Local Coverage Determination (LCD): Lab: Controlled Substance Monitoring and Drugs of Abuse Testing (L36707)

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LCD Information

Document Information

LCD ID
L36707

Original Effective Date
For services performed on or after 06/28/2016

LCD Title
Lab: Controlled Substance Monitoring and Drugs of Abuse Testing

Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Revision Effective Date
For services performed on or after 04/08/2021

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
05/12/2016

Notice Period End Date
06/27/2016

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CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A). Allows coverage and payment for only those services that are considered to be reasonable and necessary.

42 CFR 410.32(a). Order diagnostic tests.

42 CFR 411.15(k)(1). Particular Services excluded from coverage.

CMS Internet Only Manuals, Pub 100-02 Medicare Beneficiary Policy Manual chapter 15, §80 Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests, §80.1.1 Certification Changes.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Purpose

Urine drug testing (UDT) provides objective information to assist clinicians in identifying the presence or absence of drugs or drug classes in the body and making treatment decisions.

This policy details:

- The appropriate indications and expected frequency of testing for safe medication management of prescribed substances in risk stratified pain management patients and/or in identifying and treating substance use disorders.
- Designates documentation, by the clinician caring for the beneficiary in the beneficiary's medical record, of medical necessity for, and testing ordered on an individual patient basis;
- Provides an overview of presumptive urine drug testing (UDT) and definitive UDT testing by various methodologies.

Definitions

As used in this document, the following terminology relates to the basic forms of UDT:

1. **Presumptive/Qualitative Drug Testing** (hereafter called "presumptive" UDT) - Used when medically necessary to determine the presence or absence of drugs or drug classes in a urine sample; results expressed as negative or positive or as a numerical result; includes competitive immunoassays (IA) and thin layer chromatography.
2. **Definitive/Quantitative/Confirmation** (hereafter called "definitive" UDT) - Used when medically necessary to identify specific medications, illicit substances and metabolites; reports the results of analytes absent or present typically in concentrations such as ng/mL; definitive methods include, but are not limited to GC-MS and LC-MS/MS testing methods.
3. **Specimen Validity Testing** - Urine specimen testing to ensure that it is consistent with normal human urine and has not been adulterated or substituted, may include, but is not limited to pH, specific gravity, oxidants and creatinine.
4. **Immunoassay (IA)** - Ordered by clinicians primarily to identify the presence or absence of drug classes and some specific drugs; biochemical tests that measure the presence above a cutoff level

of a substance (drug) with the use of an antibody; read by photometric technology.

5. **Point of Care Testing (POCT)** - Used when medically necessary by clinicians caring for the beneficiary for immediate test results for the immediate management of the beneficiary; available when the beneficiary and physician are in the same location; IA test method that primarily identifies drug classes and a few specific drugs; platform consists of cups, dipsticks, cassettes, or strips; read by the human eye, or read by instrument assisted direct optical observation.
6. **Standing Orders** - Test request for a specific patient representing repetitive testing to monitor a condition or disease for a limited number of sequential visits; individualized orders for certain patients for pre-determined tests based on historical use, risk and community trend patient profiles; clinician can alter the standing order.
   Note: A "profile" differs from a "panel" in that a profile responds to the clinical risks of a particular patient, whereas a panel may encourage unnecessary or excessive testing when no clinical cause exists for many of the tests.
7. **Blanket Orders** - Test request that is not for a specific patient; rather, it is an identical order for all patients in a clinician's practice without individualized decision making at every visit.
8. **Reflex Testing** - Laboratory testing that is performed "reflexively" after initial test results to identify further diagnostic information essential to patient care. This testing is not based on a specific physician's order. Testing performed as a step necessary to complete a physician's order is not considered reflex testing.

Drug Test Methods

The Clinical Laboratory Improvement Amendments (CLIA) regulates laboratory testing and requires clinical labs to be certified by their State as well as the CMS before they can accept human samples for diagnostic testing. Multiple types of CLIA certificates may be obtained based on the complexity of testing a lab conducts. CLIA levels of complexity(CLIA waived, moderate complexity and high complexity) are addressed only as they correspond to the HCPCS code description found in the related billing and coding article.

