Medical Coverage Policy

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Drug Testing

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Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses drug testing. Drug testing is used as a diagnostic and therapeutic tool for the clinical care and monitoring of an individual who is undergoing treatment for addiction.

Testing may be presumptive or definitive. Presumptive drug testing, also referred to as screening, involves qualitative analysis of a sample to determine whether a specific drug, drug metabolite or substance is detectable above a threshold concentration. Definitive or confirmatory testing involves analysis of a sample to determine how much (the quantity) of a drug or metabolite is present.

Coverage Policy

Presumptive drug testing not to exceed one test per date of service is considered medically necessary when there is a suspicion of drug misuse by the individual being tested.

Presumptive drug testing that exceeds one test per date of service is not covered or reimbursable.

Definitive drug testing not to exceed one test per date of service using HCPCS code G0480 or G0659 is considered medically necessary when there is a suspicion of drug misuse by the individual being tested.

Definitive drug testing that exceeds one test per date of service using HCPCS code G0480 or G0659 is not covered or reimbursable.

Definitive drug testing using HCPCS codes G0481, G0482, and G0483 is not covered or reimbursable.

Drug testing by hair analysis is not covered or reimbursable.

Note: Specimen verification is considered part of the quality assurance process for clinical laboratory test management and is not a separately reimbursable service.

Cigna does not reimburse for drug testing when billed by an entity that did not perform the service.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Substance use disorders (SUDs) are a significant public health concern in the United States, with substantial impacts on individuals, families, and communities. The 2021 VA/DoD clinical practice guideline for the management of SUDs highlights the prevalence of SUDs among veterans with estimates that 10% of veterans are affected by alcohol use disorder and around 5% experience opioid use disorder. The prevalence of the aforementioned disorders are driven in part by factors such as military service, trauma, and mental health conditions. The general population also experiences high rates of SUDs (14.5%), with alcohol being the most used substance (5.8%), followed by opioids, cannabis, and stimulants (2.5% collectively). The epidemiology of SUDs in bot the veteran and civilian populations is influenced by various social determinants of health, including socioeconomic status, mental health conditions like PDSD, and access to healthcare services.

The impact of SUDs is multifaceted, with significant consequences for physical health, mental well-being, and society functioning. Individuals with SUDs are at an increased risk for a range of health complications, including liver disease, cardiovascular disorders, infectious diseases like HIV and hepatitis, as well as overdoes-related deaths. In 2020, there were more than 91,000 drug overdose deaths in the United States, with opioids responsible for a large portion of these fatalities. In 2019, 49,860 Americans died of opioid overdose; more than two times the number of individuals who died of opioid overdose in 2010. The 2019 statistic makes opioid overdose the 11th most common cause of death in the United States.

The guideline highlights significant racial and ethnic disparities in the care of individuals with SUDs. It highlights that racial and ethnic minorities, particularly Black, Hispanic, and Native American populations, often experience higher rates of substance misuse and face greater barriers to accessing treatment compared to White individuals. These groups are less likely to receive evidence-based treatments and may encounter challenges such as stigma, cultural barriers, and limited access to healthcare services. The guideline emphasizes the importance of addressing these disparities through culturally competent care, early intervention, and improved access to evidence-based treatments for all individuals affected by SUDs.

There is unequal deployment of drug testing with markedly different consequences for Black, Indigenous, People of Color (BIPOC) when their test results are positive. Due to the underrepresentation of BIPOC in scientific studies, the studies may yield interventions that may not be culturally appropriate.

General Background

Indications for drug testing depend upon the treatment setting and clinical purpose. According to a consensus statement from the American Society for Addiction Medicine (ASAM) on the appropriate use of drug testing in clinical addiction medicine, drug testing is recommended as a therapeutic tool for evidence-based addiction treatment and can be used in all addiction treatment settings. Treatment providers should include drug testing at intake to assist in a patient's initial assessment and treatment planning (Jarvis, et al., 2017). Using a variety of laboratory methods, clinical drug testing may be presumptive or definitive and may be used to detect prescription drugs of abuse, illicit drugs and other substances. Drug testing in a physician supervised treatment setting may be appropriate when there is a high suspicion or concern of drug abuse or misuse for the individual

being tested. This may include testing of one or more metabolites of a prescribed drug to assure actual compliance with the drug regimen rather than diversion. The results of testing should be necessary for treatment planning. Clinical records should support the need for testing for the specific drug(s) or substance(s) of interest by documentation regarding the diagnosis, history and physical examination and/or behavior of the individual being tested. Records should also reflect how results of testing will impact the treatment plan. Reimbursement is not available for a drug test when it is billed by an entity that did not perform the service being billed.

