The Future of Reimbursement for Lab Developed Mass Spec Assays

Charles Root, PhD
CodeMap, LLC
Schaumberg, IL

AACC/MSSS Mass Spectrometry and Separation Sciences
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The Future of Reimbursement for Lab Developed Mass Spec Assays . . .

- What is a Lab Developed Test (LDT) and how are they different from other tests and procedures?
- How are Mass Spec based LTDs coded and reimbursed?
- How will the Protecting Access to Medicare Act (PAMA) treat Mass Spec based LTDs? Will they be considered Advanced Diagnostic Tests?
- What future changes in coding and reimbursement are likely to occur

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Lab Developed Test (LDT) Definitions

- FDA definition: Test that is designed, manufactured and used within a single laboratory
- CLIA definition: Non-FDA cleared test or modification of FDA cleared test validated based an individual lab's methodology, equipment, clinical use and patient population
- LDTs can only be clinical laboratory tests, physician services (surgical pathology procedures for example) are not considered LDTs.

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Why are LTDs developed?

- No FDA cleared kit available for a particular analyte
- FDA product labeling does not include desired specimen, clinical use, or analytical range/precision
- Analytical technique is not appropriate for development of analyte specific FDA cleared products
- Unique performance characteristics are required by physicians who order the test

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Current Coding for Mass Spec Based LDT's:

- The most common Mass Spec LDTs are for urine drug testing
- Most are HPLC/MS/MS based
- Coding history for these tests provides insight into how codes and payment may evolve in other clinical areas
- Most other clinical applications have not received much attention because of their limited use to date . . .

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Current Coding for Mass Spec Based LDT's: Urine Drug Testing

For 2015, the AMA

- reorganized existing CPT codes for drug determinations;
- implemented more than 60 new and revised CPT codes for drug determinations;
- created 3 new subsections for:
  - **PRESUMPTIVE DRUG TESTS (screening) 80300 – 80304**
  - **DEFINITIVE DRUG TESTS (identifies specific drugs, metabolites, and structural isomers) 80320 – 80377**
  - **THERAPEUTIC DRUG TESTS 80150 - 80299**

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Current Coding for Mass Spec Based LDT's: Urine Drug Testing

- Presumptive urine drug testing by Mass Spec . .
- 80304 Drug screen, any number of drug classes, presumptive, single or multiple drug class method, not otherwise specified presumptive procedure (e.g. TOF, MALDI, LDTD, DESI, DART), each procedure

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2015 Definitive Drug Testing Codes:

21 existing quantitative drug testing codes were deleted and replaced with 58 new **DEFINITIVE** drug testing codes including:

13 New single drug codes

42 New drug class codes

3 New "not otherwise specified" codes for all others

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2015 Definitive Drug Testing Codes Single Drug Codes

- 80348 Buprenophine
- 80353 Cocaine
- 80355 Gabapentin, non-blood
- 80357 Ketamine and Norketamine
- 80358 Methadone
- 80360 Methylphenidate
- 80365 Oxycodone
- 83992 Phencyclidine
- 80367 Propoxyphene
- 80366 Pregabalin
- 80367 Propoxyphene
- 80372 Tapentadol
- 80373 Tramadol

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2015 Definitive Drug Testing Codes: Drug Class Codes

Other drugs are coded by class and number of drugs tested, for example:

- 80324 Amphetamines; 1 or 2
- 80325 Amphetamines; 3 or 4
- 80326 Amphetamines; 5 or more

- 80346 Benzodiazepines; 1 - 12
- 80347 Benzodiazepines; 13 or more

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Coding Rules for Definitive Testing

- Definitive procedures can be either qualitative or quantitative.
- Drugs not listed in codes 80320 – 80373 should be reported with an unlisted definitive code:
  - **80375** Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 1-3
  - **80376** Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 4-6
  - **80377** Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 7 or more
- Choice of code is based on the number or reported analytes.

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Coding Rules for Therapeutic Drug Assays

- Therapeutic Drug Assays are performed to monitor clinical response to a known, prescribed medication.
- Therapeutic drug assay codes always describe quantitative analyses.
- Specimen sources must **be blood, serum, plasma, or cerebrospinal fluid.**

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Medicare Uses G codes for Drug Testing

- In September, CMS stated their concern about the "potential for overpayment when billing for each individual definitive drug test rather than a single code that pays the same amount regardless of the number of drugs tested.
- For this reason, they are maintaining the 2014 status quo for 2015 and have created new HCPCS G codes to replace the 2014 CPT codes that were deleted from the CPT.

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Medicare G Codes for Drug Testing

For example . . .

