



# Medical Coverage Policy

Effective Date .....1/15/2024

Next Review Date .....1/15/2025

Coverage Policy Number..... 0513

## Drug Testing

### Table of Contents

- Overview ..... 2
- Coverage Policy..... 2
- General Background ..... 3
- Medicare Coverage Determinations ..... 10
- Coding Information..... 10
- References ..... 13
- Revision Details ..... 15

### 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

**A high-complexity laboratory drug test is considered medically necessary when it is performed in a Clinical Laboratory Improvement Amendment ([CLIA]-CMS certification)-approved laboratory and the applicable criteria are met.**

**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, and ALL of the following criteria are met:**

- **The diagnosis, history and physical examination and/or behavior of the individual being tested support the need for the specific drug testing being requested.**
- **The results of testing will impact treatment planning.**
- **Testing is performed in a physician-supervised treatment setting.**

**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, and EITHER of the following criteria are met:**

- **Presumptive test results are inconsistent with the individual's condition, history and examination**
- **Presumptive drug test is not available for the drug for which there is a suspicion of abuse or misuse and ALL of the following criteria are met:**
  - **The diagnosis, history and physical examination and/or behavior of the individual being tested support the need for the specific drug testing being requested.**
  - **Results of testing will impact treatment planning.**
  - **Testing is performed in a physician-supervised treatment setting.**

**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.**

## **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. 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.

### **Specimen Source**

A number of substances 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 on the basis of 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 commonly 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, 2018).

### **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.

**Health Evidence Review Commission (HERC) – Oregon:** In 2018 the published coverage guidance for urine drug testing. Urine drug testing (UDT) using presumptive testing is recommended for coverage when the results will affect treatment planning. Definitive testing is recommended for coverage as a confirmatory test only when the result of the presumptive testing is inconsistent with the patient's history, presentation, or current prescribed medication plan, and the results would change management. Additionally, the commission stated that definitive testing is recommended for coverage for no more than seven substances per day.

**Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment (SAMHSA):** SAMHSA published 'Federal Guidelines for Opioid Treatment Centers' (OTP) (2015) which noted opioid treatment centers must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient, in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

Regarding point of care (POC) testing SAMHSA notes that OTPs often perform onsite point of collection (POC) tests using sensitive and automated immunoassay (IA) technologies that screen urine or oral fluid samples for a relatively narrow range of drug classes (e.g. amphetamines, barbiturates, benzodiazepines, opioids) and a limited number of specific drugs. POC tests such as IAs have a place in clinical decision making but are not by themselves adequate to satisfy the regulatory requirements for drug use testing services. Laboratory testing affords the opportunity to obtain confirmation testing such as gas chromatography-mass spectrometry (GC-MS) or liquid chromatography-mass spectrometry (LC-MS) or tandem mass-spectrometry (LC-MS/MS.) This should form part of the OTP's established procedures for addressing potentially false positive and false negative urine or other toxicology test results.

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.

**Washington State Agency Medical Directors' Group (AMDG):** The AMDG published an Interagency Guideline on Prescribing Opioids for Pain (2015) which noted that drug testing is to identify aberrant behavior, undisclosed drug use and/or abuse, and verify compliance with treatment and is an important part of the baseline risk assessment for all candidates for chronic opioid therapy. According to the Guideline, testing should be repeated on a random basis at the approximate frequency determined by the patient's risk category. The frequency of testing ranges from periodic (e.g., up to one/year) for individuals at low risk, regular (e.g., up to two/year) for individuals at moderate risk, frequent (e.g., three-four/year) for individuals at high risk. For individuals with aberrant behavior, testing should be performed at time of visit.

## Medicare Coverage Determinations

	<b>Contractor</b>	<b>Determination Name/Number</b>	<b>Revision Effective Date</b>
NCD	National	No National Coverage Determination found	
LCD	CGS Administrators, LLC	Controlled Substance Monitoring and Drugs of Abuse Testing (L36029)	10/2023
LCD	Noridian Healthcare Solutions, LLC	Lab: Controlled Substance Monitoring and Drugs of Abuse Testing (L36707)	4/8/2021
LCD	Noridian Healthcare Solutions, LLC	Lab: Controlled Substance Monitoring and Drugs of Abuse Testing (L36668)	4/8/2021
LCD	National Government Services, Inc.	Urine Drug Testing (L36037)	10/1/2019
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
LCD	Palmetto GBA	Lab: Controlled Substance Monitoring and Drugs of Abuse Testing (L35724)	4/8/2021
LCD	Wisconsin Physicians Service Insurance Corporation	Drug Testing (L34645)	10/1/2021

