Molecular Testing Reimbursement: Mastering the Nuances Needed for Full Payment

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Scope of testing

- Molecular pathology - Nucleic acid targets
- “Almost everything”

- Infectious Diseases
- Inherited Diseases (Genetics)
- Oncology (Hematologic, solid tumor)
- Specialized areas (HLA, cytogenetics, etc)
- ‘Personalized Medicine’
- Sendout Testing
• CPT codes for molecular assays
• Assembling codes to describe services provided
• Edits which restrict billing for molecular assays
• Technical/medical necessity information to appeal denials, obtain coverage decisions

• Focus on outpatient testing
• Coding for some areas is complex, non-transparent and hence poorly understood by payers – denials & suboptimal coverage decisions
• Reimbursement varies, has not been updated for some time - and yet no shortage of players!
  ▪ Importance and potential for improved/personalized care
• Increasing Payer interest understanding what they are paying for puts pressure on field – pre-authorization

Not-that-distant Encounter

• Medicare CMD: How to set payment for Factor V Leiden testing? Another CMD suggested using a miscellaneous CPT code and picking a ‘fair number.’
• Several lab people pointed out that procedure-based CPT codes exist for molecular genetic testing. This was news to the inquiring CMD. Prepared outline showing how codes can vary when individual methods are correctly coded.
• Education of payers is important but the system itself is fundamentally flawed
Molecular CPT Codes

- Clinical Laboratory Fee Schedule - mostly
- Molecular Microbiology
  - Many codes (87XXX) series
- Genetics & Oncology
  - Procedural codes (“stacked”) – discussed in detail
  - ‘Genetics’ terminology is used loosely
- Specialty areas
  - Molecular Cytogenetics
    - FISH (88271-88275, 88291)
    - Arrays (88384, 88385, 88386)
  - Anatomic Pathology (Physician Fee Schedule)
    - FISH (88365, 88367, 88368)
    - Micro-dissection (88380, 88381)
    - Prep for molecular assays (88387, 88388)
  - HLA – complex

Molecular Microbiology - 1

- These are like other laboratory codes: one tests: one code
  - HSV
    - PCR - qualitative
    - 1 x 87529 $50.27
  - HIV viral load
    - PCR - quantitative
    - 1 x 87536 $121.88*
    - *$61.35 for other quantitative assays
  - HCV Genotype
    - PCR - quantitative
    - 1 x 87902 $368.73
Molecular Microbiology - 2

87520  28.72*  hepatitis C, direct probe  *note: HIV-1
87521  50.27*  hepatitis C, amplified probe
87522  61.35*  hepatitis C, quantification
87660  28.72  trichomonas, direct probe

87797-99  same infectious agent detection by NA probe, NOS
87800-01  57-101  multiple organisms, direct/amplified

Need to bill modifiers (-59) if >1 organism lacking a CPT code

Multiplex Respiratory viral panels 87798 x 8-12!

87900  186.69  drug susceptibility – genotype/bioinformatics
87901  368.73  HIV-1 genotype, RT and protease
87902  368.73  Hepatitis C genotype
87153  165.22  Bacterial ID by sequencing

Genetics and Oncology

• Coded by procedural steps performed
  ▪ Multiple different codes per test
  ▪ Multiple units of service for an individual code
• Same analyte may need different combinations of codes according to the method used
  ▪ Factor V Leiden by PCR/RFLP (LDT)
  ▪ Factor V Leiden by Invader (Hologic)
  ▪ Factor V Leiden by PCR melt analysis (Roche)
  ▪ Others
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<th>BC</th>
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<td>8.56</td>
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<tr>
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<tr>
<td>83893</td>
<td>dot/slot blot production, EACH preparation</td>
<td>5.74</td>
<td></td>
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<tr>
<td>83894</td>
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**Mitochondrial MELAS^**

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<td>3 x 83890</td>
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**RBM 450 Panel^**

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<tbody>
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<tr>
<td>X x 83890</td>
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<td>17.22</td>
<td>&gt;11K</td>
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^ Figures do not include interpretation/report for Genetics or Oncology tests

**Code Stacking**

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<td>8.56</td>
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<tr>
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<td>10.8K</td>
<td>17.22</td>
<td>&gt;11K</td>
</tr>
</tbody>
</table>
• **COL2A1 & COL11A1 genes – bill from reference laboratory**

<table>
<thead>
<tr>
<th>#</th>
<th>CPT Code</th>
<th>Description</th>
<th>Fee</th>
</tr>
</thead>
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<tr>
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<td>83890</td>
<td>DNA extraction</td>
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<tr>
<td>131</td>
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<td>PCR amplification</td>
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<tr>
<td>131</td>
<td>83894/83909</td>
<td>Electrophoresis</td>
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<tr>
<td>138</td>
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<tr>
<td>1</td>
<td>83912-26</td>
<td>Interpretation &amp; Report</td>
<td>$564</td>
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</table>

