2017 Drug Screen Tests
The ABCs of Applying the CMS 2017 HCPCS Codes

Written by: Karen D. Chappell, EJD, MBA, CIRCC, CPMA, CPC-I, CHC
Terminology

- Qualitative
- Quantitative
- Presumptive
- Definitive
- Therapeutic

Imunoassay
Gas Chromatography
GC/MS
ELISA
**Qualitative** – result that tells you if a substance or drug is present in the specimen (positive, negative, trace amount)

**Quantitative** – result that identifies the presence of a substance along with the numerical amount of that drug or substance present. (2mg/dl, 120 mcg/dl)

**Presumptive** – Identifies possible use or non-use of a drug or drug class. May be followed by definitive drug identification

**Definitive** – Drug identification is able to identify individual drugs. It can be qualitative or quantitative

**Therapeutic** – Therapeutic drug assays are performed to monitor response to prescribed medications. Test can be performed with whole blood, serum, plasma or spinal fluid.
An unconscious patient is admitted to the ER following a party. A friend of the patient informs the physician on duty that the pt had ingested a 1 liter bottle of alcohol. The patient is pulseless, apneic, and is intubated and resuscitated with epinephrine. Blood testing is ordered to determine blood levels for alcohols, including ethanol and methanol.
Answer
History of Drug Screening Tests

✓ Over the past few years there have been yearly changes in the drug screen coding – both CPT codes and HCPCS codes.

✓ Most of these changes are driven by CMS’s concern that they are paying too much for drug screening exams.

✓ Every year the lab testing methods available on the market are more simplified and use less sophisticated systems. (Drug kits)

✓ The CPT and HCPCS codes and payment rates do not catch up with these changes and may reflect more resource intensive services than those typically provided.
LAB CLFS Resources

- CPT code book – non-Medicare payers may use the CPT book for reporting these codes

- HCPCS book – Medicare uses a combination of CPT and HCPCS codes to report drug screening tests, both presumptive and determinative.

- The governing regulatory document for new yearly rules related to lab reporting is the CLFS Final Determination.

- CMS documents – Outpatient Final Rule, Quarterly OPPS Updates, Transmittals – Other CMS documentations may give directions for reporting these codes as well.
How a Service Becomes a CPT© Code

- History
- Criteria for adding or changing a code
- Approval Process
- HIPPA
- HCPCS
Drug Assay, Therapeutic Drug Assay

Drug Assay
- Presumptive Drug Class Screening (80305-80307)
- Definitive Drug Testing

Therapeutic Drug Assay (80150-80299)

Chemistry (82009-84999)

***CPT Code – 80320 - 80377

HCPCS Codes G0480 – G0483
Drug Assay, Therapeutic Drug Assays

Category Guidelines

- Specimen type:
  - Presumptive Drug Class/Definitive Drug Class
    - Any specimen type may be used unless otherwise specified in the code.
  - Therapeutic Drug Assay
    - Whole blood, serum, plasma, or cerebrospinal fluid.
Drug Assay, Therapeutic Drug Assay

- Therapeutic Drug Assay (80150-80299)
- Chemistry (82009-84999)
Therapeutic Drug Assays

- Code Series 80150-80299

- Drug testing performed to monitor clinical response to a known, prescribed medication

- Examples: Cyclosporine, Digoxin, Phenobarbital, Vancomycin
A 60 year old man with atrial fibrillation comes to the doctor’s office for his monthly digoxin blood test. He takes 0.25 mg of digoxin once a day. What CPT code is used to report the blood test for digoxin in his blood sample?

The digoxin is used therapeutically to treat a medical condition. The CPT codes for therapeutic assays are codes 80150 – 80299. Report 80162 for the digoxin test. You do not need to know the type of instrument used to perform this blood test.
The Annual Laboratory Public Meeting is held every year to talk about new HCPCS codes that are being considered for Medicare payment under the Clinical Lab Fee schedule (CLFS) for the next calendar year.

After the Laboratory Public Meeting, CMS accepts public comments for one week and then determines whether to crosswalk the payment or gapfill the payment.

Crosswalking occurs when a new test is similar to an existing test. The basis for payment may be a multiple of the payment for the similar test. This code payment will be crosswalked to an existing similar test.

Gapfilling occurs when no comparable test exists. In this case the MACs develop a local payment amount for the new test code. After one full year of this, CMS calculates a national limitation amount (NLA).
Then the Preliminary Determination is posted on the CMS website in September of each year.

The CLFS Payment Final Determination finalizes the payment and post the Final Determination on the CMS website.

Laboratory staff responsible for the Laboratory CDM need to review these documents every year to see if there are laboratory tests on the Final Determination that are not in the CPT book and/or not published in the HCPCS book. (Some years the Final Determination is posted after the HCPCS books are printed.)
• Implemented seven new HCPCS codes:

  ✓ 80305 - 80307 for presumptive drug testing

  ✓ G0480 – G0483 for definitive drug testing

  ✓ CMS priced these codes using the crosswalking formula.

