Clinical Utility of Molecular Diagnostics in Oncology

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Molecular Diagnostic Testing Challenges

- Coding issues
- Evidence
- Reasonable & Necessary
- Reimbursement
Coding Issues

- Insufficient CPT codes
- Inadequate CPT code descriptions
- Absent assay specificity for payment
- Absent ability to data mine
Supporting Scientific Evidence

- Undefined utilization
- Absent evidence-based decisions
- Absent *published* clinical utility or evidence-based decisions:
  - Improves patient outcomes, and/or
  - Changes physician management
“Reasonable & Necessary”

• CMS clarified R&N* – includes safe & effective, & improved health outcomes

• Absent published clinical evidence by:
  • RCTs, trials without randomization, cohort or case controlled trials
  • Professional societies - ASCO, NCCN, CAP
  • Subject matter experts

*42CFR Part 405
Clinical Utility

• Improved clinical outcomes:
  • Functional status
  • Quality of life
  • Disability
  • Major clinical events
  • Death

• Changes physician decision / mgmt
Adequate Clinical Utility

Palmetto GBA considers:

- RCT & well-designed controlled trials
- Cohort and case studies, multicenter
- “Accepted for publication”
- White papers by SMEs
- Professional association guidance
- Abstracts
Coverage Determinations

- Absent transparency
  - To educate physician providers
  - To educate beneficiary
- Absent review timelines
- Absent review by SMEs
- Coverage LCDs / articles
MolDx Solutions

- Require test registration
- Assign Z-code™ or PTI
- Perform tech assessment
- Publish coverage determination
- Establish reimbursement
MolDx Program Details

- Select
  - Palmetto GBA home page
  - Select from left side bar: J1 Part B MAC
  - Select at lower left: MolDx beside image of spiraling double helix, or
  - [http://www.palmettogba.com/Palmetto/Providers.nsf/docsCat/Providers~Jurisdiction%20Part%20B~Articles~MolDx?open](http://www.palmettogba.com/Palmetto/Providers.nsf/docsCat/Providers~Jurisdiction%20Part%20B~Articles~MolDx?open)
Test Registration

- MolDx Test Registry - Manual
  - Process Instructions – registration link included
  - Download Excel template
- McKesson DEX™ Solution – Web-based Summer, 2012
  - Collect/store registration data
  - Allows online status/tracking
  - Facilitates Tech Assessment process
  - Repository for public documents
<table>
<thead>
<tr>
<th>MolDx Exempt (no Z-Code or TA required)</th>
<th>Z-Code Required NO Tech Assessment Required</th>
<th>Z-Code Required Tech Assessment Required</th>
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| Tests specifically described by a single CPT/HCPCS code and submitted with one unit of service | Any test that meets the following:  
  - 101 New MDT CPT codes  
  - FDA cleared/approved (unmodified) tests  
  - Current New York State (NYS) approved tests  
  - Grandfathered NYS tests developed prior to 2003  
  - National Institute of Health Genetic Testing Registry (GTR) | A laboratory developed test (LDT) producing a single result and billed with multiple CPT codes including any combination of the following:  
  - methodology-based stacking CPT codes (83890-83914)  
  - micro-array CPT codes (88384-88386)  
  - microdissection CPT codes (88380-88371)  
  - other pathology/laboratory codes |
| Infectious disease molecular diagnostic testing described by CPT codes (87001-87905) | Coverage Determination by Palmetto GBA LCD or Article, i.e.  
  - Tumor of origin assays  
  - OncotypeDX Breast™  
  - OncotypeDX Colon™  
  - Allomap™  
  - HERmark™ | MDT/LDT that provides  
  - diagnostic determination  
  - prognostic/predictive determination  
  - risk assessment  
  - screening |
| Cytogenetics – CPT codes 88230-88291 |  | Pathology and Laboratory Not Otherwise Classified (NOC) codes  
  - Modified FDA cleared/approved tests |
| Surgical Pathology (CPT codes 88300-88372) including the following:  
  - Flow cytometry – CPT codes 88182-88189  
  - Immunohistochemistry (IHC) CPT code 88342  
  - in situ hybridization (ISH) testing CPT code 88365 |  | |

Note: For any test that does NOT match criteria in this chart, e-mail MolDx@PalmettoGBA.com.
Effective June 1, 2012

- J1 only

- Mandatory unique identifier (Z-code or PTI) for claim submission

- Z-code or PTI in claim narrative field

- Claim rejects without unique identifier in narrative field
Technical Assessment

- Review
  - Dossier & References – submitted by lab / mfg
  - Clinical Evidence Review – in public domain
- SMEs – Academia/industry
- Publish Tech Assessment summary
- Tech assessment is NOT coverage decision
MolDx Summary

- Unique Z-code or PTI identifier per assay
- Interactive data repository (McKesson Diagnostic Exchange™)
- Tech Assessment by SMEs
- Timeline accountability
- Published coverage decisions
- Expanded reimbursement data evaluation
Questions?