A. Presumptive Testing Methods:

1. **Presumptive UDT:**
   Presumptive UDT consist of various platforms including cards, dipsticks, cassettes and cups based on qualitative competitive immunoassay methodology with one or more analytes in the test. A presumptive IA test detects the presence of the amount of drug/substance present in urine above a predetermined "cut-off" value, and may be read by direct optical observation or by instrument assisted direct optical observation.
   A positive test result is reported when the concentration of drug is above the cutoff; a negative is reported when the concentration of drug is below the cut-off. Positive test results are presumptive but not necessarily definitive due to sensitivity and cross-reactivity limitations. Negative test results do not necessarily indicate the absence of a drug or substance in the urine specimen. The accuracy of the results of a presumptive UDT will depend on the testing environment, type of test, and training of the individual conducting the test.
   This type of test should only be used when results are needed immediately.
2. **Presumptive UDT by Instrumented Chemistry Analyzers:**

   Chemistry analyzers with IA UDT technology can be used in an office or clinical laboratory setting. This test may be used when less immediate test results are required. At no time is IA technology by chemistry analyzer analysis considered confirmatory (definitive) testing.
   A presumptive positive IA test detects the presence of a drug/substance in urine at or above the "cut-off" value. If the concentration of the drug is below the cut-off, the result will be negative. Presumptive positive tests are not always true positives due to sensitivity, specificity, and cross-reactivity limitations. Negative test results do not necessarily indicate the absence of a drug or substance in the urine specimen.
   Food and Drug Administration (FDA) approved/cleared test platforms are available in the marketplace as well

as, laboratory developed tests (LDTs) such as modified FDA approved/ cleared and non-FDA approved/cleared platforms and/or reagents. LDTs generally have been modified to test at a lower cutoff in order to detect substances that would have been missed at a higher cutoff. For example, a FDA labeled cutoff may be 300 ng/mL and the LDT cutoff for the same drug may be a 100 ng/mL.
Presumptive UDT can be carried out at any validated cut-off concentration. Lowering of the cut-off concentration provides more stringent cutoffs for illicit drugs. LDTs may include non-FDA cleared tests not available in CLIA-waived or moderate complexity tests (e.g. tramadol, tapentadol, carisoprodol, fentanyl, zolpidem). Lowering the cutoff increases the possibility of detecting a drug when the test has been modified from the recipe of the manufacturer.

3. **Limitations of Presumptive UDT:**

   Presumptive UDT testing is limited due to:

   - Primarily screens for drug classes rather than specific drugs, and therefore, the practitioner may not be able to determine if a different drug within the same class is causing the positive result
   - Produces erroneous results due to cross-reactivity with other compounds or does not detect all drugs within a drug class
   - Given that not all prescription medications or synthetic/analog drugs are detectable and/or have assays available, it is unclear as to whether other drugs are present when some tests are reported as positive;
   - Cut-off may be too high to detect presence of a drug

   This information could cause a practitioner to make an erroneous assumption or clinical decision.

   An IA involves an antibody that reacts best with the stimulating drug, and reacts to a lesser extent (cross-reactive) or not at all with other drugs in the drug class. While presumptive tests vary in their ability to detect illicit drugs such as tetrahydrocannabinol (THC), cocaine, 3,4-methylenedioxy-N-methylamphetamine (MDMA; "ecstasy"), and phencyclidine (PCP), they may not be optimal tests for many prescription drugs, such as: opiates, barbiturates, benzodiazepines and opioids.

   For example, opiate reagents are formulated from morphine. Consequently, the cross-reactivity for other opioids and opiates varies based on the manufacturer and lot number. The semisynthetic opioids, hydromorphone and hydrocodone, may contribute to a positive presumptive result, while the semisynthetic opioids, oxycodone and oxymorphone, will not typically be detected even at 300 ng/mL cutoff. Synthetic opioids, such as fentanyl, meperidine and methadone, will not be detected by current opiate IA testing. Consequently, a positive opiate result by IA normally necessitates more specific identification of the substance(s) that account for the positive result, and a negative result does not rule out the presence of opiates or opioids.

   Presumptive UDT reagents for benzodiazepine are typically formulated for oxazepam, a metabolite of diazepam (Valium®) and chlordiazepoxide (Librium®), the main benzodiazepines prescribed twenty years ago. However, many of the more than 10 benzodiazepines that are currently available do not cross-react with IA benzodiazepine reagents. In particular, clonazepam and lorazepam give false negative results with presumptive IA tests and may necessitate more specific identification to account for the negative result. Similarly, a positive screening test result may require definitive UDT to identify the specific drug(s).

