

# **Molecular Diagnostic Testing Challenges**

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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 / absent indications
- 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

- <http://www.palmettogba.com/palmetto/palmetto.nsf/DocsCat/Home>
- 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%201%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

<b>MolDx Exempt (no Z-Code or TA required)</b>	<b>Z-Code Required NO Tech Assessment Required</b>	<b>Z-Code Required Tech Assessment Required</b>
Tests specifically described by a single CPT/HCPCS code and submitted with one unit of service	Any test that meets the following: <ul style="list-style-type: none"> <li>• 101 New MDT CPT codes</li> <li>• FDA cleared/ approved (unmodified) tests</li> <li>• Current New York State (NYS) approved tests</li> <li>• Grandfathered NYS tests developed prior to 2003</li> <li>• National Institute of Health Genetic Testing Registry (GTR)</li> </ul>	A laboratory developed test (LDT) producing a single result and billed with multiple CPT codes including any combination of the following: <ul style="list-style-type: none"> <li>• methodology-based stacking CPT codes (83890-83914)</li> <li>• micro-array CPT codes (88384-88386)</li> <li>• microdissection CPT codes (88380-88371)</li> <li>• other pathology/laboratory codes</li> </ul>
Infectious disease molecular diagnostic testing described by CPT codes (87001-87905)	Coverage Determination by Palmetto GBA LCD or Article, i.e. <ul style="list-style-type: none"> <li>• Tumor of origin assays</li> <li>• OncotypeDx Breast™</li> <li>• OncotypeDx Colon™</li> <li>• Allomap™</li> <li>• HERmark™</li> </ul>	MDT/LDT that provides <ul style="list-style-type: none"> <li>• diagnostic determination</li> <li>• prognostic/predictive determination</li> <li>• risk assessment</li> <li>• screening</li> </ul>
Cytogenetics – CPT codes 88230-88291		Pathology and Laboratory Not Otherwise Classified (NOC) codes
Surgical Pathology (CPT codes 88300-88372) including the following: <ul style="list-style-type: none"> <li>• Flow cytometry – CPT codes 88182-88189</li> <li>• Immunohistochemistry (IHC) CPT code 88342</li> <li>• <i>in situ</i> hybridization (ISH) testing CPT code 88365</li> </ul>		Modified FDA cleared/approved tests
Analyte Specific Reagents (ASR)		

Note: For any test that does NOT match criteria in this chart, e-mail [MolDx@PalmettoGBA.com](mailto: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?**