**COL2A1**: Exon 41, c.3003G>A, p.Ser1001Ser  
**COL11A1**: No abnormalities  
Recommend testing parental samples – no charge

### Coding Issues

• Consistency  
  - Labs often code the same assay differently  
• Wishful (‘aggressive’) coding  
  - “We get paid – coding must be correct”  
• Multiplex assays (e.g. respiratory viruses)  
  - What if one test only is ordered?  
• Assays using Invader® technology  
• Arrays - # of probes or # of targets (CF)  
• Coding for ‘controls’
Coding Resources

- CAP Economic Affairs Committee
  - CPT Coding Tutorials (CAP)
  - Frequently deal with queries to AMA
- AMP Economic Affairs Committee
  - Coding and Coverage Corner
  - Coding conundrums – Annual Meeting
- Consultants - colleagues/friends!
- Specific courses/tutorials
- Other organizations, e.g. AACC, ACMG, ASM

Edits

- National Correct Coding Initiative (NCCI) Edits
  - Components of a more comprehensive service delivered the same day of service
  - Oncology patient with 87798 (amplified viral target) and any from 83890-83912 series to monitor Rx
  - 88271 through 75 and and 88365 (interpretation for karyotype and FISH assay); -59 modifier
- “Medically Unlikely Edits” (MUEs)
  - Purpose - deny payment for numerical errors,
  - Issued quarterly – generally not published >3
  - Criteria: statistical based on claims data
  - Issued by NCCI Contractor
Coding and Edits – Annual Tasks

• See if assays are still correctly coded
• Examine new codes for services previously performed and not coded, e.g. 88387
• Line description of code may not be sufficient; clinical vignette and description of service
• Applies also to sendout tests – query those labs

Coding and Edits – Annual Tasks

• Contracts: negotiate concessions for provision of patient data desired by payers
• Review claims denials due to edits
  ▪ Have you/your billing office discerned what the likely MUE is?
  ▪ If a modifier is permitted, bill separate lines
• Consultation Opportunities? – 80500/80502
  ▪ Pharmacogenetics, non-molecular areas (coag)?
  ▪ Separate request, report, abnormal or unexpected result
Coverage Issues

• Policies drafted by payers
  ▪ Draft policies available for comment – challenge is to be aware of what is pending
    • CMS contractors have Carrier Advisory Committees (CACs)
  ▪ Lack of coverage decisions not a problem; assume covered if not specifically excluded

• Increasing interest in clinical utility with payment for tests that contribute to positive outcomes; evidence-based medicine
  ▪ Work directly with private insurers

Coverage Decisions - Tasks

• Appeal denials of payment – patience and support of senior management
• Ask for revisions or withdrawal of flawed coverage decisions
  ▪ Targeted policies make sense but can result in LCDs applied to CPT codes used for other testing whose only officially covered uses are for a limited spectrum of ICD-9 codes
  ▪ Once-in-a-lifetime genetic testing (Noridian)
    ▪ ‘Logical’ except tests may improve over time
• Bring evidence – peer-reviewed publications in US journals on US patients are most convincing
• Keep after Medical Directors
Sendout Testing

- BIG savings opportunity
- Send vs. Buy
  - Large savings (5-50+X)
  - Payer mix for reimbursement
  - PT costs (regular and/or alternate)
- 3rd Party Billing
  - Reference lab bills insurance directly, patient a fixed amount
  - Special rates for self-pay patients
  - May not be possible depending on compliance policies
- Large reference lab vs. specialty subsidiary
  - Cost vs. TAT

Sendout testing

- Molecular assays are typically expensive
- Sendout testing - lab control and responsibility
  - Utility – utilization review
    - Physicians don’t necessarily know these and are ‘detailed’
    - How will results be used in patient care?
    - Tiered (or sequential) testing? One or two analytes often much more likely to be associated with positive result
  - Where to send
    - Beware of Niche laboratory (with sales force) techniques
      - Sales representatives push panels of tests with referring MDs
      - Design of requisitions
      - Beware of helpful ‘follow-up’ after submitting targeted testing
  - Follow up: ‘yields’ on testing by clinic or even MD
Utilization Review

• Utilization Review
  - Can be combination of staff and/or physician, but must have physician backing and active participation

• Pathologist as consultant for molecular sendouts
  - Develop a system to identify requests which need attention
  - Recommend ‘tiered’ testing as appropriate - example to follow
  - Review ‘yield’ on expensive tests, primarily genetics/oncology
  - Alternate methods available - FISH/functional assay?
  - Know who pays (lab, patient insurance, patient)

