

## **SPECIMEN VALIDITY TESTING**

Policy # 65

Implementation Date: 12/1/15

Review Dates:

Revision Dates:

**Disclaimer:**

1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

**Description**

Specimen validity testing is a component of urine drug testing. Because drug testing has the potential for serious personal, occupational, and legal implications, analytic standards have been set to determine the validity of a specimen. The following entities and organizations have developed analytic criteria, rules, and recommendations, to ensure the accuracy and reliability of urine drug testing: United States Department of Health and Human Services (DHHS), Centers for Medicare and Medicaid Services (CMS), Department of Transportation (DOT), College of American Pathologists (CAP), National Laboratory Certification Program and Clinical Laboratory Improvement Amendments (CLIA), and Substance Abuse and Mental Health Services Administration (SAMHSA).

Although used in a variety of settings, urine drug testing is a clinical tool in both medical and behavioral health practices, to guide treatment for pain management and in addiction recovery programs. In these settings, drug testing results are used to detect levels of prescribed, therapeutic medications, assess compliance for prescriptive drugs of abuse, and/or to detect the presence of illicit drugs or other substances of abuse.

While not common, specimen tampering, substitution, and adulteration are realities. When these practices occur, the specimen is considered invalid, leading to inaccurate test results. In situations where individuals attempt to evade detection of certain drug use or diversion, substitution, tampering, and adulteration techniques can be sophisticated and difficult to detect. The use of these avoidance methods to mask controlled or illicit substances is an ongoing challenge to drug testing. To counter these efforts, the above-referenced entities mandate or require their certified laboratories to perform the following tests on all urine specimens submitted for drug testing: 1) creatinine; 2) specific gravity; 3) pH; 4) one or more validity tests for oxidizing adulterants; and 5) additional validity tests when necessary due to atypical results. Additional validity studies, such as spectrophotometry, are frequently performed to provide both increased selectivity and specificity in the detection and identification of adulterants.

**Definitions**

**Adulterants** A foreign substance either ingested or added directly to a urine specimen to prevent the detection of drugs, alcohol, or illicit substance use. These substances are not normal constituents of human urine or are endogenous substances not present in normal physiologic concentrations.

**Creatinine** A waste product produced by the breakdown of muscle tissue that is excreted in the urine. Creatinine levels that are not within the expected range may indicate a number of medical conditions; but, in urine drug testing, low creatinine results are typically the result of excessive fluid intake. The absence of creatinine would indicate that the specimen is not urine.

**Specific Gravity** A measurement of the density of a liquid compared to the density of water. There are many medical conditions that could be responsible for abnormal urine specific gravity results. In urine drug testing, excessive fluid intake would cause an unanticipated low specific gravity result.

**pH** The pH of a substance measures its level of acidity or alkalinity. Many medical conditions can alter the pH of a urine sample, and therefore, in urine drug testing, the anticipated pH levels of normally healthy individuals are extended on both the lower and upper limits of normal. This is done in an attempt to exclude natural physiologic conditions that may exist without malicious intents to alter a specimen.

## COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Because the performance of validity testing for all urine specimens submitted for drug testing to accredited laboratories is mandated, Select Health **follows CMS guidelines and considers this testing to be inclusive to any drug screening/testing procedure and is not separately payable.**

In the January 1, 2015, revision of Chapter X (Pathology / Laboratory Services – CPT codes 80000 – 89999) of the National Correct Coding Initiative Policy Manual for Medicare Services, section E, page X-7, the following guidelines are stated:

*Providers performing validity testing on urine specimens utilized for drug testing should 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. The Internet-Only Manual, Publication 100-04, Medicare Claims Processing Manual, Chapter 16 (Laboratory Services), Section 10 (Background) indicates that a laboratory test is a covered benefit only if the test result is utilized for management of the beneficiary's specific medical problem. Testing to confirm that a urine specimen is unadulterated is an internal control process that is not separately reportable.*

The following CPT codes will be denied as inclusive when billed on the same date of service as any CPT code for urine drug testing: 81000, 81001, 81002, 81003, 81005, 82570, 83986, and 84311. The urine drug testing codes include: G0431, G0434, G6030 – G6058, G0477, G0478, G0479, G0480, G0481, G0482, G0483, and/or 80300 – 80377.

### Applicable Codes

CPT	Description
<b>81000</b>	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy
<b>81001</b>	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy
<b>81002</b>	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, without microscopy
<b>81003</b>	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, without microscopy
<b>81005</b>	Urinalysis; qualitative or semiquantitative, except immunoassays
<b>82570</b>	Creatinine; other source
<b>83986</b>	pH; body fluid, not otherwise specified
<b>84311</b>	Spectrophotometry, analyte not elsewhere specified
<b>G0431</b>	Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter
<b>G0434</b>	Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter

<b>G6030 – G6058</b>	CMS created codes for 2015 to replace the 2014 CPT codes in the chemistry section of the CPT manual that were deleted for 2015, to be billed once per date of service
<b>G0477</b>	<i>CMS code for 2016</i> Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (eg, immunoassay) capable of being ready by direct optical observation only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service
<b>G0478</b>	<i>CMS code for 2016</i> 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
<b>G0479</b>	<i>CMS code for 2016</i> Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers (eg, immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry), includes sample validation when performed, per date of service.
<b>G0480</b>	<i>CMS code for 2016</i> 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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed.
<b>G0481</b>	<i>CMS code for 2016</i> 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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed.
<b>G0482</b>	<i>CMS code for 2016</i> 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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 15-21 drug class(es), including metabolite(s) if performed.)
<b>G0483</b>	<i>CMS code for 2016</i> 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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods

	(eg, alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed.
<b>80300</b>	Drug screen, any number of drug classes from Drug Class List A; any number of non-TLC devices or procedures, (eg, immunoassay) capable of being read by direct optical observation, including instrumented-assisted when performed (eg, dipsticks, cups, cards, cartridges), per date of service
<b>80301</b>	Drug screen, any number of drug classes from Drug Class List A; single drug class method, by instrumented test systems (eg, discrete multichannel chemistry analyzers utilizing immunoassay or enzyme assay), per date of service
<b>80302</b>	Drug screen, presumptive, single drug class from Drug Class List B, by immunoassay (eg, ELISA) or non-TLC chromatography without mass spectrometry (eg, GC, HPLC), each procedure
<b>80303</b>	Drug screen, any number of drug classes, presumptive, single or multiple drug class method; thin layer chromatography procedure(s) (TLC) (eg, acid, neutral, alkaloid plate), per date of service
<b>80304</b>	Drug screen, any number of drug classes, presumptive, single or multiple drug class method; not otherwise specified presumptive procedure (eg, TOF, MALDI, LDTD, DESI, DART), each procedure
<b>80320 – 80377</b>	CPT codes for 2015 – 2016 – Definitive Drug Testing codes for confirmatory urine studies for drugs of abuse, to be billed once per date of service

Upon appeal, Select Health will consider payment for CPT codes 81000, 81001, 81002, 81003, 81005, 82570, 83986, and 84311 when the following documentation is submitted for review:

- 1) A written order for the specific study
- 2) A complete lab report with the results of the study, and;
- 3) Provider's progress notes verifying CPT codes denied for validity testing were ordered for analysis and treatment of medical condition other than for the purpose of urine drug testing.

#### **SELECT HEALTH ADVANTAGE (MEDICARE/CMS)**

Select Health Advantage **will follow the commercial plan policy.**

#### **SELECT HEALTH COMMUNITY CARE (MEDICAID)**

Select Health Community Care **will follow the commercial plan policy.**

#### **Sources**

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