

Clinical Policy: Outpatient Testing for Drugs of Abuse

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Description

Urine drug testing is a key diagnostic and therapeutic tool that is useful for patient care and monitoring of adherence to a controlled substance treatment regimen (e.g., for chronic non-cancer pain) and to identify drug misuse or addiction prior to starting or during treatment with controlled substances.

Policy/Criteria

- I. It is the policy of Pennsylvania Health and Wellness® (PHW) that outpatient drug testing for drugs of abuse (DOA) is **medically necessary** for confirmatory/definitive (quantitative) testing for a specific drug(s) when members meet the criteria in A or B:
 - A. Member has a documented history or suspicion of illicit or prescription drug use or noncompliance or a high probability of non-adherence to a prescribed drug regimen documented in the medical record; *and all of the following*:
 1. A preliminary/presumptive drug test has been previously performed unless no reliable test is in existence; *and*
 2. The findings from that preliminary/presumptive (qualitative) test (either positive or negative) are either:
 - a. Inconsistent with the expected results as suggested by the member's medical history, clinical presentation, and/or member's own statement after a detailed discussion about their recent medication and drug use, or
 - b. The test yielded results consistent with the clinical scenario but drug class-specific assays are needed to identify the precise drug(s) that resulted in the positive test result. *and*
 3. Resolving the inconsistency is essential to the ongoing care of the member, *and*
 4. The requested confirmatory/definitive test(s) is for < 14 drugs/drug classes,
 5. Tests are only for the specific drug(s) or number of drug classes for which preliminary analysis has yielded unexpected results;
 - B. The provider expects the presumptive test to be positive (e.g. the member reports recent use), *and all of the following*:
 1. Information regarding specific substance and/or quantity is desired;
 2. There are established benchmarks for clinical decision making based on specific substance and/or quantitative levels;
 3. ≤14 drugs/drug classes are requested;
 - C. The request is for a serum therapeutic drug level in relation to the medical treatment of a disease or condition (e.g. phenobarbital level in the treatment of seizures).
- II. It is the policy of PHW that outpatient confirmatory/definitive (quantitative) drug testing of more than 14 drugs/drug classes (HCPCS codes G0482, G0483) is **not medically necessary**.
- III. It is the policy of PHW that urine drug testing is considered **not medically necessary** if provided for reasons that include, but are not limited to, the following:

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- A. As a condition of:
 - 1. Employment or pre-employment purposes (pre-requisite for employment or as a requirement for continuation of employment).
 - 2. Participation in school or community athletic or extracurricular activities or programs
- B. Screening for medico-legal purposes such as court-ordered drug screening (unless required by state regulations).
- C. Screening in asymptomatic patients.
- D. As a component of a routine physical/medical examination; e.g. (enrollment in school, enrollment in the military, etc.).
- E. As a component of a medical examination for any other administrative purposes not listed above (e.g., for purposes of marriage licensure, insurance eligibility, etc.).
- F. Same-day screening of drug metabolites in both a blood and urine specimen by either preliminary or confirmatory/definitive analyses.
- G. Specimen validity/adulteration testing, as this is considered part of the laboratory quality control practices.

Authorization Protocols

Outpatient confirmatory/definitive testing for DOA requires prior authorization **except** when performed for children < 6 years of age.

Requests for prior authorization will be accepted up to 10 business days after specimen collection and reviewed for medical necessity based on the above stated criteria.

Request Requirements

A clinical laboratory may not bill for a service unless it has received a written request to perform that specific service from an authorized prescriber who is treating the member and will use the test for the purpose of diagnosis, treatment, or an otherwise medically necessary reason as defined in this policy. Any claim for a service for which a prior-authorization has not been provided may be subject to denial. Any clinical laboratory billing for a service must maintain such request in its records, and make such records available upon request.

Background

A drug of abuse is defined as a drug, chemical, or plant product known to be misused for recreational purposes. In the United States, the basic screening test for DOA includes five drugs: amphetamine, cocaine, marijuana, opioids, and phencyclidine. Other common drugs tested for include benzodiazepines, a wider range of opioids, barbiturates, and methamphetamine. These tests can vary by region based on epidemiologic trends. There currently is no uniformity for what is included in extended DOA assay testing, or what cutoff values should be used for detection of drugs that are not covered by workplace testing laws.

The three methods of drug assays include immunoassay, chromatography, and mass spectrometry. Immunoassay is the most widely used method for initial testing for DOA and offers results within minutes. They are able to detect low concentrations of a drug with a high degree of specificity. This can be most easily performed using point-of-care test kits such as a urine drug cup. Unfortunately, in the clinical setting point-of-care testing does not perform to manufacturers' claims and untrained staff can improperly interpret test results.