There is no clear evidence in the published peer-reviewed scientific literature regarding the most effective frequency of presumptive or definitive testing for misuse or abuse of prescription drugs, illicit drugs or substances. Further, professional society consensus guidelines are lacking in this regard. Guidelines and various technical assistance papers/white papers support more frequent drug testing at the beginning of treatment and less frequent testing as sobriety/abstinence is established.

Specimen Source
Several specimen sources may be used for drug testing, including urine, blood, hair, saliva and nails. Drug testing using urine has been evaluated rigorously and is the most common biological substance used in the addiction treatment setting.

There is increasing interest in the use of hair as a specimen source for drug testing. Although a longer-term history of drug use can be detected because of the slow rate of hair growth, there are limitations to use of hair as a specimen source. According to the Substance Abuse and Mental Health Services Association (SAMHSA, 2012), hair cannot detect drug use within the previous 7–10 days and results are difficult to interpret. Other limitations include difficulty in detecting low-level drug use, results may be biased with hair color, there is a possibility of environmental contamination, and the specimen can be removed by shaving. There is insufficient evidence in the published peer-reviewed scientific literature to establish the role of hair analysis for clinical drug testing. Further, there is a lack of professional society support as evidenced by published consensus guidelines to establish hair analysis as a standard of care for drug testing.

Specimen Adulteration
SAMHSA (2012) has established specific requirements for urinary specific gravity, pH, and creatinine concentration for a specimen to be considered valid for drug testing. Individuals may attempt to undermine drug testing using a number of methods, including dilution and adulteration. Large amounts of water may be ingested or added to a urine specimen with the intent to dilute the level of a drug below a detectable threshold. Masking agents, such as hydrastis canadensis tea or niacin may be consumed with the intent to hide the presence of a misused or abused drug. Other adulterants including ammonia, bleach, hydrogen peroxide, liquid soaps, vinegar, and radish and mustard seed extracts may be added to the urine specimen. Some individuals may substitute a drug-free urine specimen or submit a sample of synthetic urine in an attempt to prevent the detection of the drug(s) or substance of abuse. According to ASAM, if there is suspicion that a sample had been tampered with, it should be tested for specimen validity including creatinine concentration, pH level, specific gravity, and adulterants (Jarvis, et al., 2017). The clinical utility of routine urinalysis to establish specimen integrity has not been established.

Specimen Verification
DNA analysis and other methods have been proposed to ensure that the source of a specimen for testing is the same as the individual for whom testing is intended. Specimen verification is considered part of the quality assurance process for laboratory test management and is not a separately reimbursable service.

Drug Testing Place of Service

Most point of care tests (POCT) are used in an environment that is external to a clinical laboratory, such as a health care provider's office, where the specimen is collected. POCT tests are usually CLIA-waived, indicating they are simple tests and have a low risk of producing an incorrect result (Centers for Disease Control and Prevention [CDC], 2021). A POCT offers immediate results but may be conducted by non-laboratory personnel and errors in technique and interpretation are more likely (SAMHSA, 2012). POCT tests use immunoassay technologies for drug detection but are less sensitive and less specific than immunoassays performed in a laboratory setting. Although POCT should be US Food and Drug Administration (FDA) approved, these tests are calibrated and validated by the individual manufacturer of the test kit and are not subject to national quality control standards, such as those established by Clinical Laboratory Improvement Amendments ([CLIA]-CMS certified) accreditation.

