Proper Coding for Specimen Validity Testing Billed in Combination with Drug Testing

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PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for laboratories and other providers billing Medicare Administrative Contractors (MACs) for urine drug test services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This MLN Matters Special Edition article reminds laboratories and other providers about how to properly bill for specimen validity testing done in conjunction with drug testing. This article contains no policy changes, but serves as a reminder to laboratories and providers of current Medicare requirements. Please make sure your billing staffs are aware of these instructions.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) is issuing SE18001 to remind laboratories and other providers about the correct coding and instructions for billing specimen validity testing when done as a part of drug testing.

Section 1862(a)(1)(A) of the Social Security Act provides that Medicare payment may not be made for services that are not reasonable and necessary. Clinical laboratory services must be ordered and used by the physician who is treating the beneficiary as described in 42 CFR 410.32(a), or by a qualified nonphysician practitioner, as described in 42 CFR 4310.32(a)(3).

Current coding for testing for drugs of abuse relies on a structure of “screening” (known as “presumptive” testing) and “quantitative” or “definitive” testing that identifies the specific drug and quantity in the patient.

Beginning January 1, 2017, presumptive drug testing may be reported with CPT codes 80305-80307. These codes differ based on the level of complexity of the testing methodology. Only one code from this code range may be reported per date of service.
The descriptors for Presumptive Drug Testing codes are:

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

- **80307**: Drug tests(s), presumptive, any number of drug classes, qualitative, 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.

As mentioned in the National Correct Coding Initiative Policy Manual, Chapter 10, Section E, beginning January 1, 2016, definitive drug testing may be reported with HCPCS codes G0480-G0483. These codes differ based on the number of drug classes including metabolites tested. Only one code from this code range may be reported per date of service.

The descriptors for Definitive Drug Testing codes are:

- **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 (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., 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 calibration and matrix-matched quality control material (e.g., to control for instrument 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, 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 (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., 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 calibration and matrix-matched quality control material (e.g., to control for instrument variations and
mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 8-14 drug class(es), including metabolite(s) if performed

- **G0482**: 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 (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., 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 calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 15-21 drug class(es), including metabolite(s) if performed

- **G0483**: 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 (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., 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 calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 22 or more drug class(es), including metabolite(s) if performed

In addition, definitive drug testing code G0659 was created to recognize those laboratories that are performing a less sophisticated version of these tests than is usually performed in drug testing laboratories:

- **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 and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), performed without method 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

The work performed in this test approximates the work performed in CPT code 80307.

Providers performing validity testing on urine specimens utilized for drug testing shall not separately bill the validity testing. For example, if a laboratory performs a urinary pH, specific gravity, creatinine, nitrates, oxidants, or other tests to confirm that a urine specimen is not adulterated, this testing is not separately billed.
ADDITIONAL INFORMATION


The Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) recently completed a report that illustrated improper payments for specimen validity tests as part of urine drug testing. To review that report, visit https://oig.hhs.gov/oas/reports/region9/91602034.pdf.

If you have any questions, please contact your MAC at their toll-free number. That number is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/.

DOCUMENT HISTORY

<table>
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<tr>
<th>Date of Change</th>
<th>Description</th>
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<td>March 29, 2018</td>
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