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. 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.

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Presumptive drug testing not to exceed one (1) unit per date of service up to 32 units per year 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.**

Definitive drug testing not to exceed 16 dates of service per year for a maximum of eight (8) units (a unit may include a specific individual drug and/or its metabolite(s), or its structural isomer(s)) per date of service up to 128 units per year 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.**

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

Drug testing by hair analysis is considered experimental, investigational or unproven.

Any other drug testing to determine drug misuse, including but not limited to the following indications is considered not medically necessary:

- **routine tests for confirmation of specimen integrity (e.g., urinalysis, creatinine concentration, presence of oxidizing agents, pH, temperature)**
- **testing ordered by or on behalf of third parties (e.g., school, courts, employers)**

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 white paper on Drug Testing published by the American Society for Addiction Medicine (ASAM, 2013), testing is a key diagnostic and therapeutic tool that is useful for patient care and in monitoring of the ongoing status of a person who is being treated for addiction. 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
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 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 (2013), collection devices should have built in integrity checks to measure temperature, pH, creatinine concentration and the presence of oxidizing agents. 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], 2018). 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, 2018). 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, 2018). 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 when a substantial period of abstinence is achieved, the frequency can be lower (ASAM, 2013). 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, up to a maximum of 32 units per year 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 (2013), there is no compelling rationale in clinical practice for subjecting all negative immunoassay results to definitive testing. To date there are no published professional society consensus guidelines regarding the effectiveness of definitive (i.e., confirmatory) drug testing if presumptive testing is negative and the role of such testing has not been established. However, if a presumptive drug screen yields a positive result and more detail is required for a specified medically necessary reason, definitive drug testing may be appropriate. In general, positive immunoassay results need only be subjected to definitive testing when the results conflict with patients' account of their drug use or when drug specificity is needed in class-specific assays (i.e., amphetamines, benzodiazepines, opiates) (ASAM, 2013). 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 (2013; 2015), there is no universal standard today in clinical drug testing for medication monitoring or for drug testing in addiction treatment. 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, 2015). 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 eight units per date of service to a maximum of 128 units per year, not to exceed 16 dates of service per year allows an opportunity for effective monitoring of an individual's misuse of a broad variety of drug(s), drug class(es) or substance(s). A unit may include a specific individual drug and/or its metabolite(s), and/or its structural isomer(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 Use of Medications in the Treatment of Addiction Involving Opioid Use (2015). Regarding urine drug testing, the guideline noted that urine drug testing during the assessment process and frequently during treatment is recommended. 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.

ASAM also published a document titled "Drug Testing: A White Paper of the American Society of Addiction Medicine (ASAM; 2013) which suggests that random drug testing be used instead of scheduled testing. Further, although there are no established guidelines for testing, frequency of testing should be higher at the start of treatment and when a substantial period of abstinence is achieved, the frequency can be lower. The White Paper notes that most physician health programs set testing at once a week early in monitoring, progressing to once a month when long-term sobriety is achieved. Cost benefit analysis and risk stratification is necessary in deciding the frequency of testing, balancing laboratory and behavioral science.

American Society of Interventional Pain Physicians (ASIPP): ASIPP Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 – Guidance noted urine drug testing (UDT) must be implemented from initiation along with subsequent adherence monitoring, in an in-office setting with

immunoassay and confirmation for accuracy with chromatography 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., 2012)

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 illicit drug use (2008). Although the primary focus of the document is on preventive screening by use of questionnaires, the USPSTF notes that while clinicians should be alert to the signs and symptoms of illicit drug use in patients, the added benefit of screening asymptomatic patients in primary care practice remains unclear. Toxicologic tests of blood or urine can provide objective evidence of drug use, but such tests do not distinguish between occasional users and those who are impaired by drug use.

Washington State Agency Medical Directors' Group (AMDG): The AMDG published an Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain (2010) which notes 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.