Clinical laboratory test systems are assigned a moderate or high complexity category based on seven criteria given in the CLIA regulations. The final score is used to determine whether the test system is classified as moderate or high complexity (CDC, 2021). High-complexity tests should be performed in a CLIA accredited laboratory to ensure that consistent quality control standards for testing and interpretation are in place. In general, the more complicated the test, the more stringent the requirements under CLIA (CDC, 2021). Tests performed in laboratories have several important advantages over POCTs: higher degree of precision and are performed by trained laboratory professionals. As such, the role of high-complexity testing performed in a non-CLIA-accredited laboratory setting has not been established. High-complexity test methods include gas chromatography with single or tandem mass spectrometry (GC/MS), thin layer chromatography and liquid chromatography single or tandem mass spectrometry (LC/MS), among others.

Laboratories should take all reasonable steps to ensure that they are not submitting claims for services that are not covered, reasonable and necessary consistent with guidance from the Office of the Inspector General ([OIG], 1998), which notes "Fundamentally, compliance efforts are designed to establish a culture within a clinical laboratory that promotes prevention, detection and resolution of instances of conduct that do not conform to Federal and State law, and Federal, State and private payer health care program requirements, as well as the clinical laboratory's ethical and business policies." Regarding medical necessity, the OIG further notes, "Laboratory compliance programs, to be effective, should communicate to physicians that claims submitted for services will only be paid if the service is covered, reasonable, and necessary for the beneficiary, given his or her clinical condition. Laboratories should take all reasonable steps to ensure that it is not submitting claims for services that are not covered, reasonable and necessary."

Type of Drug Testing/Testing Methodologies

Generally there is no set drug testing panel and the drugs tested vary by laboratory and within laboratories. No single drug panel is suitable for all clinical uses; many testing options exist that can be adapted to clinical needs (SAMHSA, 2012). There should be a suspicion/concern of drug abuse or misuse for the individual being tested, and the clinical record should reflect the diagnosis, history and physical examination and/or behavior of the person being tested and support testing for the specific drug(s) or substance(s) being requested. Similarly, the clinical record should document how results of the testing will impact treatment planning.

Drug testing may involve a two-step process including an initial drug screen that identifies potentially or presumptively positive and negative specimens. This may be followed by a definitive confirmatory test of any screened positive assays (SAMHSA, 2012) or there is suspicion regarding the abuse or misuse of other drugs or substances and a presumptive test is not available.

Testing procedures can be qualitative (e.g., positive/negative or present/absent), semi-quantitative or quantitative (measured) depending on the purpose of the testing.

Presumptive Drug Testing (Screening)
Presumptive drug screening uses qualitative analysis to determine whether a specific drug, drug metabolite or substance is detectable above a threshold concentration in a sample. The results may be read by direct optical observation with or without instrument assistance. If detectable, the result is considered positive, if the drug/metabolite/substance is not detected, it is considered a negative result. Presumptive methods include the use of dipsticks, cups, cards, cartridges or instrumented test systems, such as discrete multichannel chemistry analyzers utilizing immuno- or enzyme assay. Immunoassays are most used for presumptive drug screening. They may detect low concentrations of a substance with a high degree of specificity and are the most common laboratory method used for presumptive testing. Testing methods include Enzyme Immunoassays (EIA), Radioimmunoassay (RIA), Enzyme Linked Immunoassay Sorbent Assay (ELISA), Enzyme Multiplied Immunoassay Test (EMIT), Cloned Enzyme Donor Immunoassay (CEDIA), Fluorescence Polarization Immunoassay (FPIA) and enzymatic methods (e.g. alcohol dehydrogenase).

Specific professional society recommendations for the frequency of presumptive testing are lacking. In general, initial baseline testing is performed to establish the presence of prescription drugs of abuse, illicit drugs and other substances. Based on the risk profile of the individual, the frequency of testing should be higher at the start of treatment and should be decreased as recovery progresses (Jarvis, et al., 2017). If there is suspicion of abuse or misuse of a drug or substance, presumptive testing at one unit per date of service may be appropriate if results will guide treatment planning. Likewise, repeat testing may be appropriate to allow for monitoring of abstinence or identification of continued abuse. The clinical utility of presumptive testing on a more frequent schedule has not been established in the published, peer-reviewed scientific literature.

