

Clinical Policy: Drugs of Abuse: Definitive Testing

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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 health plans affiliated with Centene Corporation® 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).

It is the policy of health plans affiliated with Centene Corporation that routine outpatient confirmatory/definitive (quantitative) drug testing of more than 14 drugs/drug classes is **not medically necessary**. **Current literature and specialty clinical guidelines do not support their routine use.**

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- II.** It is the policy of health plans affiliated with Centene Corporation 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);
 - B. Screening for medico-legal purposes such as court-ordered drug screening (unless required by state regulations);
 - C. Same-day screening of drug metabolites in specimens sourced from any combination of blood, saliva and urine by either preliminary or confirmatory/definitive analyses;
 - D. Blanket orders;
 - E. Reflex definitive drug tests when presumptive testing is performed at point of care;
 - F. Billing of individual definitive CPT codes when a comprehensive definitive drug testing panel (CDDP) is ordered;
 - G. Performing presumptive point of care testing and ordering presumptive immunoassay (IA) testing from a reference laboratory;
 - H. Performing presumptive IA testing and ordering presumptive IA testing from a reference laboratory with or without reflex testing;
 - I. Performing IA presumptive screening prior to definitive testing without a specific physician's order for the presumptive testing;
 - J. 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;
 - K. Specimen validity/adulteration testing, as this is considered part of the laboratory quality control practices.

***No prior authorization required for definitive drug testing less than 14 drugs/drug classes for in-network providers.**

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

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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

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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

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 2022, 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.

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 to 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 to 14 drug class(es), including metabolite(s) if performed

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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 to 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	Revision Date	Approval Date
CCH Policy Developed	04/24	04/24

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

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benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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