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.
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:**

<b>CPT®* Codes</b>	<b>Description</b>
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:**

<b>CPT®* Codes</b>	<b>Description</b>
0011U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites

<b>HCPCS Codes</b>	<b>Description</b>
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),

HCPCS Codes	Description
	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)

**\*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.**

## References

1. American Society of Addiction Medicine (ASAM). Public Policy Statement on Advancing Racial Justice in Addiction Medicine. 2021 Feb 25. Accessed on December 10, 2023. Available at: <https://www.asam.org/advocacy/find-a-policy-statement>
2. American Society of Addiction Medicine (ASAM). Racial Justice Beyond Healthcare: Addressing the broader structural issues at the intersection of race, drug use and addiction. 2022 Dec 15. Accessed on Dec 10, 2023. Available at URL address: <https://www.asam.org/advocacy/public-policy-statements>
3. American Society of Addiction Medicine (ASAM). Public Policy Statement on the Ethical Use of Drug Testing in the Practice of Addiction Medicine. 2019 Apr 3. Accessed on December 10, 2023. Available at: <https://www.asam.org/advocacy/find-a-policy-statement>
4. American Society of Addiction Medicine. Drug testing: a white paper of the American Society of Addiction Medicine (ASAM). Chevy Chase, MD: ASAM: October 26, 2013. Archived.
5. The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update. J Addict Med. 2020 Mar/Apr;14(2S Suppl 1):1-91. Erratum in: J Addict Med. 2020 May/Jun;14(3):267.
6. Argoff CE, Alford DP, Fudin J, Adler JA, Bair MJ, Dart RC, et al. Rational urine drug monitoring in patients receiving opioids for chronic pain: consensus recommendations. Pain Med 2018 Jan 1;19(1):97-117.
7. Centers for Disease Control and Prevention (CDC). Clinical Laboratory Improvement Amendments (CLIA). 2022 Nov 14. Accessed December 10, 2023. Available at URL address: <http://wwwn.cdc.gov/clia/Resources/TestComplexities.aspx>
8. Centers for Medicare and Medicaid Services. Clinical Laboratory Improvement Amendments (CLIA) Oct 22, 2013. Accessed on December 10, 2023. Available at URL address: [http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/LDT-and-CLIA\\_FAQs.pdf](http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/LDT-and-CLIA_FAQs.pdf)
9. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCDs) alphabetical index. Accessed December 10, 2023. Available at URL address: [https://www.cms.gov/medicare-coverage-database/indexes/lcd-alphabetical-index.aspx?Cntrctr=373&ContrVer=1&CntrctrSelected=373\\*1&DocType=Active%7cFuture&s=All&bc=AggAAAQAAAA&](https://www.cms.gov/medicare-coverage-database/indexes/lcd-alphabetical-index.aspx?Cntrctr=373&ContrVer=1&CntrctrSelected=373*1&DocType=Active%7cFuture&s=All&bc=AggAAAQAAAA&)
10. Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) alphabetical index. Accessed December 10, 2023. Available at URL address: <https://www.cms.gov/medicare-coverage-database/reports/reports.aspx>