Definitive (Confirmatory) Drug Testing
Definitive laboratory methods identify (confirm) the type and amount of a drug/metabolite/substance in a sample and may be qualitative, quantitative or a combination of both. Methods typically used for definitive testing include gas chromatography with single or tandem mass spectrometry (GC/MS), thin layer chromatography and liquid chromatography single or tandem mass spectrometry (LC/MS) and exclude immunoassays and enzymatic methods (e.g., alcohol dehydrogenase). Chromatography/spectrometry methods offer a highly sensitive and specific technique for detecting drugs or metabolites. These high-complexity tests should be performed in a CLIA (CMS-certified) accredited laboratory where national quality control standards for testing and laboratory personnel training have been established.

According to ASAM, immunoassay results should be used cautiously when monitoring a patient's adherence to prescribed benzodiazepines. If a patient reports that he or she is taking the drug but a urine drug screen is negative, further analysis using definitive testing should be considered. Additionally, definitive testing can be used when the results inform clinical decisions with major clinical or non-clinical implications for the patient (e.g., treatment transition, changes in medication therapies, changes in legal status) (Jarvis, et al., 2017). Clinical correlation may suffice; if the patient or a family member affirms that drug use has occurred, a confirmation drug test is not usually needed (SAMHSA, 2012). Clinical documentation should identify the specific drug(s)/substances of interest, clinical rationale for each definitive test ordered and how the results of such testing will be used to guide clinical care (i.e., clinical utility). Definitive drug testing may also be appropriate if a presumptive drug test is not available for the drug or substance for which there is a suspicion of abuse. The definitive test will allow detection if the drug or substance of interest is present in the specimen.

Published professional society recommendations are lacking regarding the specific frequency for definitive testing or the specific number of drug analytes or analogs that should be tested for in any encounter. According to the ASAM there are no universal standards in clinical drug testing for

addiction identification, treatment, medication monitoring, or recovery (Jarvis, et al., 2017). As with presumptive drug testing, the frequency of testing should be based on the risk profile of the individual, including the stability of the patient, the type of treatment, and the treatment setting (ASAM, 2020). Results should impact the treatment plan. Generally the frequency of testing should be higher at the start of treatment and when a period of abstinence is achieved, the frequency can be decreased. Drug testing at a frequency of one unit for up to seven classes allows an opportunity for effective monitoring of an individual's misuse of a broad variety of drug(s), drug class(es) or substance(s). There is insufficient evidence in the published peer-reviewed scientific literature to establish the clinical utility for more frequent drug testing.

U.S. Food and Drug Administration (FDA)
Numerous point-of-care tests have been cleared for testing drugs of abuse. FDA regulates and reviews drugs of abuse tests before they can be sold to consumers or healthcare professional in the United States. In its review, the FDA evaluates the design and performance of tests and sample collection systems to help ensure that they produce accurate results (FDA, 2023).

Literature Review/Professional Society/Organizations
There is insufficient evidence in the published peer-reviewed scientific literature to establish the clinical utility or effectiveness of presumptive or definitive drug testing at a specific frequency. Further, no professional society or organization has published consensus guidelines regarding the frequency of drug testing. However, several published professional society white papers and technical assistance papers have recommended parameters regarding the principles of testing in a substance abuse treatment program. In general, testing should be more frequent at the start of treatment. After initial baseline testing, drug test monitoring can progress to once per week with once per month testing as long-term abstinence/sobriety is achieved.

American Academy of Pain Medicine (AAPM): The AAPM published a consensus statement on urine drug monitoring (UDM) in patients with chronic pain who are prescribed opioids (Argoff, et al., 2018). The expert panel recommended that definitive UDM is the most clinically useful method for assessing baseline opioid use and misuse in patients with chronic pain. The panel suggested the following strategies to determine UDM frequency:

- a physical examination to obtain patient history and behaviors that can be used to predict opioid misuse should be conducted
- validated tools to assess the risk for aberrant medication-taking behavior, opioid misuse, opioid use disorder, and the potential for respiratory depression/overdose should be used
- prescription drug monitoring programs (PDMPs) along with previous UDM results should be checked

Additionally, AAPM recommended that low-risk patients should be tested at least annually, moderate risk patients should be tested two or more times per year, and high risk patients should be tested three or more times per year. Additional monitoring can be performed as frequently as necessary according to clinical judgment.

