Clinical Policy: Drugs of Abuse: Definitive Testing

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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 confirmatory/definitive (quantitative) testing for a specific drug(s) when meeting *the criteria in A, B, or C*:

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 exists (e.g. synthetic cannabinoids);
2. The findings from that preliminary/presumptive (qualitative) test (either positive or negative) are either:
   a. Inconsistent with the expected results as suggested by medical history, clinical presentation, and/or member's/enrollee's own statement after a detailed discussion about their recent medication and drug use;
   b. 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;
3. Resolving the inconsistency is essential to the ongoing care of the member/enrollee;
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).

II. It is the policy of PHW that outpatient confirmatory/definitive (quantitative) drug testing of more than 14 drugs/drug classes is **not medically necessary.**

III. It is the policy of PHW that urine drug testing (UDT) 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);
   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;
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 (DOA) is defined as a drug, chemical, or plant product known to be misused for recreational purposes.[8] In the United States, the basic screening test for DOA includes five drugs: amphetamine, cocaine, marijuana, opioids, and phencyclidine.[3,8,12] Other common drugs tested

for include benzodiazepines, a wider range of opioids, barbiturates, and methamphetamines.[3,8,12] These tests can vary by region based on epidemiologic trends. There currently is no uniformity for what is included in extended DOA testing or cutoff values that should be used for detection of drugs that are not covered by workplace testing laws.[8]

According to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), a review examining the relevance and role of urine drug testing for treatment of opioid misuse found that providers are better equipped to evaluate opioid therapy with the aid of urine drug testing.[22] However, two literature searches, one from the timeframe 1995-2017 and one from 2000 to present, revealed a significant gap in research evidence regarding the clinical significance of urine drug screening for substance-related disorders.[22,23]

In 2019, the American Society of Addiction Medicine (ASAM) developed a consensus document on the ethical use of drug testing in clinical addiction medicine, which provides a broad discussion of drug testing methods, procedures, and practices. Drug testing can provide a treating clinician with objective information regarding a patient's recent substance use. It can assist with the identification, diagnosis and treatment of addiction and support patients in recovery.[27]

Drug testing should be used only when clinically necessary. Presumptive testing should be a routine part of initial and ongoing assessments. Definitive testing may be used to detect specific substances not identified in presumptive methods and to refine the accuracy of the test results. Definitive testing may be used to detect specific substances not identified by presumptive methods, quantify levels of the substance present, and to refine the accuracy of the test results.[27] In addition, definitive testing may be used when the results are needed to inform clinical decisions with major clinical or non-clinical implications for the patient (e.g., treatment transitions, changes in medication therapies, changes in legal status).[27]

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.[8] These tests provide a relatively inexpensive method to detect low concentrations of a substance with an increased degree of specificity.[8] This can be most easily performed using point-of-care test kits such as a urine drug cup. However, 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 (GC/MS) or liquid chromatography (LC/MS) are typically used as confirmatory tests.[1] Chromatography is used to separate a specimen into its component parts and mass spectrometry is used to identify those parts. Chromatography, LC/MS and GC/MS require specialized training for lab staff and instruments to provide a highly sensitive and specific technique for detecting drugs or metabolites.[8] It often takes many hours to obtain results; therefore, these tests are generally not used for preliminary screening in the clinical setting.[8] 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.[8] It is most commonly used for confirmatory test results that are primarily of forensic importance.[1,8] GC/MS rarely provides results that are clinically necessary or useful beyond those obtained by standard immunoassays or chromatography.[8]

The ordering clinician must be knowledgeable regarding the type of testing being requested, level of suspicion for drug use or exposure, the reason for obtaining the test, and the likelihood of false-positive or false-negative results.[8] 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.[8] If initial screening does not correlate with expected findings and there is concern for false-positive or false-negative results, then confirmatory testing improves the accuracy of initial results.[9]

