

Clinical Policy: Outpatient Testing for Drugs of Abuse

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[Coding Implications](#)

[Revision Log](#)

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* testing for drugs of abuse (DOA) is **medically necessary** for presumptive (preliminary) testing for a specific drug(s) when meeting both of the following:
 - A. Indication meets one of the following:
 1. Verification of compliance with treatment, identification of undisclosed drug use or abuse, or evaluation of aberrant* behavior beginning at the start of treatment, as part of a routine monitoring program for individuals who meet one of the following (*Note: aberrant behavior includes, but is not limited to, lost prescriptions, repeated requests for early refills, and prescriptions from multiple providers, unauthorized dose escalation, and apparent intoxication):
 - a. Receiving treatment for chronic pain with prescription opioid or other potentially abused medications;
 - b. Undergoing treatment for, or monitoring for relapse of, opioid addiction or substance use disorder;
 2. Clinical evaluation suggests use of non-prescribed medications or illegal substances;
 3. On initial entrance into a pain management program;
 - B. If requesting for chronic opioid therapy, frequency of testing with any combination of codes 80305, 80306, and 80307 meets all of the following:
 1. One unit or less per day;
 2. One unit or less per 30 days;
 3. 12 units or less per 365 days.
- II. 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 member/enrollees meet the criteria in A, B or C:
 - A. Member/enrollee 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:

CLINICAL POLICY

Outpatient Testing for Drugs of Abuse

- a. Inconsistent with the expected results as suggested by the member/enrollee's medical history, clinical presentation, and/or member/enrollee'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/enrollee, *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/enrollee 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;
 4. Tests are only for the specific drug(s) or number of drug classes for which the presumptive test is expected to be positive;
- 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).

III. 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**.

IV. 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:

- A.** As a condition of:
1. Employment or pre-employment purposes (pre-requisite for employment or as a requirement for continuation of employment). OR
 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, except as listed in sections I or II.
- 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 specimens sourced from any combination of blood, saliva and urine by either preliminary or confirmatory/definitive analyses.
- G.** Blanket orders.
- H.** Reflex definitive drug tests when presumptive testing is performed at point of care.
- I.** Routine standing orders for all patients in a physician's practice. Physician-defined standing orders for pre-determined drug panels according to specific patient profiles for a limited sequential period may be reasonable and necessary and must be documented in the patient's medical record.

CLINICAL POLICY

Outpatient Testing for Drugs of Abuse

- J. Billing of individual definitive CPT codes when a comprehensive definitive drug testing panel (CDDP) is ordered.
- K. Performing presumptive point of care testing and ordering presumptive immunoassay (IA) testing from a reference laboratory.
- L. Performing presumptive IA testing and ordering presumptive IA testing from a reference laboratory with or without reflex testing.
- M. Performing IA presumptive screening prior to definitive testing without a specific physician's order for the presumptive testing.
- N. IA testing, regardless of whether it is qualitative or semi-quantitative used to "confirm" or definitively identify a presumptive test result obtained by cups, dipsticks, cards, cassettes or other CLIA-waived methods. Semi-quantitative IA testing provides a presumptive test (numerical) result. Definitive UDT provides specific identification and/or quantification by GC-MS or LC-MS/MS.
- O. Specimen validity/adulteration testing, as this is considered part of the laboratory quality control practices.

Protocols for testing requiring prior authorization

- Testing for children < 6 years of age is exempt from prior authorization.
- 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.

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 sensitivity but lack some 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.

Gas chromatography/mass spectrometry (GCMS) 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

CLINICAL POLICY

Outpatient Testing for Drugs of Abuse

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 2020, 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 That Support Coverage Criteria

CPT® Codes	Description
0011U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites
80184	Phenobarbital
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only (eg, utilizing immunoassay [eg, dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; read by instrument assisted direct optical observation (eg, utilizing immunoassay [eg, dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service

CLINICAL POLICY
Outpatient Testing for Drugs of Abuse



CPT [®] Codes	Description
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
80320	Alcohols
80321	Alcohol biomarkers; 1 or 2
80322	Alcohol biomarkers; 3 or more
80323	Alkaloids, not otherwise specified
80324	Amphetamines; 1 or 2
80325	Amphetamine; 3 or 4
80326	Amphetamines; 5 or more
80327	Anabolic steroids; 1 or 2
80328	Anabolic steroids; 3 or more
80332	Antidepressants, serotonergic class; 1 or 2
80333	Antidepressants, serotonergic class; 3-5
80334	Antidepressants, serotonergic class; 6 or more
80335	Antidepressants, tricyclic and other cyclicals; 1 or 2
80336	Antidepressants, tricyclic and other cyclicals; 3-5
80337	Antidepressants, tricyclic and other cyclicals; 6 or more
80338	Antidepressants, not otherwise specified
80339	Antiepileptics, not otherwise specified; 1-3
80340	Antiepileptics, not otherwise specified; 4-6
80341	Antiepileptics, not otherwise specified; 7 or more
80342	Antipsychotics, not otherwise specified; 1-3
80343	Antipsychotics, not otherwise specified; 4-6
80344	Antipsychotics, not otherwise specified; 7 or more
80345	Barbiturates
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

