Clinical Policy: Drugs of Abuse: Presumptive Testing

Reference Number: WA.CP.MP.208
Date of Last Revision: 08/21
Effective Date: 09/01/21

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 Coordinated Care of Washington, Inc. *outpatient* testing for drugs of abuse (DOA) is **medically necessary** for presumptive (preliminary) testing for a specific drug(s) when meeting one 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. Twenty-four (24) units or less per 365 days.

II. 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 drug in asymptomatic patients, except as listed in section I.

C. Screening in asymptomatic patients, except as listed in section I.

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. 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.

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 (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. 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
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 (e.g., utilizing immunoassay [e.g., 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 (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; by instrument chemistry analyzers (e.g., utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (e.g., GC, HPLC), and mass spectrometry either with or without chromatography, (e.g., DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service

CPT® Codes That Do Not Support Coverage Criteria

CPT®* Codes	Description
0227U	Drug assay, presumptive, 30 or more drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, includes sample validation

Reviews, Revisions, and Approvals	Review Date	Approval Date
New Policy. Split from CP.MP.50 Drugs of Abuse: Definitive Testing, formerly referred to as Outpatient Testing for Drugs of Abuse. Criteria, codes and information applicable to presumptive drug testing included in this policy. Removed UM language regarding PA not being required for children < 6 years of age, and a 10 day post-test window for PA.	03/21	04/21
Added 2021 CPT-0227U to table of codes that do not support coverage criteria.	05/21	06/21
Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." Removed diagnosis code listing. Removed reference to WA.CP.MP.50, Drugs of Abuse, Definitive Testing.	08/21	09/21

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21. Washington State Health Care Authority. Physician-Related Services/Health Care Professional Services Billing Guide. https://www.hca.wa.gov/assets/billers-and-providers/physician-related-serv-bg-20210305.pdf Revision effective March 5, 2021.

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 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.