   Synthetic/analog or "designer" drugs manufactured to elude law enforcement require definitive testing for detection. Most commercially available IA reagents fail to detect designer drugs, such as psychedelic phenethylamines even at very high concentrations.

In summary, presumptive IA UDT is often unable to identify specific drugs within many drug classes, particularly within the amphetamine, barbiturate, benzodiazepine, tricyclic antidepressants, and opiate/opioid drug classes. Drugs such as buprenorphine, amphetamines, benzodiazepines, and cocaine/heroin yield false negative IA results

due to low cross-reactivity or non-reactivity and drugs such as fentanyl, carisoprodol, tramadol, tapentadol and synthetic designer drugs cannot be detected by presumptive IA. Therefore, it may be medically necessary for clinicians to utilize definitive UDT when the presumptive tests for these drugs are negative.

B. Definitive UDT:

Gas Chromatography coupled with Mass Spectrometry (GC-MS) and Liquid Chromatography coupled with Mass Spectrometry (LC-MS/MS) are complex technologies that use the separation capabilities of gaseous or liquid chromatography with the analytical capabilities of mass spectrometry. These methodologies require the competency of on-site highly trained experts in this technology and interpretation of results. While these tests require different sample preparation and analytical runs, they identify specific drugs, metabolites, and most illicit substances and report the results as absent or present typically in concentrations of ng/mL.

Quantification should not be used to determine adherence with a specific dosage or time of dose of a pain medication or illicit drug for clinical purposes. Rather, the use of quantitative drug data may be important for many reasons such as in a differential patient assessment. For example, when several opioids are present in the urine of a patient prescribed a single opioid, quantification may help the clinician decide whether the presence of the other opioids is consistent with metabolism of the prescribed opioid, opioid contamination during manufacturing, or if more than one drug within a class is being used.

Quantification may also provide information in the setting of illicit drug use. Serial creatinine-corrected quantitative values may assist in the differential assessment of ongoing drug use or cessation of drug use with continued drug excretion.

1. **GC-MS**
   GC-MS can only be performed on molecules that are volatile. If the test drug is not volatile in its own right, it must be modified or derivatized to a volatile form. To derivatize, the test drug must be extracted from the urine, eluted from the extraction device, concentrated, and then reacted with a chemical reagent to make a volatile product. Each drug class may require a different derivatizing agent. For patients on multiple classes of medications, laboratories using GC procedures must make different volatile derivatives in order to perform comprehensive testing. Since a GC column may not be able to separate more than one class of compounds, multiple chromatographic runs on different column types may be required to monitor multiple drug classes. Newer GC-MS instruments often use tandem systems. GC-MS methodology allows for the testing of multiple substances but differs in ease of run.
2. **LC-MS/MS**
   LC-MS/MS is roughly 100 times more sensitive and selective, involves less human steps, provides quicker turn-around time, uses less specimen volume and can test for a larger number of substances simultaneously when compared to GC-MS. After sample preparation, it is injected into the LC-MS/MS. The sample has to undergo hydrolysis to break the glucuronide bond that frees the drug and drug metabolites. Hydrolysis is followed by multiple additional steps including protein precipitation, centrifugation and purification. Deuterium-labeled isotopic internal standards are added to quantify the drugs and drug metabolites.
   The sample is injected when the mobile phase is flowing through the chromatographic column. Each drug and drug metabolite interacts with the mobile phase and stationary phase differently and moves at different speeds depending on their chemical properties. In other words, each analyte elutes at different times. Specific drugs and metabolites are identified by their retention time and quantified against isotopic internal standards for each drug and metabolite. Each drug peak has to be compared to drug standards (calibrators) in order to ensure identification.

CLIA-Certified Laboratories

CLIA specifies quality standards for proficiency testing, facility administration, general laboratory systems, pre-analytic, analytic and post-analytic systems, onsite supervision requirements, personnel qualifications and responsibilities, quality control, and quality assessment.

High complexity laboratories must ensure that testing is carried out by onsite qualified, trained personnel using validated reliable methods compliant with regulatory procedures (42 CFR Part 493). Both GC-MS and LC-MS/MS require a quality program to monitor the quality and audit the competency of the staff. LC-MS/MS instrument maintenance must be performed daily as well as the validation of instrument performance prior to patient specimens. Final review and approval of GC-MS and LC-MS/MS results must be performed by a qualified clinical laboratory scientist as defined in 42 CFR Part 493.1489 (Testing Personnel Qualifications). A GC-MS or LC-MS/MS laboratory must have a qualified laboratory director, qualified physician, or qualified clinical laboratory scientist, as provided in 42 CFR 493.1443 (Laboratory Director Qualifications).

