Local Coverage Determination (LCD)

LCD - Urine Drug Testing (L34645)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05101 - MAC A	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05102 - MAC B	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05201 - MAC A	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05202 - MAC B	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05301 - MAC A	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05302 - MAC B	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05401 - MAC A	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05402 - MAC B	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05901 - MAC A	J - 05	Alabama Alaska Arizona Arkansas California - Entire State Colorado Connecticut Delaware Florida Georgia Hawaii Idaho Illinois Indiana Iowa Kansas

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
				Kentucky Louisiana Maine Maryland Massachusetts Michigan Mississippi Missouri - Entire State Montana Nebraska Nevada New Hampshire New Jersey New Mexico North Carolina North Dakota Ohio Oklahoma Oregon Pennsylvania Rhode Island South Carolina South Dakota Tennessee Texas Utah Vermont Virginia Washington West Virginia Wisconsin Wyoming
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08101 - MAC A	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08102 - MAC B	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08201 - MAC A	J - 08	Michigan
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08202 - MAC B	J - 08	Michigan

LCD Information

Document Information

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Issue

Issue Description

This LCD is being revised as part of a collaborative process for consistency and clarity of coverage across all MAC regions.

Issue - Explanation of Change Between Proposed LCD and Final LCD

No changes made between the draft LCD DL34645 and the final LCD L34645.

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 On-Line Manual, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, §§80.0, 80.1.1, 80.1.2. Clinical Laboratory services.

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 timely, objective, and actionable information to clinicians by identifying the presence or absence of drugs of potential abuse in the body to assist the clinician in making treatment decisions.[1]

This policy details:

- The appropriate indications and allowed number of UDTs billed over time for safe medication management of prescribed substances in risk stratified pain management patients and/or in identifying and treating substance use disorders (SUDs);
- 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 UDT and definitive UDT testing by various methodologies.

This policy addresses UDT for Medicare patients only.

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) - Covered when medically necessary to immediately 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]
2. **Definitive/Quantitative/Confirmation** (hereafter called "definitive" UDT) - Covered when clinically indicated and medically reasonable and necessary based on this LCD 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 only.[2]
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. This however is quality assurance, not a Medicare benefit, and thus not separately payable by Medicare.
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.[2]
5. **Point of Care Testing (POCT)** - Covered 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.[3]

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 is developed based on specific characteristics of a specific patient, while a panel is a general non-specific group of tests that may have unnecessary tests for the specific patient being treated.
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 necessarily based on a specific physician's order.

Drug Testing Methods

The Clinical Laboratory Improvement Amendments (CLIA) regulates laboratory testing and requires clinical labs to be certified by their State as well as the Center for Medicare & Medicaid Services (CMS) before they can accept human samples for diagnostic testing.[3] 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 Healthcare Common Procedure Coding System (HCPCS) code description in the related billing and coding article.

A. **Presumptive Testing Methods**

1. **Presumptive UDT:**

   A presumptive UDT that consists 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.[4] Negative test results do not necessarily indicate the absence of a drug or substance in the urine specimen.[3] The accuracy of the results of a presumptive UDT will depend on the testing environment, type of test, the drug being tested for, 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 provides less immediate test results. 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.[3]

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, an FDA labeled cutoff may be 300 ng/mL and the LDT cutoff for the same drug may be 100 ng/mL.[3]

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;[5]
- 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.[5]

These limitations may mean that presumptive testing is insufficient for certain clinical needs.

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 a 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.[6]

Presumptive UDT reagents for benzodiazepine are typically formulated for oxazepam, a metabolite of diazepam (Valium®) and chlordiazepoxide (Librium®), the main benzodiazepines prescribed 20 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 may 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.[1,5]

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.[2]

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.[1] 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 1 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]

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[1]. 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 fewer 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.[1] 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 a minimum of 2 mass transmissions to be compared to drug standards (calibrators) to ensure identification.

CLIA-Certified Laboratories-Informational only

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.[3]

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).

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 considered reasonable and necessary when the clinical information supplied supports the definitive testing as in:

- Identify a specific substance or metabolite that is inadequately detected by a presumptive UDT screen;
- 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.[1] **To establish that a test is reasonable and necessary, 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 typically involves testing for multiple analytes based on the specific beneficiary's clinical history and risk assessment and must be documented in the medical record. May be ordered as a panel and billed a "Per Patient encounter" regardless of the number of analytes tested.
B. Definitive UDT Panels
   Physician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient **based upon historical use, clinical findings, 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.[1] 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.