CLINICAL POLICY
Outpatient Testing for Drugs of Abuse



CPT[®] Codes	Description
80365	Oxycodone
80366	Pregbalin
80367	Propoxyphene
80368	Sedative Hypnotics (non-benzodiazepines)
80369	Skeletal muscle relaxants; 1 or 2
80370	Stimulants, synthetic
80371	Stimulants, synthetic
80372	Tapentadol
80373	Tramadol
80374	Stereoisomer (enantiomer) analysis, single drug class
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
83992	Phencyclidine (PCP)

CPT Codes That Do Not Support Coverage Criteria

CPT[®] Codes	Description
0006U	Detection of interacting medications, substances, supplements and foods, 120 or more analytes, definitive chromatography with mass spectrometry, urine, description and severity of each interaction identified, per date of service
0143U	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0144U	Drug assay, definitive, 160 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0145U	Drug assay, definitive, 65 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0146U	Drug assay, definitive, 80 or more drugs or metabolites, urine, by quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0147U	Drug assay, definitive, 85 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0148U	Drug assay, definitive, 100 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service

CLINICAL POLICY
Outpatient Testing for Drugs of Abuse



CPT® Codes	Description
0149U	Drug assay, definitive, 60 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0150U	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service

HCPCS Codes That Support Coverage Criteria

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 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
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 (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

HCPCS Codes That Do Not Support Coverage Criteria

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),

CLINICAL POLICY
Outpatient Testing for Drugs of Abuse



HCPCS Codes	Description
	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

ICD-10-CM Codes That Support Coverage Criteria

ICD-10-CM	Description
F10.11	Alcohol abuse, in remission
F10.20	Alcohol dependence, uncomplicated
F11.11	Opioid abuse, in remission
F11.20	Opioid dependence, uncomplicated
F11.220	Opioid dependence with intoxication, uncomplicated
F11.221	Opioid dependence with intoxication delirium
F11.222	Opioid dependence with intoxication with perceptual disturbance
F11.229	Opioid dependence with intoxication, unspecified
F11.23	Opioid dependence with withdrawal
F11.24	Opioid dependence with opioid-induced mood disorder
F11.250	Opioid dependence with opioid-induced psychotic disorder with delusions
F11.251	Opioid dependence with opioid-induced psychotic disorder with hallucinations
F11.259	Opioid dependence with opioid-induced psychotic disorder, unspecified
F11.281	Opioid dependence with opioid-induced sexual dysfunction
F11.282	Opioid dependence with opioid-induced sleep disorder
F11.288	Opioid dependence with other opioid-induced disorder
F11.29	Opioid dependence with unspecified opioid-induced disorder
F12.11	Cannabis abuse, in remission
F13.11	Sedative, hypnotic or anxiolytic abuse, in remission
F14.11	Cocaine abuse, in remission
F15.11	Other stimulant abuse, in remission
F16.11	Hallucinogen abuse, in remission
F18.10	Inhalant abuse, uncomplicated
F18.11	Inhalant abuse, in remission
F18.120	Inhalant abuse with intoxication, uncomplicated
F18.90	Inhalant use, unspecified, uncomplicated

CLINICAL POLICY
Outpatient Testing for Drugs of Abuse



ICD-10-CM	Description
F19.11	Other psychoactive substance abuse, in remission
F19.20	Other psychoactive substance dependence, uncomplicated
F55.0	Abuse of antacids
F55.1	Abuse of herbal or folk remedies
F55.2	Abuse of laxatives
F55.3	Abuse of steroids or hormones
F55.4	Abuse of vitamins
F55.8	Abuse of other non-psychoactive substances

CLINICAL POLICY
Outpatient Testing for Drugs of Abuse



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	1/22/2020
<p>Added criteria for presumptive testing. In II.B, added that “Tests are only for the specific drug(s) or number of drug classes for which the presumptive test is expected to be positive.” Added the following not medically necessary indications: blanket orders; reflex definitive testing when presumptive testing is performed at point of care; physician standing orders for all patients; billing codes for individual drugs which are included in a billed panel; presumptive immunoassay testing in a lab when presumptive POC testing has been performed; presumptive screening before definitive testing if presumptive testing not ordered; IA testing used to confirm a presumptive test result obtained by cups, dipsticks, cards, cassettes or other CLIA-waived methods. Removed authorization protocol information about requests for ages <6 not being on PA, and for a 10 day window to submit PA requests after testing. Removed request requirements section. Added more CPT codes to support coverage criteria. Added the following CPT codes as not medically necessary: 0143U, 0144U, 0145U, 0146U, 0147U, 0148U, 0149U, 0150U. Added HCPCS codes 0011U and G0659 as medically necessary. Added ICD-10-CM codes.</p> <p>Reinstated notes regarding PA not being required for children < 6 years of age, and a 10 day post-test window for PA.</p> <p>Corrected medical necessity statement in section I. to state that “one” of the following must be met, instead of “both.”</p> <p>Added presumptive drug testing limits in chronic opioid therapy to I.B.</p> <p>Replaced all instances of “member” with “member/enrollee.”</p> <p>References reviewed and updated. Specialist review.</p>	12/2020	01/2021

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CLINICAL POLICY

Outpatient Testing for Drugs of Abuse

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