Assay validation must be consistent with FDA guidelines. Laboratories that use "application notes" from vendors to establish drug validation do not comply with federal standards, and put patients and providers at risk by potentially reporting inaccurate test results. Only FDA 510K cleared test methods may be distributed by vendors.

Purpose of UDT:

Presumptive UDT may be ordered by the clinician caring for a beneficiary when it is necessary to rapidly obtain and/or integrate results into clinical assessment and treatment decisions.

Definitive UDT is reasonable and necessary for the following circumstances:

- Identify a specific substance or metabolite that is inadequately detected by a presumptive UDT;
- Definitively identify specific drugs in a large family of drugs;
- Identify a specific substance or metabolite that is not detected by presumptive UDT such as fentanyl, meperidine, synthetic cannabinoids and other synthetic/analog drugs;
- Identify drugs when a definitive concentration of a drug is needed to guide management (e.g., discontinuation of THC use according to a treatment plan);
- Identify a negative, or confirm a positive, presumptive UDT result that is inconsistent with a patient's self-report, presentation, medical history, or current prescribed pain medication plan;
- Rule out an error as the cause of a presumptive UDT result;
- Identify non-prescribed medication or illicit use for ongoing safe prescribing of controlled substances; and
- Use in a differential assessment of medication efficacy, side effects, or drug-drug interactions.

Definitive UDT may be reasonable and necessary based on patient specific indications, including historical use, medication response, and clinical assessment, when accurate results are necessary to make clinical decisions. The clinician's rationale for the definitive UDT and the tests ordered must be documented in the patient's medical record.

Drug Testing Panels

A. **Presumptive UDT Panels**
   Presumptive UDT testing typically involves testing for multiple analytes based on the beneficiary's clinical history and risk assessment, and must be documented in the medical record.
B. **Definitive UDT Panels**
   Physician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient based upon historical use and community trends. However, the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice. Definitive UDT orders should be individualized based on clinical history and risk assessment, and must be documented in the medical record.

Specimen Type

Urine or oral fluid is the preferred biologic specimen for testing because of the ease of collection, storage, and cost-effectiveness. UDT cannot detect the dosage of drug ingested/used, the time of use, or the means of delivery (intravenous vs. oral vs. inhaled). Detection time of a substance in urine is typically 1-3 days depending on the drug, rate of metabolism, and rate of excretion. Lipid-soluble drugs, such as marijuana, may remain in body fat and be

detected upwards of a week or more.

Parent Drugs and Metabolite

The following chart illustrates parent drugs and their metabolites but may not be totally inclusive of all drugs and metabolites.

Note: Ethanol is a significant drug of abuse. Alcohol metabolites of ethyl glucuronide and ethyl sulfate are typically detected by definitive (GC-MS or LC-MS/MS) UDT, and should only be performed based on clinician's documentation of medical necessity.

Parent Drugs and Metabolite Chart

Drugs Class/Drugs	**Common Names**
Alcohol/Alcohol Metabolites	
Ethyl Glucuronide	Alcohol
Ethyl Sulfate	
Barbiturates	
	Amytal Sodium®
Amobarbital	
	Butisol Sodium®, Butibel
Butabarbital	
	Fiorinal®, Fioricet®
Butalbital	
	Nembutal®
Pentobarbital	
	Belladonna, Luminal®
Phenobarbital	
	Seconal®
Secobarbital	
Benzodiazepines	
	Xanax®, Niravam®, Xanor
Alprazolam	
	Librax®, Libritabs
Chlordiazepoxide	
	Klonopin®
Clonazepam	
	Tranxene®
Clorazepate	
	Valium®
Diazepam	
	Ativan®, Lorax
Lorazepam	
	Adumbran, Alepam, Murelax, Serax, Serepax
Oxazepam	
	Restoril®, Tenox, Euhypnos
Temazepam	
Illicit Drugs	Blow, Coke, Crack, Snow