Ethanol is not discussed in this LCD:

Note: Ethanol is a known drug of abuse but is routinely tested in blood, not urine. In addition, the DEA Resource Guide[7] states that alcohol is exempt from control by the Controlled Substances Act (CSA).

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 presumptive, then definitive testing to determine the cause(s) of the presentation. The need for definitive UDT is based upon presumptive test findings, responses to medical interventions, and treatment plan.[1] A presumptive UDT should be performed as part of the evaluation and management of a patient who presents in an emergency room or urgent care setting with any 1 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 a 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.[1] 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.[3] 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 SUD, the clinician may screen for a broad range of commonly abused drugs using presumptive UDT. For patients with known indicators of risk for SUD, 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 to properly monitor the patient3. 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 number of UDTs billed over time based on the stage of screening, treatment, or recovery;**[8] **and the rationale for the drugs/drug classes ordered; the results must be documented in the medical record and used to direct care.**[3]

1. **Maximum Number of Allowed Presumptive UDTs for SUD**

The number of UDTs billed over time must meet medical necessity and be documented in the patient's medical record.[8]

a. For patients with **0 to 30 consecutive days of abstinence**, presumptive UDT is not to exceed 3 presumptive UDTs in a rolling 7 days. More than 3 presumptive UDTs in a rolling 7 days 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 not to exceed 3 presumptive UDTs in a rolling 7 days. More than 3 presumptive UDTs in a rolling 7 days is not reasonable and necessary and is not covered by Medicare.
c. For patients with > **90 consecutive days of abstinence**, presumptive UDT is not to exceed 3 presumptive UDTs in a rolling 30 days. More than 3 presumptive UDTs in a rolling 30 days is not reasonable and necessary and is not covered by Medicare.

2. **Maximum Number of Allowed Definitive UDTs 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 number of UDTs billed over time and the rationale 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 not to exceed 1 definitive UDT in a rolling 7 days. More than 1 definitive UDT in a rolling 7 days 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 not to exceed 3 definitive UDTs in a rolling 30 days. More than 3 definitive UDTs in a rolling 30 days is not reasonable and necessary and is not covered by Medicare.
c. For patients with > **90 days of consecutive abstinence**, definitive UDT is not to exceed 3 definitive UDTs in a rolling 90 days. More than 3 definitive UDTs in a rolling 90 days is not reasonable and necessary and is not covered by Medicare.

Group C - Treatment for patients on chronic opioid/opiate 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.[9] A broad cross section of the general population will develop either cancer pain syndrome or non-cancer pain which will require prolonged or chronic opioid therapy for management with normal risk of addiction inherent to the substance(s) exposed.[10]

1. **COT UDT Testing Objectives:**

a. Identifies absence of prescribed medication and potential for abuse, misuse, and diversion;
b. Identifies undisclosed substances, unsanctioned prescription medication, or illicit substances;
c. Identifies substances that contribute to adverse events or drug-drug interactions;
d. Provides objectivity to the treatment plan;[9]
e. Reinforces therapeutic compliance with the patient;

f. Provides additional documentation demonstrating compliance with patient evaluation and monitoring;[11]
g. Provides 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 UDT 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:[12]

a. Patient history, physical examination, and previous laboratory findings;
b. Current treatment plan;
c. Prescribed medication(s);
d. Risk assessment plan.

National pain organizations, physician societies, and the Federation of State Medical Boards[13] recommend a practical management approach to definitive UDT for COT. The number of UDTs billed over time 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:

3. **COT Baseline Testing:**

Depending on the patient's specific circumstances, 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.

4. **COT Monitoring Testing:**

a. 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.[14] As part of the clinical evaluation of the patient, the provider should inquire about prescription compliance and potential issues of abuse or diversion such as lost prescriptions, early refill requests, or requests for escalating dose of medication.[14] The number of UDTs billed over time must be based on the individual's risk potential.[1] Appropriate number of UDTs billed over time based on risk is listed in the table below.[14]
b. The clinician should perform random UDT at random intervals to properly monitor a patient.[15] UDT testing does not have to be associated with an office visit.
c. 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.