  ✓ CMS continues to be concerned that inappropriate testing continues to occur including simplified testing billed at the higher codes with suspect results.
CLFS 2017 Guidelines

✓ Continue to **not** recognize CPT codes 80300 – 80377 for definitive drug tests
Example for Aetna

• Presumptive (qualitative) testing
  
  • For presumptive drug testing, Aetna allows one encounter per day up to eight (8) encounters per 12 month period. Applicable codes...80305, 80306, 30307

  Definitive (quantitative) testing (same restrictions as above)

G0480, G0481, G0482, G0483
Example for Anthem

• …the Health Plan has taken guidance from CMS and considers the CPT definitive drug screen testing codes (80320-80377) to be always bundled codes that are not eligible for reimbursement. The Health Plan DOES accept the HCPCS “G” codes (G0480-G0483 and G0659) for definitive drug screen testing
The Majority of the presenters at the 2016 Annual Laboratory Public Meeting and the CDLT Advisory Panel meeting raised concerns that much of the high volume of claims containing G0483 that were billed during the first part of 2016 were being performed by physician office laboratories that lacked the quality control and multiple calibrations necessary for accurate results.
CMS proposed to create a new G code that would recognize those laboratories that are performing a less sophisticated version of these tests than is usually performed in drug testing laboratories.

New Code G0659 Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods, performed without methods or drug-specific calibration without matrix-matched quality control material or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes.
Diagnosis

Presumptive Drug Class Screening

- Identify the use or non-use of a drug or drug class.

- Controlled Pain Medications
- History of Past Drug Abuse
- Symptomatic Patients
CONTROLLED SUBSTANCE PRESCRIPTION REQUIREMENTS

- The prescribing practitioner is responsible for ensuring that the prescription conforms to all requirements of both state and federal regulations
- Prescription Drug Monitoring Programs
Presumptive Drug Class Screening

- **80305** - *Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg immunoassay); capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service*

- **80306** - *(eg immunoassay); read by instrument assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service)*
Presumptive Drug Class Screening

- 80307 – Drug test(s), presumptive, any number of drug classes, any number of devices or procedures, by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC HPLC), and mass spectrometry either with or without chromatography, (eg, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service
35 year old female comes in for refill of prescription of Hydrocodone for moderate low back pain. She collects a sample in a Tox 14 Panel cup. The result was positive for opioids and negative for all other drugs. Dr. Green writes a refill prescription for the Hydrocodone.

80305 - Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg immunoassay) capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service

Tox Cup 14 Panel CLIA Waived cup – Tests for amphetamine, barbiturates, buprenorphine, benzodiazepines, cocaine, ecstasy, methamphetamine, methadone, opiates, oxycodone, phenylcyclidine, propoxyphene, tricyclic antidepressants, and marijuana
Definitive Drug Class Testing

- **G0480 (Drug test(s), definitive**, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); (2) stable isotope or other universally recognized internal standards in all samples (e.g. to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibrations and matrix-matched quality control material (e.g. to control for instrumentation variations and mass spectral drift); **qualitative or quantitative**, all sources, includes specimen validity testing, **per day, 1-7 drug class(es)**, including metabolite(s) if performed

- **G0481 (Drug test(s), definitive; per day, 8-14 drug class(es)**, including metabolite(s) if performed

- **G0482 (Drug test(s), definitive; per day, 15-21 drug class(es)**, including metabolite(s) if performed

- **G0483 (Drug test(s), definitive; per day, 22 or more drug class(es)**, including metabolite(s) if performed
Definitive Drug Class Testing

- G0659 (Drug test(s), **definitive**, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but no necessarily stereoisomers), including but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase), performed without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes)
Drug Testing Abbreviations

HPLC/MS – High performance liquid chromatography/mass spectrometry

GC/MS – Gas chromatography/mass spectrometry

MS/MS – Mass spectrometry/mass spectrometry (MS/MS instruments run multiple filters in tandem which filters down to a single instrument)

MS-TOF – Mass spectrometry time of flight

MALDI – Matrix assisted laser desorption/Ionization mass spectrometry
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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>LDTD</td>
<td>Laser diode thermal desorption</td>
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<tr>
<td>DESI</td>
<td>Desorption-ElectroSpray-Ionization</td>
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<tr>
<td>DART</td>
<td>Direct-Analysis-in-Real-Time</td>
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<tr>
<td>IA</td>
<td>Immunoassay; EIA – Enzyme-Immuno-Assay</td>
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<td>ELISA</td>
<td>Enzyme-Linked Immunosorbent Assay</td>
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<tr>
<td>EMIT</td>
<td>Enzyme-Multiplied-Immunoassay-Test</td>
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<td>FPIA</td>
<td>Fluorescence-Polarization-Immuno-Assay</td>
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