Cocaine	Black Tar, Brown Sugar, Dragon, H, Horse, Tar
Heroin	Marinol, Pot, Reefer, Weed
Marijuana	Ecstasy, X
MDA	Ecstasy, X
MDMA	Crank, Crystal Meth, Didrex®, Eldepryl®, Ice
Methamphetamine	Angel Dust
Phencyclidine (PCP)	
Synthetic Cannabinoids	"K2"/"Spice"
	"Bath Salts"
Cathinones	
	Kratom
General Anesthetic	Ketamine
Ketamine	Norketamine
Muscle Relaxants	
	Soma®, Soprodoal
Carisoprodol	
	Equinal, Miltown®, Meprospan
Meprobamate	
Neuroleptics	
	Neurontin®
Gabapentin	
	Lyrica®
Pregabalin	
Opiates	
	Tylenol® 3
Codeine	
	Hycodan®, Lorcet®, Lortab®, Norco® Vicodin®, Vicoprofen®
Hydrocodone	
	Dilaudid®, Exalgo®
Hydromorphone	
	Avinza®, Hymorphan, Kadian®, MS Contin®, MSER, MSIR, Roxanol
Morphine	
	OxyContin®, OxyIR®, Percocet®, Percodan®, Roxicodone®, Tylox®
Oxycodone	
	Numorphan®, Opana® ER, Opana®
Oxymorphone	
Opioids	Buprenex®, Butrans®, Suboxone®, Subutex®
Buprenorphine	Actiq®, Duragesic®, Fentora®, Onsolis® Sublimaze
Fentanyl	Demerol®, Mepergan®
Meperidine	Dolophine®, Methadose®

Methadone	Darvocet®, Darvon®
Propoxyphene	Nucynta®
Tapentadol	Ryzolt®, Ultracet®, Ultram®, Tramadol
Tramadol	
Stimulants	
Amphetamine	Adderall®, Benzedrine, Dexedrine®, Vyvanse®
Methylphenidate	Concerta®, Focalin®, Methylin®, Ritalin®
Nicotine	Nicoderm®, Nicorette®

Covered Indications for UDT

Group A – Symptomatic patients, Multiple drug ingestion and/or Patients with unreliable history

A patient who presents in a variety of medical settings with signs or symptoms of substance use toxicity will be treated presumptively to stabilize the patient while awaiting rapid, then definitive testing to determine the cause(s) of the presentation. The need for definitive UDT is based upon rapid test findings, responses to medical interventions, and treatment plan. A presumptive UDT should be performed as part of the evaluation and management of a patient who presents in an urgent care setting with any one of the following:

- Coma
- Altered mental status in the absence of a clinically defined toxic syndrome or toxidrome
- Severe or unexplained cardiovascular instability (cardiotoxicity)
- Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome
- Seizures with an undetermined history
- To provide antagonist to specific drug

The presumptive findings, definitive drug tests ordered and reasons for the testing must be documented in the patient's medical record.

Group B - Diagnosis and treatment for substance abuse or dependence

A patient in active treatment for substance use disorder (SUD) or monitoring across different phases of recovery may undergo medical management for a variety of medical conditions. A physician who is writing prescriptions for medications to treat either the SUD or other conditions may need to know if the patient is taking substances which can interact with prescribed medications or taking prescribed medications as expected. The risk of drug-drug interactions is inherent to the patient, and may be compounded by prescribed medications. UDT is a medically necessary and useful component of chemical dependency diagnosis and treatment. The UDT result influences treatment and level of care decisions. Ordered tests and testing methods (presumptive and/or definitive) must match the stage of screening, treatment, or recovery; the documented history; and Diagnostic and Statistical Manual of Mental Disorders (DSM V) diagnosis. For patients with no known indicators of risk for SUDs, the clinician may screen for a broad range of commonly abused drugs using presumptive UDT. For patients with known indicators of risk for SUDs, the clinician may screen for a broad range of commonly abused drugs using definitive UDT. For patients with a diagnosed SUD, the clinician should perform random UDT, at random intervals in order to properly monitor the patient. Testing profiles must be determined by the clinician based on the following medical necessity guidance criteria:

- Patient history, physical examination, and previous laboratory findings
- Stage of treatment or recovery;
- Suspected abused substance;
- Substances that may present high risk for additive or synergistic interactions with prescribed medication (e.g., benzodiazepines, alcohol).

The patient's medical record must include an appropriate testing frequency based on the stage of screening, treatment, or recovery; the rationale for the drugs/drug classes ordered; and the results must be documented in the medical record and used to direct care.

