

The Future of Reimbursement for Lab Developed Mass Spec Assays

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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

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 on 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.

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

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 . . .

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**

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

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

2015 Definitive Drug Testing Codes

Single Drug Codes

- 80348 Buprenorphine
- 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

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

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.

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.**

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.

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

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**

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.

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**

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

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

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 reimbursement is “per specimen” for all codes
- **2016 Reimbursement for revised codes will be the same since they are not “new” codes.**

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

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, Coronavirus Parainfluenza virus)
- Existing codes for the above organisms all specify non-MS methods (immunofluorescence, 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

Future Market Based Reimbursement for Lab Tests

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

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.**

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

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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