exon 18 (detects most variants). If 18 is negative, only then it is run for 12 and 14.

In the new system, how do we charge appropriately for performance of the work associated with PDGFRa?
Example 2: PDGFRa

Initial Test: PDGFRa exon 18

Option 1: Use 81404, even though we run only 1 exon? General description indicates 2 – 5 exons, but this is where the specific description for PDGFRa 12 & 18 is.

Option 2: Use the new unlisted code 8XX99

Subsequent Test (only if needed): PDGFRa exon 12 & 14

Use 81404 here since it’s 2 exons and fits the specific analyte description.

OR - - Should we just bill 81404 once to reflect the entire series of 1 – 3 exons? Would it matter if they are run on different days or interpreted by different professional?
Status of Implementation with Payers

- To our knowledge, no payers have required implementation for 2012. (perhaps in other geographic areas)
- Some commercial payers are allowing either set of codes for 2012.
- Medicare / CMS
  - New codes do not appear on the 2012 Clinical Lab Fee Schedule.
  - New codes appear on the 2012 OPPS Schedule, but with a status of “B” (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B Type of Bill; An alternative code that is recognized by OPPS when submitted on an outpatient hospital Part B TOB may be available.)
  - New codes appear on the 2012 Professional Fee Schedule, but with a status of “I” (Not valid for Medicare Purposes – Medicare uses another code for reporting of, and payment for, these services.)
- Anticipate full implementation with all payers for 2013. (no choice without valid stacking codes)
Something to watch:

- **Palmetto LCDs / MolDx Program**
  - Creating their own molecular diagnostic evaluation program with “z-codes” to identify tests, reported in addition to stacking codes for 2012.
  - 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.
How will we get paid?

**Current Reimbursement (Medicare):**

<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>
</tr>
<tr>
<td>Molecular Array Codes</td>
<td>88384 – 88386</td>
<td>✗</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>
How will we get paid?

**Current Reimbursement (Medicare):**

<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>$100 - $400</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Molecular Interp &amp; Report</td>
<td>83912</td>
<td>$3 - 6</td>
<td>✗</td>
<td>$17 - 25</td>
</tr>
<tr>
<td>Molecular Array Codes</td>
<td>88384 – 88386</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

**Future Reimbursement (Medicare):**

<table>
<thead>
<tr>
<th>New Tier 1 &amp; Tier 2 Codes</th>
<th>CPTs</th>
<th>CLFS</th>
<th>OPPS</th>
<th>PFS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1 &amp; Tier 2 Codes</td>
<td>81200 - 81408</td>
<td>?</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>
How will we get paid?

Future Reimbursement:

<table>
<thead>
<tr>
<th>New Tier 1 &amp; Tier 2 Codes</th>
<th>CPTs</th>
<th>CLFS</th>
<th>OPPS</th>
<th>PFS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1 &amp; Tier 2 Codes</td>
<td>81200 - 81408</td>
<td>?</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>

- Some indication this will be on PFS, although nothing definitive
  - Many codes already valued through RUC (RVS Update Cmmt)
- Little clarity on whether it will appear in CLFS or OPPS
- Should become more clear once CMS meetings and draft rules begin this summer (~ July for CLFS Meeting and draft rules for OPPS and PFS)
Which Fee Schedule does the Provider Community Want?

• Pathologists support Physician Fee Schedule
  • CAP (College of American Pathologists) and AMP (Association for Molecular Pathology) both recommend that the codes be placed on the Physician Fee Schedule.
  • AACC (American Association for Clinical Chemistry) supports codes being placed on the Physician Fee Schedule if pathologist interpretation is required, with a separate way to recognize non-physician interpretation work as well.
  • Would help pathologists receive better compensation for interpreting tests.
  • Encourages pathologist participation in the field.
  • Provides for regular revision of the costs through RUC review.
Which Fee Schedule does the Provider Community Want?

- Laboratories relying on PhD interpretation support Clinical Lab Fee Schedule
  - Laboratory community is pushing for inclusion on the CLFS so they will retain their reimbursement for PhD work.
    - . . . Unless exception is made to allow for PhD reimbursement off PFS.
  - PFS would require co-pay from patient which is not currently required.
  - PFS would require higher cost resources to perform work and get reimbursed (eg, MD vs PhD), and would require physician signature.
1. Alliance of Dedicated Cancer Centers (ADCC) **Cross-walk Collaboration Project** to facilitate mapping of new codes and requests for additional codes.
   - Assist with complex cross-walk exercise that is required
   - Confirm accuracy of application of new codes
   - Gain economies of scale & leverage with new code applications

2. Trying to work with AMA to achieve greater transparency in the **process for assigning Mol Path CPT codes** and technical assistance in correctly applying the codes.

3. ADCC in on-going communications with CMS regarding how to price and on which fee schedule.
Questions?

Michelle Ruben
Project Manager, Revenue and Rate Setting Strategy
MD Anderson Cancer Center

mruben@mdanderson.org
713-563-8850