1. **Frequency of Presumptive UDT for SUD:**

   The testing frequency must meet medical necessity and be documented in the clinician's medical record.
   a. For patients with 0 to 30 consecutive days of abstinence, presumptive UDT is expected at a frequency of 1 to 3 presumptive UDT per week. More than 3 presumptive panels in one week is not reasonable and necessary and is not covered by Medicare.
   b. For patients with 31 to 90 consecutive days of abstinence, presumptive UDT is expected at a frequency of 1 to 3 UDT per week. More than 3 presumptive UDT in one week is not reasonable and necessary and is not be covered by Medicare.
   c. For patients with > 90 consecutive days of abstinence, presumptive UDT is expected at a frequency of 1 to 3 UDT in one month. More than 3 physician-directed UDT in one month is not reasonable and necessary and is not covered by Medicare.
2. **Frequency of Definitive UDT for SUD:**
   Depending on the patient's specific substance use history, definitive UDT to accurately determine the specific drugs in the patient's system may be necessary. Definitive testing may be ordered when accurate and reliable results are necessary to integrate treatment decisions and clinical assessment. The frequency and the rational for definitive UDT must be documented in the patient's medical record.
   a. For patients with 0 to 30 consecutive days of abstinence, definitive UDT is expected at a frequency not to exceed 1 physician-directed testing profile in one week. More than 1 physician-directed testing profile in one week is not reasonable and necessary and is not covered by Medicare.
   b. For patients with 31 to 90 consecutive days of abstinence, definitive UDT is expected at a frequency of 1-3 physician-directed testing profiles in one month. More than 3 UDT in one month is not reasonable and necessary and is not covered by Medicare.
   c. For patients with > 90 day of consecutive abstinence, definitive UDT is expected at a frequency of 1-3 physician-directed testing profiles in three months. More than 3 definitive UDT in 3 months is not reasonable and necessary and is not covered by Medicare.

Group C - Treatment for patients on chronic opioid therapy (COT).

A physician who is writing prescriptions for medications to treat chronic pain can manage a patient better if the physician knows whether the patient is consuming another medication or substance, which could suggest the possibility of SUD or lead to drug-drug interactions. Additionally, UDT may help the physician monitor for medication adherence, diversion, efficacy, side effects, and patient safety in general.

1. **COT UDT Testing Objectives:**
   1. Identifies absence of prescribed medication and potential for abuse, misuse, and diversion;
   2. Identifies undisclosed substances, such as alcohol, unsanctioned prescription medication, or illicit substances;
   3. Identifies substances that contribute to adverse events or drug-drug interactions;
   4. Provides objectivity to the treatment plan;
   5. Reinforces therapeutic compliance with the patient;
   6. Provides additional documentation demonstrating compliance with patient evaluation and monitoring;

7. Provide diagnostic information to help assess individual patient response to medications (e.g., metabolism, side effects, drug-drug interaction, etc.) over time for ongoing management of prescribed medications.

2. **Medical Necessity Guidance:**

Criteria to establish medical necessity for drug testing must be based on patient-specific elements identified during the clinical assessment, and documented by the clinician in the patient's medical record and minimally include the following elements:

- Patient history, physical examination and previous laboratory findings;
- Current treatment plan
- Prescribed medication(s)
- Risk assessment plan

National pain organizations, physician societies, and the Federation of State Medical Boards recommend a practical approach to definitive UDT for COT. Frequency of testing beyond the baseline presumptive UDT must be based on individual patient needs substantiated by documentation in the patient's medical record. Recommendations for the ordering of presumptive and definitive UDT for patients on COT are as follows:

a. **COT Baseline Testing:**
   - Initial presumptive and/or definitive COT patient testing may include amphetamine/ methamphetamine, barbiturates, benzodiazepines, cocaine, methadone, oxycodone, tricyclic antidepressants, tetrahydrocannabinol, opioids, opiates, heroin, and synthetic/analog or "designer" drugs.

b. **COT Monitoring Testing:**
   - Ongoing testing may be medically reasonable and necessary based on the patient history, clinical assessment, including medication side effects or inefficacy, suspicious behaviors, self-escalation of dose, doctor-shopping, indications/symptoms of illegal drug use, evidence of diversion, or other clinician documented change in affect or behavioral pattern. The frequency of testing must be based on a complete clinical assessment of the individual's risk potential for abuse and diversion using a validated risk assessment interview or questionnaire and should include the patient's response to prescribed medications and the side effects of medications.
   - The clinician should perform random UDT at random intervals, in order to properly monitor a patient. UDT testing does not have to be associated with an office visit.
   - Patients with specific symptoms of medication aberrant behavior or misuse may be tested in accordance with this document's guidance for monitoring patient adherence and compliance during active treatment (<90 days) for substance use or dependence.