American Society of Addiction Medicine (ASAM): The ASAM published a public policy statement on the ethical use of drug testing in the practice of addiction medicine (2019). The statement included the following recommendations:

- Drug testing is recommended as a therapeutic tool in evidence-based addiction treatment.
- Drug testing should be used only when clinically necessary.
- Presumptive testing should be a routine part of initial and ongoing patient assessment.
- Definitive testing may be used when the results will alter the care plan.

- It is inappropriate to order definitive testing for all analytes in every drug test conducted on a patient.
- Clinicians should ensure that drug test results remain confidential.
- Clinicians ordering drug tests should be aware of the costs of different testing methods and the financial burden that the patient and society may incur.
- If clinicians responsible for making clinical decisions based on drug test results do not have training in toxicology, collaboration should occur with a toxicologist or an individual with Medical Review Officer certification
- It is unethical to provide or receive incentives for the use of drug testing independent of a clinical rationale.

In 2017 ASAM published a consensus statement on the appropriate use of drug testing in clinical addiction (Jarvis, et al., 2017). The ASAM stated that drug testing assists with monitoring adherence and abstinence in treatment and can improve patient outcomes. Therefore, drug testing should be used in addiction treatment settings. The guidelines included the following recommendations regarding the frequency of testing:

- Frequency of testing should be dictated by patient acuity and level of care.
- Providers should look to tests' detection capabilities and windows of detection to determine the frequency of testing.
- During the initial phase of treatment, drug testing should be done at least weekly.
- When a patient is stable in treatment, drug testing should be done at least monthly.
- Increasing the frequency of testing does not result in decreased substance use.
- When possible, testing should occur on a random schedule.

ASAM published a National Practice Guideline for the Treatment of Opioid Use Disorder (2020). The guideline noted that urine drug testing can be used during assessment and diagnosis to validate patient self-reported information and to identify poly-substance use. Additionally, testing can be used to monitor patients for adherence to medication and for use of illicit and controlled substances during treatment. The frequency of drug testing is determined by a number of factors including the stability of the patient, type of treatment and treatment setting. The guideline also notes that no further clarification was found in the literature related to urine drug testing and this is considered a gap in literature.

American Society of Interventional Pain Physicians (ASIPP): ASIPP Guidelines for Responsible, Safe, and Effective Prescription of Opioids for Chronic Non-Cancer Pain noted that presumptive urine drug testing (UDT) is implemented from initiation along with subsequent adherence monitoring, using in-office point of service testing, followed by confirmation with chromatography/mass spectrometry for accuracy in select cases, to identify patients who are non-compliant or abusing prescription drugs or illicit drugs. Urine drug testing may decrease prescription drug abuse or illicit drug use when patients are in chronic pain management therapy (Manchikanti, et al., 2017)

Centers for Disease Control and Prevention (CDC): In 2022 the CDC published a guideline for prescribing opioids for pain. The guideline recommended that when opioids are prescribed for subacute or chronic pain, clinicians should consider the benefits and risks of toxicology testing to assess for prescribed medications as well as other prescribed and nonprescribed controlled substances (recommendation category: B; evidence type: 4) (Dowell, et al., 2022).

Toxicology Implementation Considerations:
- testing should not be punitive
- clinicians should consider the benefits and risks of testing before starting opioids and at least annually during opioid therapy

- clinicians should minimize bias and should not use this recommendation differently based on assumptions about patients
- toxicology screening results can be considered potentially useful data when used in the context of other clinical information
- discuss with the patient what expected results are and ask whether there may be unexpected results
- clinicians should know what drugs are included in toxicology screening panels
- confirmatory/definitive testing should be used when:
    - results will guide decisions with major clinical or nonclinical implications for the patient;
    - to detect specific opioids or other drugs within a class or those that cannot be identified on standard immunoassays
    - to confirm unexpected screening toxicology test results
- restricting confirmatory testing to situations and substances that will affect patient management can reduce costs of toxicology testing
- discuss with unexpected results with patients before specific confirmatory testing may remove the need for confirmatory testing
- if unexpected results from toxicology screening are not explained, a confirmatory test on the same sample using a method selective enough to differentiate specific opioids and metabolites (e.g., gas or liquid chromatography–mass spectrometry) might be warranted
- unexpected results should be used to improve patient safety

Category B recommendations might not apply to all persons in the group addressed in the recommendation; therefore, different choices will be appropriate for different patients, and decisions should be made based on the patient's circumstances. For category B recommendations, clinicians must help patients arrive at a decision consistent with patient values and preferences and specific clinical situations (shared decision-making).
Evidence type 4 include clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations; equivalent to AHRQ low strength of evidence with serious limitations.