• Follow-up responsibilities
  - Order ‘reflex’ tiered testing, stay in touch with clinician
  - Follow-up tests with long TATs
  - Result review and entry to EMR – talk with colleagues about interesting or problematic results, refer to others as needed

Sendout Testing for Charcot-Marie-Tooth Disease (HMSN)

• Complete CMT - $10,475
  - PMP dup/del, type 1A
  - MPZ, type 1B/2
  - CMT-X linked (connexin-32)
  - 13 other gene tests for type 1, 2 or 4; most rare or unknown incidence (16 total)
  - There is no ‘short’ panel with PMP22 dup/del and MPZ

• Individual tests - $2,735
  - PMP Dup/del  $  685
  - MPZ  $  685
  - CMTX  $ 1365

  - Savings  $ 7740

• Recommendations
  - Hered (M to M): PMP + MPZ
  - Hered (no M to M) or no Fam hx: PMP+MPZ+ CMTX
  - X-linked inheritance: CMTX
  - CMT2 phenotype: MPZ + CMTX

Disclaimer: ‘Partial’ panels are available; note: institutional prices, August 2009
TPMT (Thiopurine methyl transferase) is an enzyme which metabolizes azathioprine or 6-mercaptopurine which are used in the Rx of inflammatory bowel disease (IBD) and some acute leukemias.

The lab began receiving samples for TPMT genotype to be sent to an outside laboratory (supported by a national sales force) which offers tests aimed at clinicians treating IBD.

The genetic test assesses common variants associated with functional loss of TPMT activity.

A blood assay for TPMT enzyme activity available from another laboratory costs ~80% of genotype fee.

Responsibility for sendout testing was transferred to chemistry laboratory, and molecular volume decreased to zero(!)

Limitations of genetic and enzymatic tests.

Alternate methods

- TPMT (Thiopurine methyl transferase) is an enzyme which metabolizes azathioprine or 6-mercaptopurine which are used in the Rx of inflammatory bowel disease (IBD) and some acute leukemias.
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- The genetic test assesses common variants associated with functional loss of TPMT activity.
- A blood assay for TPMT enzyme activity available from another laboratory costs ~80% of genotype fee.
- Responsibility for sendout testing was transferred to chemistry laboratory, and molecular volume decreased to zero(!)
- Limitations of genetic and enzymatic tests.
Genetic Testing Sendout ‘Yield’

<table>
<thead>
<tr>
<th>Test</th>
<th>Neg</th>
<th>Pos</th>
<th>Possible</th>
<th>Other family</th>
<th>Rate %</th>
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Sendout Testing - Tasks

- Review sendout testing patterns
  - Buy vs. perform (if that is an option)
  - Consolidate reference laboratories (reduced prices, shipping costs, hassle for lab staff)
  - Mother ship vs. provider owned by mother ship
- Talk to friends/colleagues, payers about reimbursement policies tests you are considering bringing in-house
- Review utilization review efforts, new directions
- Contracts:
  - 3rd party payers
  - ?negotiate additional reimbursement concessions for provision of patient data desired by payers?
‘Enhancing’ the system

• AMA CPT Panel
  - Molecular Pathology Workgroup
  - More transparency for payers and labs
  - High numbers (units of service) must go
  - Sooner vs. later
  - Lots of different tests being done
    • Some very high volume
  - Open process (with confidentiality agreement)
    • Meetings before each Panel Meeting

• Transparent system should promote more rational coverage decisions

• Codes also as vehicles for refined understanding of patterns and patient outcomes (McKesson)

• New money for molecular testing?

Trends/Movements

• Molecular tests are complex and require sophisticated technical interpretation
  - Some/many may be appropriate for Physician Fee Schedule
  - RUC Valuation process vs. CLFS

• ‘Value-based’ Reimbursement
  - Payment should reflect (reward) overall savings to the healthcare system
  - Oncology assay with companion algorithm
    • ~$3,500 (paid on miscellaneous CPT code) with >$10,000 savings per patient with test – 3X benefit, 1 QALY = $34,000 (<$50,000 considered cost-effective)
  - Performance-based payment
    • No benefit to patient – payer gets refund
    • Applicable to established lab tests, e.g. troponin?
Trends/Movements - 2

• Reimbursement for development costs
• Reimbursement for Multiplex Testing, and while not yet here, likely full genome sequencing.
• 14 day 'wait' on hospital-acquired specimens
  ▪ $100M Demonstration project (Wyden Amendment) in Healthcare Reform bill
• Increased reliance of CPT Editorial Panel on evidence of utility for category 1 CPT codes
• Increased reliance by payers on coverage with evidence development (e.g. CMS and warfarin)
• Bundling
  ▪ Tests included with therapies
  ▪ Outpatient DRGs?

“All the things I could do…. if I had a little money........”

Money, Money, Money
ABBA, 1976