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Gas chromatography/mass spectrometry (GC/MS) or liquid chromatography (LC/MS) are typically used as confirmatory tests. Chromatography is used to separate a specimen into its component parts and mass spectrometry to identify those parts. Chromatography, LC/MS and GC/MS require highly trained lab staff and instruments to provide a highly sensitive and specific technique for detecting drugs or metabolites. It often takes many hours to obtain results, thus these methods are generally not used for initial screening in the clinical setting. The mass spectrometer is capable of detecting even minute amounts of a given substance and is considered to have the highest specificity of all lab detection methods. It is most commonly used for confirmatory test results that are primarily of forensic importance. GC/MS rarely provides results that are clinically necessary or useful beyond those obtained by standard immunoassays or chromatography.

The ordering clinician must be knowledgeable regarding the type of testing being requested, level of suspicion for drug use or exposure, the purpose for obtaining the test, and the likelihood of false-positive or false-negative results. Knowledge of potential drug exposure allows a clinician working in an addiction or chronic pain management program to include testing for a metabolite of a parent drug instead of simply testing for the parent drug for a patient with a tendency for opioid abuse. If initial screening does not correlate with expected findings, then confirmatory testing improves the accuracy of initial results especially with concern of false-positive or false-negative results.

Immunoassays can yield false-positive results when cross-reacting medications or drugs are present. Cross-reacting substances can be found in common prescription medications, over-the-counter cold medications, and even in some food substances. The highest false-positive results occur with amphetamine testing due to the chemical structure of amphetamine being present in many over-the-counter medications and herbal supplements. False-negative results can occur from improper specimen collection, transport, or testing procedures or from patient attempts to subvert the testing. The most common cause of false-negative results is a test failure to detect a specific drug within a given class of drugs.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
80184	Phenobarbital
80324	Amphetamines; 1 or 2
80325	Amphetamine; 3 or 4
80326	Amphetamines; 5 or more
80345	Barbiturates

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CPT® Codes	Description
80346	Benzodiazepines; 1-12
80347	Benzodiazepines; 13 or more
80348	Buprenorphine
80349	Cannabinoids, natural
80350	Cannabinoids, synthetic; 1-3
80351	Cannabinoids, synthetic; 4-6
80352	Cannabinoids, synthetic; 7 or more
80353	Cocaine
80354	Fentanyl
80356	Heroin metabolite
80357	Ketamine and norketamine
80358	Methadone
80359	Methylenedioxyamphetamines (MDA, MDEA, MDMA)
80360	Methylphenidate
80361	Opiates, 1 or more
80362	Opioids and opiate analogs; 1 or 2
80363	Opioids and opiate analogs; 3 or 4
80364	Opioids and opiate analogs; 5 or more
80365	Oxycodone
80367	Propoxyphene
80368	Sedative Hypnotics
80369	Skeletal muscle relaxants; 1 or 2
80370	Stimulants, synthetic
80371	Stimulants, synthetic
80372	Tapentadol
80373	Tramadol
83992	Phencyclidine (PCP)

HCPCS Codes	Description
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(s), 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

HCPCS Codes	Description
	mass spectral drift); definitive, qualitative or quantitative, all sources(s), 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); definitive, qualitative or quantitative, all sources(s), 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); definitive, qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed

HCPCS Codes considered NOT medically necessary

HCPCS Codes	Description
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

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HCPCS Codes	Description
	quantitative, all sources, includes specimen validity testing, per day; 22 or more drug class(es), including metabolite(s) if performed

Reviews, Revisions, and Approvals	Date	Approval Date
Developed PA Policy	09/17	12/17
Modified criteria in I.A.1 that a presumptive test must be performed before a definitive test unless no reliable test is available. Added an indication for testing when the presumptive test is assumed to be positive based on patient history, but quantitative levels are required. Modified II.C. to state that screening in asymptomatic patients is medically unnecessary, unless otherwise stated in section I.	09/18	10/18
Revised background to clarify that immunoassays are able to detect low concentrations of a drug with a high degree of sensitivity but lack some specificity.	12/19	
Revised policy to state that HCPCS codes G0482 & G0483 are not medically necessary, and to reflect a 10 day post-collection authorization period. Updated coding tables to include 80367, 80368, 80369, 80370, 80372, 80373. Revised I.A.1 from “unless no reliable test is available” to “unless no reliable test is in existence” for clarification. References reviewed and updated.	12/19	

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