UDT Frequency Based on 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	Presumptive and definitive UDT not to exceed 2 times each in a rolling 365 days fo 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 COT	Presumptive and definitive UDT not to exceed 2 times each in a rolling 180 days fo prescription medications, non- prescribed medication that may pose a safety risk i taken with prescribed medications, and illicit substances, based on patient history, clinical presentation, and/or community usage.
High Risk	Prior to Initiation of COT	Presumptive and definitive UDT not to exceed 3 times each in a rolling 90 days 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 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;
- Change in patient's medical condition;
- Patient admits to use of illicit or non-prescribed controlled substance.

Opioid Risk Tool:

The patient's risk category must be clearly defined in the medical record and is essential in determining number of UDTs billed over time and medical necessity.

This TOOL is to be used as a suggestion for defining Risk and this document is just an example and other tools accepted by the Opioid Use treating community may be used. Example, accepted by SAMHSA (Substance Abuse and Mental Health Services Administration)

The Opioid Risk Tool (ORT)[16] is a brief, self-report screening tool designed for use with adult patients in primary care settings to assess risk for opioid abuse among individuals prescribed opioids for treatment of chronic pain.[13,14] Patients categorized as high-risk are at increased likelihood of future abusive drug-related behavior.[12] The ORT can be administered and scored in less than 1 minute and has been validated in both male and female patients, but not in non-pain populations. This tool should be administered to patients upon an initial visit prior to beginning opioid therapy for pain management. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse.[13,16]

Mark each box that applies	**Female**	**Male**
Family history of substance abuse		
Alcohol		
Illegal drugs		

Rx drugs		
Personal history of substance abuse		
Alcohol		
Illegal drugs		
Rx drugs		
Age between 16-45 years		
History of preadolescent sexual abuse		
Psychological disease		
ADD, OCD, bipolar, schizophrenia		
Depression		
Scoring totals		

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. When medical record documentation that is individualized for a particular patient satisfies medical necessity requirements found elsewhere in this LCD (e.g., risk assessment, frequency), direct to definitive UDT without a presumptive UDT may be reasonable and necessary.
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. When there is an unexpected negative presumptive UDT result, and it is clinically imperative to know if it is truly positive or negative; the medical record should state such.
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-therefore not reasonable and necessary services

1. Blanket Orders-same orders for all patients in a health care provider's practice.
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. 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. Semi-Quantitative is defined as a numerical estimation of the approximate concentrations.
8. Drug testing of 2 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

Providers should consider the prescribed medications, risk assessment, and clinical presentation when selecting which tests to order.

Analysis of Evidence (Rationale for Determination)

There are multiple validated surveys the provider can use as part of routine assessment of the individual's risk potential for abuse and diversion. These surveys typically ask the same questions that are part of the routine clinical assessment. WPS removed the validated survey requirement as this should already be part of the required clinical assessment.

Risk assessment is a widely accepted standard by expert treating entities to be used in clinical treatments and follow-up. The provider shall clearly define risk assessment as part of the reasonable and necessary criteria for UDT.

General Information

Associated Information

N/A

Sources of Information

Other Contractor(s)' Policies

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
11/12/2023	R20	Posted 09/28/2023: No changes made from DL34645.	• Other
10/01/2021	R19	09/30/2021 Review completed 08/09/2021. Grammar and punctuation corrections made throughout the LCD. Relocated references listed under "Sources of Information" to "Bibliography", and AMA formatting corrections made.	• Other (Review)
05/10/2020	R18	03/26/2020 Removed and relocated Documentation Requirements Section to A56915 Billing and Coding: Drug Testing effective 05/10/2020. Removed the following sentence because it is no longer relevant, "*Italicized* font represents CMS national language/wording copied directly from CMS Manuals or CMS transmittals. Contractors are prohibited from changing national language." No change in coverage.	• Other
11/01/2019	R17	11/01/2019 Added related NCD to Associated Documents. Format revisions completed. No change in coverage.	• Other ((Changes in response to CMS Change Request 10901, Review completed.))
08/29/2019	R16	08/29/2019 Change Request 10901 Local Coverage Determinations (LCDs): it will no longer be appropriate to include Current Procedure Terminology (CPT)/Health Care Procedure Coding System (HCPCS) codes or International Classification of Diseases Tenth Revision-Clinical Modification (ICD-10-CM) codes in the LCDs. All CPT/HCPCS, ICD-10 codes, and Billing and Coding Guidelines have been removed from this LCD and placed in Billing and Coding: Drug Testing linked to this LCD. The applicable manual/regulation has been referenced in CMS National Coverage Policy Section. Review completed 08/08/2019. There will not be a lapse in coverage and there has been no change to the coverage content of this LCD.	• Other (Changes in response to CMS Change Request 10901, Review completed.)
12/01/2018	R15	12/01/2018 Annual review completed on 11/05/2018 with	• Other (Annual