- **G6039** Acetaminophen $27.54
- **G6040** Alcohol (ethanol); any specimen except breath $14.70
- **G6041** Alkaloids, urine, quantitative $40.85
- **G6030** Amitriptyline $24.35
- **G6042** Amphetamine or methamphetamine $21.15
- **G6043** Barbiturates, not elsewhere specified $15.58
- **G6031** Benzodiazepines $25.17

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Medicare G Codes for Drug Testing

CONFIRMATION TESTING

The following new G code will be used to report drug confirmation testing

- **G6058** Drug confirmation, each procedure
- Medicare Reimbursement: **$18.03**

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Coding for Other New Mass Spec Based LTDs

- Rules are same for virtually any type of new assays: i.e., proteins, steroids, infectious agents, endocrine assays, etc.
- Rule 1. Does an existing analyte specific code already exist?
  If yes, that code must be used if no analytical method is specified
- Rule 2. If no applicable code exists, general method codes for mass spec and chromatography/mass spec are reported.

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Current Mass Spec Method Codes

- **83788** Mass spectrometry and tandem mass spectroscopy (MS, MS/MS), analyte not elsewhere specified, qualitative, each specimen
- **83889** quantitative, each specimen

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Current Chromatography/Mass Spec Method Codes

- **82541** Column chromatography/mass spectrometry (e.g., GC/MS or HPLC/MS), non-drug analyte not elsewhere specified; qualitative, single stationary and mobile phase
- **82542** quantitative, single stationary and mobile phase
- **82543** stable isotope dilution, single analyte, quantitative, single stationary and mobile phase
- **82544** stable isotope dilution, multiple analytes, quantitative, single stationary and mobile phase

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2016 Chromatography/Mass Spec Method Codes

- **82542** Column chromatography, includes mass spectrometry, if performed (eg, HPLC, LC, LC/MS, LC/MS-MS, GC, GC/MS-MS, GC/MS, HPLC/MS), non-drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen
- **83789** Mass spectrometry and tandem mass spectrometry (eg, MS, MS/MS, MALDI, MS-TOF, QTOF), non-drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen

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Mass Spec Method Code Reimbursement

- All current mass spec and chromatography/mass spec method codes are reimbursed the same amount by Medicare:
- $24.58 per specimen or per stationary/mobile phase if used with chromatographic separation
- For 2016 reimbursment is "per specimen" for all codes
- 2016 Reimbursement for revised codes will be the same since they are not "new" codes.

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Coding New Mass Spec Assays . . .

Example 1: 25-hydroxy Vitamin D and fractions

- An existing codes for 15-hydroxy vitamin D exists:
  - **82306** Vitamin D; 25 hydroxy, includes fraction(s) if performed
- The above code must be used
- Reimbursement for 82306 is $40.29

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Coding New Mass Spec Assays . . .

Example 2: Respiratory Virus Panel by MALDI

- 6 respiratory viruses determined, reported as pos/neg (influenza virus, Rhinovirus, RSV, Adenovirus, Coronovirus Parainifuenza virus)
- Existing codes for for the above organisms all specify non-MS methods (immunofluoresence, EIA, DNA, or direct optical observation), thus a Mass Spec method code must be used.
  - **83788** Mass spectrometry and tandem mass spectroscopy (MS, MS/MS), analyte not elsewhere specified, qualitative, each specimen
- The code can be reported only once for each specimen
- Reimbursement will be $24.58 compared to $290.45 if performed by DNA based method

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Future Market Based Reimbursement for Lab Tests

Congress has passed legislation to totally revise how Medicare pays for lab tests. . .

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Reimbursement for Lab Tests Currently on the CLFS and PFS

- Effective January 1, 2017 reimbursement will be based on the rates paid by commercial insurance including:
  - Medicare Advantage plans
  - Medicaid managed care organizations
- During 2016, Laboratories will be required report the volume and amounts received from all third party payers for all tests performed during a specified period of time.
- Rates must include all discounts and other price concessions
- Effective 1/1/2017, payment for each test on the CLFS will be based on the weighted median of all payment amounts for that test.

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Advanced Diagnostic Test (ADT) Definition

- An ADT is a test offered and furnished by a single laboratory,
- not sold by any laboratory other than the original developing laboratory or a successor owner, and
- meeting one of the following criteria:
  - The test is an analysis of multiple biomarkers of DNA, RNA or proteins combined with a unique algorithm to yield a single patient-specific result
  - The test is cleared or approved by the FDA
  - The test meets other similar criteria established by the CMS
  - Thus, many mass spec LDTs will probably be classified as ADTs

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Payment for Advanced Diagnostic Tests

- For ADTs not currently paid under the CLFS . . .
- During an "initial period" of 3 quarters, payment will be the list charge for the test.
- The laboratory must report the actual payments received from all private payers no later than last day of the second quarter of the initial period period
- After the initial period, the market rate payment will be the median of the actual amounts reported
- If list charge exceed market rate by more then 30%, CMS will recoup difference
- Payment will remain same until next data collection period.

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Contact Information

Charles Root, Ph.D.
charlesroot@codemap.com

CodeMap®
1901 N. Roselle Rd., Suite 640
Schaumburg, IL 60195
www.codemap.com

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