Department of Veterans Affairs Department of Defense (VA/DoD): In a 2022 clinical practice guideline for the use of opioids in the management of chronic pain, the VA/DoD provided a "weak for" recommendation for urine drug testing (UDT) for patients on long-term opioids to decrease the risk of self-directed violence (e.g., suicide). The recommendation was given a "weak for" rating due to the low quality of evidence, including small sample sizes and lack of available evidence, and varied patient values and preferences regarding the stigma associated with UDT. The guideline does not address the frequency of testing.

The 2021 VA/DoD clinical practice guideline for the management of SUDs doesn't provide recommendations related to drug testing.

Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment (SAMHSA): SAMHSA published 'Federal Guidelines for Opioid Treatment Centers' (OTP) (2024) which stated that, "When conducting random drug testing,
OTPs must use drug tests that have received the Food and Drug Administration's (FDA) marketing authorization for commonly used and misused substances that may impact patient safety, recovery, or otherwise complicate substance use disorder treatment, at a frequency that is in accordance with generally accepted clinical practice and as indicated by a patient's response to and stability in treatment, but no fewer than eight random drug tests per year patient, allowing for extenuating circumstances at the individual patient level. This requirement does not preclude distribution of legal harm reduction supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose."

Regarding point-of-care testing, the SAMHSA (2024) noted that in 2017, the SAMHSA and the CDC published a joint announcement stating that, "federal funding could be used to purchase rapid fentanyl test strips for drug-checking purposes. 181 In the summer of 2023, the FDA approved a moderate-complexity point-of-care (POC) urine test for detecting fentanyl in human urine samples. OTPs should be familiar with FDA-approved tests for distribution and use in the clinic."

In a technical assistance paper titled 'Clinical Drug Testing in Primary Care', SAMHSA (2012) notes that when used appropriately, drug testing can be an important clinical tool in patient care. The document also note that a negative screening test result is rarely followed by a confirmatory test; that laboratories perform confirmatory tests on positive results, either routinely or only for certain drug/drug class positives (e.g., amphetamines, opiates).

U.S. Preventive Service Task Force (USPSTF): USPSTF published a recommendation on screening for unhealthy drug use (2020). The recommendation is to screen adults 18 years or older by asking questions about unhealthy drug use. Screening refers to asking one or more questions about drug use. Screening does not refer to testing urine, saliva, blood, or other biological specimens for the presence of drugs. Screening should be implemented when services for accurate diagnosis, effective treatment, and appropriate care can be offered or referred. The USPSTF concluded that the current evidence is insufficient to assess the balance of benefits and harms of screening for unhealthy drug use in adolescents.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No National Coverage Determination found	
LCD	First Coast Service Options, Inc.	Controlled Substance Monitoring and Drugs of Abuse Testing (L36393)	10/1/2019
LCD	Novitas Solutions, Inc.	Controlled Substance Monitoring and Drugs of Abuse Testing (L35006)	10/17/2019

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Presumptive/Screening/Qualitative Drug Testing Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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
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

Services in excess of one test per date of service are not covered or reimbursable.

Definitive/Confirmatory/Quantitative Drug Testing Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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, includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed
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

Services in excess of one test per date of service are not covered or reimbursable.

Not Covered or Reimbursable:

HCPCS Codes	Description
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, (1) 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 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 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

Not Covered or Reimbursable:

HCPCS Codes	Description
P2031	Hair analysis (excluding arsenic)

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	Removed policy statement for CLIA approved laboratories. Revised policy statements for presumptive and definitive drug testing	2/15/2025
Focused Review	Added policy statements regarding testing limits on presumptive and definitive drug testing. Removed the not medically necessary policy statement for additional testing to determine drug misuse.	12/3/2023
Annual Review	Removed annual limits for drug testing	1/15/2024