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		punctuation error corrected. No changes in coverage.	Review)
10/01/2018	R14	10/01/2018 ICD-10 CM Code Updates: added codes 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, and T43.644S to Group One.	• Revisions Due To ICD-10-CM Code Changes
01/01/2018	R13	01/01/2018 CPT/HCPCS code updates; description changes for Group 1 codes 80305, 80306, and 80307.	• Revisions Due To CPT/HCPCS Code Changes
12/01/2017	R12	12/01/2017 Annual review completed on 11/07/2017 with no changes in coverage. Typographical error corrected.	• Typographical Error • Other (Annual)
08/01/2017	R11	08/01/2017 Added F11.23 to Group 1 Codes effective 08/01/2017. Corrected typographical errors. 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.	• Typographical Error • Other (Added ICD-10-CM Code)
01/01/2017	R10	03/01/2017 Moved G0659 from the Group 1 Paragraph to the Group 1 Table. Long description change for Group 1 codes: G0480, G0481, G0482, and G0483 effective 01/01/2017.	• Revisions Due To CPT/HCPCS Code Changes
01/01/2017	R9	02/01/2017 HCPCS code G0659 added effective 01/01/2017.	• Revisions Due To CPT/HCPCS Code Changes
01/01/2017	R8	01/01/2017 CPT code changes added codes 80305, 80306 and 80307. Deleted codes 80300, 80301, 80302, 80303, 80304, G0477, G0478 and G0479. Annual review 12/02/2016.	• Revisions Due To CPT/HCPCS Code Changes
08/01/2016	R7	08/01/2016- changed CPT descriptions to short description no change in coverage.	• Other

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
01/01/2016	R6	02/01/2016: Added G0477, G0478, G0479, G0480, G0481, G0482, and G0483 to Group 1 codes section as technically unable to do so last month.	• Other
01/01/2016	R5	01/01/2016 Annual review 12/04/2015. CPT/HCPCS code updates for 2016: G0431, G0434, and G6058 are deleted and added G0477, G0478, G0479, G0480, G0481, G0482, and G0483 to Group 1 codes. Added code range 80320-80377 to Group 2 non-covered codes. Added Z03.89 to Group 1 Paragraph codes. CAC information removed.	• Revisions Due To CPT/HCPCS Code Changes • Other (CPT/HCPCS code changes ICD 10 code additions Other) • Revisions Due To ICD-10-CM Code Changes
10/01/2015	R4	10/06/2015 - Due to CMS guidance, we have removed the Jurisdiction 8 Notice and corresponding table from the CMS National Coverage Policy section. No other changes to policy or coverage.	• Other
10/01/2015	R3	04/01/2015 Annual review 03/02/2015, added codes T40.5X1A, T40.5X2A, T40.5X3A, and T40.5X4A. “qualitative” was removed from Indications D 3. Updated sources of information.	• Other (Revisions due to ICD 10 addition Annual Review) • Revisions Due To ICD-10-CM Code Changes
10/01/2015	R2	01/01/2015 CPT/HCPCS code updates 2015, added codes G6058, 80300,80301, 80302, 80303 and 80304 Deleted codes 80100, 80101 and 80102. Removed Qualitative from title and Changed references from qualitative to qualitative/ presumptive to reflect new reporting mechanisms in CPT for 2015.	• Revisions Due To CPT/HCPCS Code Changes
10/01/2015	R1	05/01/2014 Annual review 03/26/2014, no change to policy coverage.	• Other (Maintenance)

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A56915 - Billing and Coding: Urine Drug Testing

DA56915 - Billing and Coding: Urine Drug Testing (MCD Archive Site)

A59562 - Response to Comments: Urine Drug Testing (DL34645)

LCDs

DL34645 - Urine Drug Testing (MCD Archive Site)

Related National Coverage Documents

NCDs

130.5 - Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic

130.6 - Treatment of Drug Abuse (Chemical Dependency)

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
09/21/2023	11/12/2023 - N/A	Currently in Effect (This Version)
09/20/2021	10/01/2021 - 11/11/2023	Superseded
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

- N/A