Centers for Medicare & Medicaid Services (CMS)

- National Coverage Determinations (NCDs): No National Coverage Determination (NCD) found.
- Local Coverage Determinations (LCDs): Multiple LCDs found. Refer to the LCD table of contents link in the reference section.

Use Outside of the US

No relevant information.

Appendix A
Definitions

Adulteration	Any process used to attempt to alter the results of a drug test.
Clinical Laboratory Improvement Amendments (CLIA-accredited)	A national program that regulates laboratories which perform testing on patient specimens in order to ensure accurate and reliable test results.
Chromatography	A high-complexity method of drug testing which involves passing a mixture that's dissolved in a mobile phase through to a stationary phase. This process isolates different molecules by type, after which each type can identified and measured. This type of test should be performed in a CLIA-accredited laboratory
Definitive Drug Test	A drug test designed to determine how much (the quantity) of a drug or metabolite is present in a specimen. Laboratory method to identify the presence or absence of a specific drug or metabolite; detecting substances only when they are present above a predetermined thresholds. May be quantitative, qualitative or a combination of both.
High-complexity test	A test used to confirm results of a presumptive test using very specific chromatography or spectrometry techniques. This type of test should be performed in a CLIA-accredited laboratory which follows consistent quality control standards for testing and interpretation. The complexity of a test is designated by the US Food and Drug Administration.
Point-of-Care Test	A drug test conducted at the collection site, such as a health care provider's office that uses dipsticks, cups, cards, cartridges or instrumented test systems, such as discrete multichannel chemistry analyzers utilizing immuno- or enzyme assay. These tests are simple and have a low-risk of incorrect results.
Presumptive Drug Test	Positive or negative results from a qualitative drug analysis which classifies substances as either present or absent in a specimen based on a predetermined cutoff.
Spectrometry	A type of high-complexity test used to measure the quantity of a substance in a specimen. This type of testing should be performed in a CLIA-accredited laboratory

Coding/Billing Information

Note: 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, not to exceed one (1) unit per date of service up to 32 units per year:

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

HCPCS Codes	Description
G0477	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service (Code deleted 12/31/2016)
G0478	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) read by instrument-assisted direct optical observation (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service (Code deleted 12/31/2016)
G0479	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers utilizing immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry), includes sample validation when performed, per date of service (Code deleted 12/31/2016)

Definitive/Confirmatory/Quantitative Drug Testing Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met, not to exceed 16 dates of service per year for a maximum of eight (8) units per date of service, up to 128 units per year:

CPT®* Codes	Description
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

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
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
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

Considered Not Medically Necessary:

CPT®* Codes	Description
0006U	Detection of interacting medications, substances, supplements and foods, 120 or more analytes, definitive chromatography with mass spectrometry, urine, description and severity of each interaction identified, per date of service (Code deleted 03/31/2020)
0051U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service
0054U	Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service
0082U	Drug test(s), definitive, 90 or more drugs or substances, definitive chromatography with mass spectrometry, and presumptive, any number of drug classes, by instrument chemistry analyzer (utilizing immunoassay), urine, report of presence or absence of each drug, drug metabolite or substance with description and severity of significant interactions per date of service
0143U	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0144U	Drug assay, definitive, 160 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0145U	Drug assay, definitive, 65 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0146U	Drug assay, definitive, 80 or more drugs or metabolites, urine, by quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0147U	Drug assay, definitive, 85 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0148U	Drug assay, definitive, 100 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0149U	Drug assay, definitive, 60 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0150U	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service

HCPCS Codes	Description
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

Considered Experimental/Investigational/Unproven:

HCPCS Codes	Description
P2031	Hair analysis (excluding arsenic)

Considered Not Medically Necessary:

CPT®* Codes	Description
81000	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy
81001	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy
81002	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, without microscopy
81003	Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, without microscopy
81005	Urinalysis; qualitative or semiquantitative, except immunoassays
82570	Creatinine; other source
83986	pH; body fluid, not otherwise specified

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