3. **UDT Frequency Based on Validated Risk Assessment and Stratification*:**

Testing must be based on clinician's documented medical necessity and reviewed by the clinician in the management of prescribing/renewing a controlled substance for every risk group outlined below.

Risk Group	**Baseline**	**Frequency of Testing**
Low Risk	Prior to Initiation of COT	Random testing 1-2 times every 12 months for prescribed medications, non-prescribed medications that may pose a safety risk if taken with prescribed medications, and illicit substances based on patient history, clinical presentation, and/or community usage.
Moderate Risk	Prior to Initiation of	Random testing 1-2 times every 6 months for prescription medications, non-prescribed medication that may pose a safety risk if taken with prescribed

	COT	medications, and illicit substances, based on patient history, clinical presentation, and/or community usage.
High Risk	Prior to Initiation of COT	Random testing performed 1-3 times every 3 months for prescribed medications, non-prescribed medications that may pose a safety risk if mixed with prescribed and illicit substances based on patient history, clinical presentation and/or community usage.

*Note: Any additional definitive UDT beyond recommendations above must be justified by the clinician in the medical record in situations in which changes in prescribed medications may be needed, such as:

- Patient response to prescribed medication suddenly changes
- Patient side effect profile changes
- To assess for possible drug-drug interactions
- Sudden change in patient's medical condition
- Patient admits to use of illicit or non-prescribed controlled substance.

Other Covered Services

1. Reflex Testing by Reference Laboratories – since reference laboratories do not have access to patient-specific data, reflex testing under the following circumstances is reasonable and necessary:
    a. To verify a presumptive positive UDT using definitive methods that include, but are not limited to GC-MS or LC-MS/MS before reporting the presumptive finding to the ordering clinician and without an additional order from the clinician; or
    b. To confirm the absence of prescribed medications when a negative result is obtained by presumptive UDT in the laboratory for a prescribed medication listed by the ordering clinician
2. Direct to definitive UDT without a presumptive UDT is reasonable and necessary, when individualized for a particular patient.
3. Definitive testing to confirm a negative presumptive UDT result, upon the order of the clinician, is reasonable and necessary in the following circumstances:
    a. The result is inconsistent with a patient's self-report, presentation, medical history, or current prescribed medication plan (should be present in the sample);
    b. Following a review of clinical findings, the clinician suspects use of a substance that is inadequately detected or not detected by a presumptive UDT; or
    c. To rule out an error as the cause of a negative presumptive UDT result.
4. Definitive testing to confirm a presumptive UDT positive result, upon the order of the clinician, is reasonable and necessary when the result is inconsistent with the expected result, a patient's self-report, presentation, medical history, or current prescribed medication plan.

Non-Covered Services

1. Blanket Orders
2. Reflex definitive UDT is not reasonable and necessary when presumptive testing is performed at point of care because the clinician may have sufficient information to manage the patient. If the clinician is not satisfied, he/she must determine the clinical appropriateness of and order specific subsequent definitive testing (e.g., the patient admits to using a particular drug, or the IA cut-off is set at such a point that is sufficiently low that the physician is satisfied with the presumptive test result).
3. Routine standing orders for all patients in a physician's practice are not reasonable and necessary.
4. It is not reasonable and necessary for a physician to perform presumptive POCT and order presumptive IA testing from a reference laboratory. In other words, Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers.
5. It is not reasonable and necessary for a physician to perform presumptive IA testing and order presumptive IA

testing from a reference laboratory with or without reflex testing. Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers.
6. It is not reasonable and necessary for a reference laboratory to perform and bill IA presumptive UDT prior to definitive testing without a specific physician's order for the presumptive testing.
7. IA testing, regardless of whether it is qualitative or semi-quantitative (numerical), may not be used to "confirm" or definitively identify a presumptive test result obtained by cups, dipsticks, cards, cassettes or other IA testing methods. Definitive UDT provides specific identification and/or quantification typically by GC-MS or LC-MS/MS.
8. Drug testing of two different specimen types from the same patient on the same date of service for the same drugs/metabolites/analytes.
9. UDT for medico-legal and/or employment purposes or to protect a physician from drug diversion charges.
10. Specimen validity testing including, but not limited to, pH, specific gravity, oxidants, creatinine.