11. Chou R, Fanciullo GJ, Fine PG, Adler JA, Ballantyne JC, Davies P, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain*. 2009 Feb;10(2):113-30.
12. Christo PJ, Manchikanti L, Ruan X, Bottros M, Hansen H, Solanki DR, Jordan AE, Colson J. Urine drug testing in chronic pain. *Pain Physician*. 2011 Mar-Apr;14(2):123-43.
13. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. *MMWR Recomm Rep* 2022;71(No. RR-3):1-95.
14. Dupouy J, Mémier V, Catala H, Lavit M, Oustric S, Lapeyre-Mestre M. Does urine drug abuse screening help for managing patients? A systematic review. *Drug Alcohol Depend*. 2014 Mar 1;136:11-20.
15. Health Evidence Review Commission (Oregon) Evidence-Based Reports: Urine Drug Testing. 2018. Accessed December 10, 2023. Available at: <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports-Blog.aspx?View={DE654D2C-76D6-4607-B754-C7862C05B54F}&SelectedID=86>
16. Hoffman RJ. Testing for drugs of abuse (DOAs). In: UpToDate, Traub SJ. (Ed), UpToDate, Waltham, MA. Literature review current through: November 2023. Topic last updated: September 21, 2022. Accessed December 22, 2022.
17. Jarvis M, Williams J, Hurford M, Lindsay D, Lincoln P, Giles L, et al. Appropriate Use of Drug Testing in Clinical Addiction Medicine. *J Addict Med*. 2017 May/Jun;11(3):163-173.
18. Larochelle MR, Cruz R, Kosakowski S, Gourlay DL, Alford DP, Xuan Z, et al. Do Urine Drug Tests Reveal Substance Misuse Among Patients Prescribed Opioids for Chronic Pain? *J Gen Intern Med*. 2022 Aug;37(10):2365-2372.
19. Manchikanti L, Kaye AM, Knezevic NN, McAnally H, Slavin K, Trescot AM, et al. Responsible, Safe, and Effective Prescription of Opioids for Chronic Non-Cancer Pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines. *Pain Physician*. 2017 Feb;20(2S):S3-S92.
20. Morin KA, Dabous JR, Vojtesek F, Marsh D. Evaluating the association between urine drug screening frequency and retention in opioid agonist treatment in Ontario, Canada: a retrospective cohort study. *BMJ Open*. 2022 Oct 12;12(10):e060857.
21. National Institute on Drug Abuse [NIDA]. Screening Tools and Prevention. National Institute on Drug Abuse website. January 6, 2023. Accessed December 10, 2023. Available at URL address: <https://www.drugabuse.gov/nidamed-medical-health-professionals/screening-tools-prevention>
22. Rosano TG, Wood M, Hooten WM, Rumberger JM, Fudin J, Argoff CE. Application and Clinical Value of Definitive Drug Monitoring in Pain Management and Addiction Medicine. *Pain Med*. 2022 Apr 8;23(4):821-833.
23. Sobel HG, Warrington JS, Francis-Fath S, Crocker AM, Berger CA. A Descriptive analysis of urine drug screen results in patients with opioid use disorder managed in a primary care setting. *Addict Sci Clin Pract*. 2021 Sep 30;16(1):59.

24. Substance Abuse and Mental Health Services Administration. Federal guidelines for opioid treatment programs. March 2015. Accessed December 10 2023. Available at URL address: <https://store.samhsa.gov/product/Federal-Guidelines-for-Opioid-Treatment-Programs/PEP15-FEDGUIDEOTP>
25. Substance Abuse and Mental Health Services Administration. Clinical Drug Testing in Primary Care. Technical Assistance Publication (TAP) 32. HHS Publication No. (SMA) 12-4668. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012.
26. U.S. Department of Health and Human Services. Office of Inspector General. Publication of OIG Compliance Program Guidance for Clinical Laboratories. Fed. Reg. 45076; August 24, 1998. Accessed December 10, 2023. Available at URL address: <https://www.oig.hhs.gov/compliance/compliance-guidance/index.asp>
27. U.S. Food and Drug Administration (FDA). Drugs of Abuse Tests. Current as of Nov 21, 2023. December 10, 2023. Available at URL address: <https://www.fda.gov/medical-devices/vitro-diagnostics/drugs-abuse-tests>
28. U.S. Preventive Services Task Force. Unhealthy Drug Use: Screening. Release date June 9, 2020. Accessed December 10, 2023. Available at URL address: [http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/drug-use-illicit-screening?ds=1&s=drug screening](http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/drug-use-illicit-screening?ds=1&s=drug%20screening)
29. Washington State Agency Medical Director’s Group. Interagency Guideline on Prescribing Opioids for Pain. June 2015. Accessed December 10, 2023. Available at URL address: <http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf>

## Revision Details

Type of Revision	Summary of Changes	Date
Focused Review	<ul style="list-style-type: none"> <li>Added policy statements regarding testing limits on presumptive and definitive drug testing.</li> <li>Removed the not medically necessary policy statement for additional testing to determine drug misuse.</li> </ul>	12/3/2023
Annual Review	<ul style="list-style-type: none"> <li>Removed annual limits for drug testing</li> </ul>	1/15/2024

---

“Cigna Companies” refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2024 The Cigna Group.