Immunoassays can yield false-positive results when cross-reacting medications or drugs are present.[8] Cross-reacting substances can be found in common prescription medications, over-the-counter cold medications, and even in some food substances.[8] 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.[8] False-negative results can occur from inappropriate specimen collection, transport, testing procedures or from patient attempts to undermine the testing.[8] The most common cause of false-negative results is failure to detect a specific drug within a given class of drugs because the chemical combination makes it unreactive with the test.[8]

Coding Implications

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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
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

CPT®* Codes	Description
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
80365	Oxycodone
80366	Pregbalin
80367	Propoxyphene
80368	Sedative Hypnotics (non-benzodiazepines)
80369	Skeletal muscle relaxants; 1 or 2
80370	Skeletal muscle relaxants; 3 or more
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
82077	Alcohol (ethanol); any specimen except urine and breath, immunoassay (eg, IA, EIA, ELISA, RIA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)

CPT®* Codes	Description
83992	Phencyclidine (PCP)

CPT Codes That Do Not Support Coverage Criteria

CPT® Codes	Description
0054U	Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service
0082U	Drug test(s), definitive, 90 or more drugs or substances, definitive chromatography with mass spectrometry, and presumptive, any number of drug classes, by instrument chemistry analyzer (utilizing immunoassay), urine, report of presence or absence of each drug, drug metabolite or substance with description and severity of significant interactions per date of service
0328U	Drug assay, definitive, 120 or more drugs and metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), includes specimen validity and algorithmic analysis describing drug or metabolite and presence or absence of risks for a significant patient-adverse event, 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

HCPCS Codes	Description
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), 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

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	01/22/2020
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. Reinstated notes regarding PA not being required for children < 6 years of age, and a 10 day post-test window for PA. Corrected medical necessity statement in section I. to state that "one" of the following must be met, instead of "both." Added presumptive drug testing limits in chronic opioid therapy to I.B. Replaced all instances of "member" with "member/enrollee." References reviewed and updated. Specialist review.	12/2020	01/29/2021
Changed name of policy from Outpatient Testing for Drugs of Abuse to Drugs of Abuse: Definitive Testing. Removed presumptive drug testing	12/16/2021	

Reviews, Revisions, and Approvals	Date	Approval Date
criteria from policy and created new policy, CP.MP.208 Drugs of Abuse: Presumptive Testing. Removed codes for presumptive drug testing: 80305, 80306, 80307. Added CPT-0054U to list of codes that do not support coverage criteria. Removed CPT-0006U, as code is deleted in 2021. Removed UM language regarding PA not being required for children < 6 years of age, and a 10-day post-test window for PA. Added 2021 CPT- 82077 to list of codes that support coverage criteria. Annual review. References updated and coding reviewed. Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." Updated ICD-10 codes to include code ranges. Deleted note referring to CP.MP.208 Drugs of Abuse, Presumptive Testing. **References reviewed and updated. Specialist review.**		
Annual review. Updated background with no impact to criteria. Description updated for CPT code 80370. Added CPT 0328U to the list of CPT codes that do not support coverage criteria. Removed (HCPCS codes G0482, G0483) from the policy statement in II. Added protocols for prior authorization details: Testing for children < 6 years of age is exempt from prior authorization and 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. References reviewed and updated. Specialist review.	2/20/2023	
Annual Review. Added an example of synthetic cannabinoids to I.A.1., drugs for which presumptive testing is not reliable. Coding reviewed. Replaced all instances of dashes (-) with the word "to" within the CPT and HCPCS codes. Added 0082U to the CPT codes that do not support coverage criteria list. Removed table of ICD-10 CM codes. Updated background information to include information regarding American Society of Addiction Medicine (ASAM). Other minor wording changes made to background with no clinical significance. References reviewed and updated. Policy reviewed by an internal specialist. Removed deleted codes 0143U, 0144U, 0145U, 0146U, 0147U, 0148U, 0149U, 0150U from table of CPT codes that do not support coverage criteria.	06/2023	

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