Summary of Evidence

N/A

Analysis of Evidence
(Rationale for Determination)

N/A

General Information

Associated Information

N/A

Sources of Information

N/A

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
04/08/2021	R10	Under **CMS National Coverage Policy** revised the verbiage for the CMS on-line Manual regulation Chapter 15 by removing §80.2 of this regulation. References were moved from the **Sources of Information** section to the **Bibliography** section and related links were removed or replaced as appropriate. Formatting, punctuation and typographical errors were corrected, and acronyms were defined where appropriate throughout the policy. *At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.*	• Provider Education/Guidance
10/01/2019	R9	10/01/2019: This LCD is being revised in order to adhere to CMS requirements per chapter 13, section 13.5.1 of the Program Integrity Manual. Title XVIII of the Social Security Act, §1833(e) was removed from the **CMS National Coverage Policy** section of this LCD and placed in the related Billing and Coding:	• Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		Lab: Controlled Substance Monitoring and Drugs of Abuse Testing A55030 article. *At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.*	
10/01/2019	R8	10/01/2019: All coding located in the **Coding Information** section has been moved into the related Billing and Coding: Lab: Controlled Substance Monitoring and Drugs of Abuse Testing A55030 article and removed from the LCD. Under **Coverage Indications, Limitations and/or Medical Necessity** changed verbiage under **Drug Test Methods** from "CLIA levels of complexity (CLIA-waived, moderate complexity and high complexity) are addressed only as they relate to the HCPCS code description and the coding/billing guidance to be attached to this document" to "CLIA levels of complexity (CLIA waived, moderate complexity and high complexity) are addressed only as they correspond to the HCPCS code description found in the related billing and coding article." At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage.	• Provider Education/Guidance • Revisions Due To Code Removal
12/27/2018	R7	01/07/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy. Effective Date of 12/27/2018 entered to be consistent with Palmetto GBA. Removed reference #4: Bolen J. Survey of Drug Testing Policy in the Management of Chronic Pain. Added "Lab" to	• Creation of Uniform LCDs With Other MAC Jurisdiction

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		title.	
10/01/2018	R6	09.05.18: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy. The following ICD-10 code was deleted from the ICD-10 Codes that Support Medical Necessity field: M79.1 was deleted from Group 1. The following ICD-10 Codes were added to the ICD-10 Codes that Support Medical Necessity field: F12.23, F12.93, T43.641A, T43.641D, T43.641S, T43.642A, T43.642D, T43.642S, T43.643A, T43.643D, T43.643S, T43.644A, T43.644D, T43.644S. This revision is due to the Annual ICD-10 Code Update and becomes effective October 1, 2018.	• Revisions Due To ICD-10-CM Code Changes
10/01/2017	R5	05/14/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy. Addition of ICD -10- Codes to Group I codes; M54.12; M25.511; M25.512	• Creation of Uniform LCDs With Other MAC Jurisdiction
10/01/2017	R4	LCD revised to correct the table under the heading "Parent Drugs and Metabolite"	• Typographical Error
10/01/2017	R3	08/31/2017: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy. Effective 10/1/2017, LCD is revised per the annual ICD-10-CM code update to: Add ICD-10-CM codes: F10.11; F11.11; F12.11; F13.11; F14.11; F15.11; F16.11; F18.11; F19.11	• Creation of Uniform LCDs With Other MAC Jurisdiction • Revisions Due To ICD-10-CM Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
10/01/2017	R2	DATE (08/29/2017): At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy. Effective 10/1/2017, LCD is revised per the annual ICD-10-CM code update to: Add ICD-10-CM codes: R41.82; R45.850; R45.851	• Creation of Uniform LCDs With Other MAC Jurisdiction • Revisions Due To ICD-10-CM Code Changes
01/01/2017	R1	Revised for 2017 CPT code changes: Codes Deleted and invalid:G0477, G0478 and G0479; Added G0659, 80305, 80306 and 80307.	• Revisions Due To ICD-10-CM Code Changes

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)
A55030 - Billing and Coding: Lab: Controlled Substance Monitoring and Drugs of Abuse Testing
A55031 - Response to Comments: Controlled Substance Monitoring and Drugs of Abuse Testing Comment Period Ending 05/02/2014.

Related National Coverage Documents

N/A

Public Version(s)

Updated on 03/30/2021 with effective dates 04/08/2021 - N/A
Updated on 12/05/2019 with effective dates 10/01/2019 - 04/07/2021
Updated on 09/20/2019 with effective dates 10/01/2019 - N/A
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A