CMS Policy for Urine Drug Screen

HCPCS Codes: 80305, 80306, 80307, G0480, G0481, G0482, G0483

Medically Supportive ICD Codes and additional HCPCS information are listed on subsequent page(s) of this document.

Coverage Indications, Limitations, and/or Medical Necessity

A qualitative/presumptive drug screen is used to detect the presence of a drug in the body. A blood or urine sample may be used. However, urine is the best specimen for broad screening, as blood is relatively insensitive for many common drugs, including psychotropic agents, opioids, and stimulants.
Common methods of drug analysis include chromatography, immunoassay, chemical ("spot") tests, and spectrometry. CCL performs urine drug screens.

Analysis is comparative, matching the properties or behavior of a substance with that of a valid reference compound (a laboratory must possess a valid reference agent for every substance that it identifies). Drugs or classes of drugs are commonly assayed by qualitative/presumptive testing. A test may be followed by confirmation with a second method, only if there is a positive or negative inconsistent finding from the qualitative/presumptive test in the setting of a symptomatic patient, as described below.

Examples of drugs or classes of drugs that are commonly assayed by qualitative/presumptive tests, followed by confirmation with a second method, are: alcohols, amphetamines, barbiturates/sedatives, benzodiazepines, cocaine and metabolites, methadone, antihistamines, stimulants, opioid analgesics, salicylates, cardiovascular drugs, antipsychotics, cyclic antidepressants, and others. Focused drug screens, most commonly for illicit drug use, may be more useful clinically.

Indications:

1. Although technology has provided the ability to measure many toxins, most toxicological diagnoses and therapeutic decisions are made based on historical or clinical considerations:

- Laboratory turnaround time can often be longer than the critical intervention time course of an overdose
- The cost and support of maintaining the instruments, staff training, and specialized labor involved in some analyses are prohibitive.
- For many toxins, there are no established cutoff levels of toxicity, making interpretation of the results difficult.

2. Although comprehensive screening is unlikely to affect emergency management, the results may assist the admitting physicians in evaluating the patient if the diagnosis remains unclear. Screening panels should be used when the results will alter patient management or disposition.

CMS Policy for Urine Drug Screen (Continued)

1. A qualitative/presumptive drug test may be indicated for a variety of reasons including the following:
    1. A symptomatic patient when the history is unreliable, when there has been a suspected multiple-drug ingestion, to determine the cause of delirium or coma, or for the identification of specific drugs that may indicate when antagonists may be used.
    2. For monitoring patient compliance during active treatment for substance abuse or dependence.
    3. To monitor for compliance/adherence to the treatment plan or illicit drug use in patients under treatment or seeking treatment for a chronic pain condition. The clinical utility of drug tests in the emergency setting may be limited because patient management decisions are unaffected, since most therapy for drug poisonings is symptom directed and supportive.

2. Medicare will consider performance of a qualitative/presumptive drug test reasonable and necessary when a patient presents with suspected drug overdose and one or more of the following conditions:
    1. Unexplained coma
    2. Unexplained altered mental status in the absence of a clinically defined toxic syndrome or toxidrome
    3. Severe or unexplained cardiovascular instability (cardiotoxicity)
    4. Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome
    5. Testing on neonates suspected of prenatal drug exposure
    6. Seizures with an undetermined history

3. Medicare will consider performance of a qualitative/presumptive drug test reasonable and necessary when a patient presents with one or more of the following conditions:
    1. For monitoring patient compliance during active treatment for substance abuse or dependence.
    2. A drug screen is considered medically reasonable and necessary in patients on chronic opioid therapy:
       In whom illicit drug use, non-compliance, or a significant pre-test probability of non-adherence to the prescribed drug regimen is suspected and documented in the medical record; and/or
       - In those who are at high risk for medication abuse due to psychiatric issues, who have engaged in aberrant drug- related behaviors, or who have a history of substance abuse.
    3. Medicare will consider performance of a drug test reasonable and necessary in patients with chronic pain to:
       - determine the presence of other substances prior to initiating pharmacologic treatment
       - detect the presence of illicit drugs
       - monitor adherence to the plan of care

To view the complete policy and the full list of medically supportive codes, please refer to the CMS website at: www.cms.gov

CMS Policy for Urine Drug Screen (Continued)

Drugs, or drug classes for which testing is performed, should reflect only those likely to be present, based on the patient's medical history, current clinical presentation, and illicit drugs that are in common use. Drugs for which specimens are being tested must be indicated by the referring provider in a written order.

A drug test may be reasonable and necessary for patients with known substance abuse or dependence, only when the clinical presentation has changed unexpectedly and one of the above indications is met.

A drug test may be reasonable and necessary for patients with symptoms of schizophrenia suspected to be secondary to drug or substance intoxication.

Definitive drug testing is indicated when:

1. The results of the screen are presumptively positive.
2. Results of the screen are negative, and this negative finding is inconsistent with the patient's medical history.
3. This test may also be used, when the coverage criteria of the policy are met AND there is no presumptive test available, locally and/or commercially, as may be the case for certain synthetic or semi-synthetic opioids.

A positive screen often results in an inadequate result upon which to make a proper determination. A more specific method, such as gas or liquid chromatography coupled with mass spectrometry, may be needed to obtain a confirmed analytical result. In particular, screens are frequently inadequate for interpretation of opiate and benzodiazepine results. Therefore, quantitative testing may be needed in these instances. Confirmation testing is usually not required for drugs like methadone, wherein false positive results are rare. However, factors such as cross-reactivity with other similar compounds or interfering substances in the specimen may affect test results. Confirmatory testing eliminates the risk of false positives. Also, eliminated by confirmation, is the risk of a “pill scraper” slipping through. Patients diverting their drug, attempt to cheat the test by scraping a bit of drug from a pill into their urine sample. It would screen positive, but there would be no metabolite upon confirmation. Frequent use of this code will be monitored for appropriateness.

Limitations:
It is considered not reasonable or necessary to test for the same drug with both a blood and a urine specimen simultaneously.

Drug screening for medico-legal purposes (e.g., court-ordered drug screening) or for employment purposes (e.g., as a pre-requisite for employment or as a requirement for continuation of employment) are not covered.

Summary of Evidence
NA

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TOXICOLOGY DRUG TESTING

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ICD-10 Codes

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. **If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.**

F11.20 - Opioid dependence, uncomplicated
F19.20 - Other psychoactive substance dependence
F41.9 - Anxiety disorder, unspecified
R41.82 - Altered mental status, unspecified
Z03.89 - Encounter for observation for other suspected diseases
Z79.891 - Long term (current) use of opiate analgesic
Z79.899 - Other long term (current) drug therapy

Disclaimer:
This diagnosis code reference guide is provided as an aid to physicians and office staff in determining when an ABN (Advance Beneficiary Notice) is necessary. Diagnosis codes must be applicable to the patient's symptoms or conditions and must be consistent with documentation in the patient's medical record. Central Clinical Labs does not recommend any diagnosis codes and will only submit diagnosis information provided to us by the ordering physician or his/her designated staff. The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

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Drug Testing HCPCS Codes

Presumptive Drug Testing HCPCS Codes

- **80305:** Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg, immunoassay) capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service.

- **80306:** Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg, immunoassay) read by instrument-assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service.

- **80307:** Drug tests(s), presumptive, any number of drug classes, qualitative, 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.

Definitive Drug Testing HCPCS Codes

- **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, 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); qualitative or quantitative, all sources, includes specimen validity testing, per day; 8-14 drug class(es), including metabolite(s) if performed

- **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

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