Clinical Policy: Drugs of Abuse: Presumptive Testing

Reference Number: CP.MP.208 Coding Implications
Date of Last Revision: 08/21 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 health plans affiliated with Centene Corporation® 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, 80307, and 0227U 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. 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.
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. 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
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

CPT®* Codes	Description
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
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
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

ICD-10-CM Codes for which COT procedure code frequencies do not apply

ICD-10-CM	Description
F10.10-F10.19	Alcohol abuse
F10.20-F10.29	Alcohol dependence
F10.90-F10.99	Alcohol abuse, unspecified
F11.10-F11.19	Opioid abuse
F11.20-F11.29	Opioid dependence
F11.90-F11.99	Opioid use, unspecified
F12.10-F12.19	Cannabis abuse
F12.20-F12.29	Cannabis dependence
F12.90-F12.99	Cannabis use, unspecified
F13.10-F13.19	Sedative, hypnotic or anxiolytic-related abuse
F13.20-F13.29	Sedative, hypnotic or anxiolytic-related dependence
F13.90-F13.99	Sedative, hypnotic or anxiolytic- related use, unspecified
F14.10-F14.19	Cocaine abuse
F14.20-F14.29	Cocaine dependence
F14.90-F14.99	Cocaine use, unspecified
F15.10-F15.19	Other stimulant abuse
F15.20-F15.29	Other stimulant dependence
F15.90-F15.99	Other stimulant use, unspecified
F16.10-F16.19	Hallucinogen abuse
F16.20-F16.29	Hallucinogen dependence
F16.90-F16.99	Hallucinogen use, unspecified
F18.10-F18.19	Inhalant abuse
F18.20-F18.29	Inhalant dependence
F18.90-F18.99	Inhalant use, unspecified
F19.10-F19.19	Other psychoactive substance abuse
F19.20-F19.29	Other psychoactive substance dependence
F19.90-F19.99	Other psychoactive substance use, unspecified
F55.0	Abuse of antacids

ICD-10-CM	Description
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

Reviews, Revisions, and Approvals	Revision Date	Approval Date
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.	02/21	
Added 2021 CPT-0227U to I.B. and table of codes that support coverage criteria.	03/21	
Annual review. References and coding reviewed and updated. Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date."	06/21	06/21
Removed note to refer to CP.MP.50 for definitive testing. Changed ICD-10 table label from "ICD-10 Codes that Support Coverage Criteria" to "ICD-10 Codes for which COT procedure code frequencies do not apply." Combined opioid dependence and opioid use codes into ranges. Added the following codes: F10.90, F11.90, F12.90, F13.90, F14.90, F15.90, F16.90, F18.90, F19.90. Removed Z79.891.	08/21	

References

1. Rabelo Alves MN, Piccinotti A, Tameni S, Polettini A. Evaluation of buprenorphine LUCIO immunoassay versus GCMS using urines from a workplace drug testing program. *J Anal Toxicol*. 2013;37(3):175-8. doi: 10.1093/jat/bkt006.
2. Argoff CE, Alford DP, Fudin J, et al. Rational urine drug monitoring in patients receiving opioids for chronic pain: consensus recommendations. *Pain Medicine.* 2018;19(1), p. 97–117.
3. Treatment Improvement Protocol 63: Medications for Opioid Use Disorder. Substance Abuse and Mental Health Services Administration. https://store.samhsa.gov/sites/default/files/product_thumbnails/TIP%2063_CompCover_updated_4.1.20_thumbnail_3x4inch_300dpi.jpg. Published 2018. Accessed June 1, 2021.
4. Becker W, Starrels JL. Prescription drug misuse: Epidemiology, prevention, identification, and management. UpToDate. www.uptodate.com. Updated April 6, 2021. Accessed May 27, 2021.
5. Treatment Improvement Protocol 47: Substance Abuse: Clinical Issues in Intensive Outpatient Treatment. Substance Abuse and Mental Health Services Administration. https://store.samhsa.gov/product/TIP-47-Substance-Abuse-Clinical-Issues-in-Intensive-Outpatient-Treatment/SMA13-4182. Published 2013. Accessed June 1, 2021
6. Christo PJ, Manchikanti L, Ruan X, et al. Urine drug testing in chronic pain. *Pain Physician*. 2011;14(2):123-43.

7. Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain - United States, 2016. *JAMA*. 2016 Apr 19; 315(15): 1624–1645. doi: 10.1001/jama.2016.1464
8. Hoffman RJ. Testing for drugs of abuse (DOA). UpToDate. www.uptodate.com. Updated January 15, 2021. Accessed May 27, 2021.
9. Interagency guideline on prescribing opioids for pain. Agency Medical Directors' Group. http://www.agencymeddirectors.wa.gov/files/2015amdgopioidguideline.pdf. Published June 2015. Accessed May 27, 2021.
10. Manchikanti L, Malla Y, Wargo BW, Fellows B. Comparative evaluation of the accuracy of immunoassay with liquid chromatography tandem mass spectrometry (LC/MS/MS) of urine drug testing (UDT) opioids and illicit drugs in chronic pain patients. *Pain Physician*. 2011;14:175-187.
11. McKay JR. Continuing care for addiction: Implementation. UpToDate. www.uptodate.com. Updated March 15, 2018. Accessed May 27, 2021.
12. Moeller KE, Lee KC, Kissack JC. Urine Drug Screening: Practical Guide for Clinicians. Mayo Clin Proc 2008;83(1):66-76. doi: 10.4065/83.1.66.
13. Wilfong A. Seizures and epilepsy in children: Initial treatment and monitoring. UpToDate. www.uptodate.com. Updated November 18, 2020. Accessed May 27, 2021.
14. Consensus Statement: Appropriate Use of Drug Testing in Clinical Addiction Medicine. American Society of Addiction Medicine. https://www.asam.org/docs/default-source/quality-science/appropriate_use_of_drug_testing_in_clinical-1-(7).pdf?sfvrsn=2. Adopted April 5, 2017. Accessed June 1, 2021.
15. Gourlay DL, Heit HA, Caplan YH. Urine Drug Testing in Clinical Practice. The Art and Science of Patient Care. Edition 6. https://www.remitigate.com/wp-content/uploads/2015/11/Urine-Drug-Testing-in-Clinical-Practice-Ed6_2015-08.pdf. Published 2015. Accessed June 1, 2021.
16. Dasgupta A. Challenges in Laboratory Detection of Unusual Substance Abuse: Issues with Magic Mushroom, Peyote Cactus, Khat, and Solvent Abuse. *Adv Clin Chem*. 2017;78:163-186. doi: 10.1016/bs.acc.2016.07.004. Epub 2016 Sep 1.
17. Snyder ML, Fantz CR, Melanson S. Immunoassay-Based Drug Tests Are Inadequately Sensitive for Medication Compliance Monitoring in Patients Treated for Chronic Pain. Pain Physician. 2017 Feb;20(2S):SE1-SE9.
18. Local coverage determination: controlled substance monitoring and drugs of abuse testing (L36029). Centers for Medicare and Medicaid Services. https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. Published October 5, 2015 (revised April 8, 2021). Accessed June 1, 2021.
19. Local coverage determination: Controlled substance monitoring and drugs of abuse testing (L36668). Centers for Medicare and Medicaid Services. https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. Published June 28, 2016 (revised April 8, 2021). Accessed June 1, 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.

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.