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

- 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

MolDx Exempt (no Z-Code or TA required)	Z-Code Required NO Tech Assessment Required	Z-Code Required Tech Assessment Required
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
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		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.

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?