

## Client Communication

# Medicare Local Coverage Determination Policy: CGS

# **Coverage Policy**

# L36029 - Urine Drug Testing

CPT: 80305, 80306, 80307, G0480, G0481, G0482, G0483, G0659, 0143U, 0144U, 0145U, 0146U, 0147U, 0148U, 0149U, 0150U 0227U

Revision Effective Date: 10/14/2023

# **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<sup>1</sup>.

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<sup>2</sup>.

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- 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<sup>2</sup>.
- 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<sup>2</sup>.
- 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<sup>3</sup>.
- 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 testing3. 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

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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<sup>4</sup>. Negative test results do not necessarily indicate the absence of a drug or substance in the urine specimen<sup>3</sup>. 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<sup>3</sup>.

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<sup>3</sup>.

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

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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<sup>5</sup>;
- 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<sup>5</sup>.

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<sup>6</sup>.

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).

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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<sup>1,5</sup>.

#### **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<sup>2</sup>.

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<sup>1</sup>. 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<sup>1</sup>.

#### 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

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may be required to monitor multiple drug classes<sup>1</sup>. 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 turnaround time, uses less specimen volume, and can test for a larger number of substances simultaneously when compared to GC-MS¹. 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 guantify 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<sup>3</sup>.

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.

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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<sup>1</sup>. 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.** 

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#### **Specimen Type**

Urine or oral fluid is the preferred biologic specimen for testing because of the ease of collection, storage, and cost-effectiveness<sup>1</sup>. 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<sup>8</sup> states that alcohol is exempt from control by the Controlled Substances Act (CSA). Ethanol is not under discussion in this LCD.

#### **Indications**

#### **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<sup>1</sup>. 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

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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<sup>1</sup>. 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<sup>3</sup>. 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 patient<sup>3</sup>. 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<sup>9</sup> and the rationale for the drugs/drug classes ordered; and the results must be documented in the medical record and used to direct care<sup>3</sup>.

#### 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<sup>9</sup>.

- 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.

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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 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<sup>11</sup>. 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<sup>12</sup>.

#### 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<sup>11</sup>;
- e. Reinforces therapeutic compliance with the patient;

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- f. Provides additional documentation demonstrating compliance with patient evaluation and monitoring<sup>13</sup>;
- 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:<sup>14</sup>

- 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<sup>15</sup> 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<sup>16</sup>. As part of the clinical evaluation of the patient, the provider should inquire about prescription compliance and potential issues of abuse or

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- b. diversion such as lost prescriptions, early refill requests, or requests for escalating dose of medication<sup>16</sup>. The number of UDTs billed over time must be based on the individual's risk potential<sup>1</sup>.
   Appropriate number of UDTs billed over time based on risk is listed in the table below<sup>14</sup>.
- c. The clinician should perform random UDT at random intervals to properly monitor a patient<sup>17</sup>.UDT testing does not have to be associated with an office visit.
- d. 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.

#### **Limitations**

#### 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.

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- 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.

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# **Client Communication**

# L36029 - Urine Drug Testing

CPT: 80305, 80306, 80307, G0480, G0481, G0482, G0483, G0659, 0143U, 0144U, 0145U, 0146U, 0147U, 0148U, 0149U, 0150U 0227U

The ICD10 codes listed below are the top 40 diagnosis codes Sonic most commonly receives from ordering physicians for this limited-coverage test. Medicare supports provider utilization of all the diagnosis codes listed below, except those notated in bold. If you are providing a diagnosis code that is <u>bolded</u> below, please submit a valid ABN form with the order. To view the complete policy and the full list of medically supported diagnosis codes, please refer to the CMS website for guidance: <a href="https://www.cms.gov/medicare-coverage-database/search.aspx">https://www.cms.gov/medicare-coverage-database/search.aspx</a>

Codes	Description
Z79.899	Other long term (current) drug therapy
I10	Essential (primary) hypertension
Z51.81	Encounter for therapeutic drug level monitoring
Z79.891	Long term (current) use of opiate analgesic
Z94.0	Kidney transplant status
R56.9	Unspecified convulsions
E55.9	Vitamin D deficiency, unspecified
E78.5	Hyperlipidemia, Unspecified
E03.9	Hypothyroidism, Unspecified
G40.909	Epilepsy, unspecified, not intractable, without status epilepticus
F11.20	Opioid dependence, uncomplicated
R79.9	Abnormal finding of blood chemistry, unspecified
Z48.298	Encounter for aftercare following other organ transplant
E11.9	Type 2 Diabetes Mellitus without complications
D84.9	Immunodeficiency, unspecified
M05.79	Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement
F11.90	Opioid use, unspecified, uncomplicated
Z94.4	Liver transplant status
M79.7	Fibromyalgia
M81.0	Age-related osteoporosis without current pathological fracture
R53.83	Other Fatigue
E78.2	Mixed Hyperlipidemia

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F15.10	Other stimulant abuse, uncomplicated
Z94.4	Liver transplant status
M79.7	Fibromyalgia
M81.0	Age-related osteoporosis without current pathological fracture
R53.83	Other Fatigue
E78.2	Mixed Hyperlipidemia
F15.10	Other stimulant abuse, uncomplicated
M54.9	Dorsalgia, unspecified
R55	Syncope and collapse
Z41.8	Encounter for other procedures for purposes other than remedying health state
E61.2	Magnesium deficiency
R40.4	Transient alteration of awareness
Z13.858	Encounter for screening for other nervous system disorders
F11.10	Opioid abuse, uncomplicated
E11.65	Type 2 diabetes mellitus with hyperglycemia
Z48.23	Encounter for aftercare following liver transplant
D64.9	Anemia, Unspecified
E78.00	Pure hypercholesterolemia, unspecified
F13.10	Mental and behavioural disorders due to use of sedatives or hypnotics Acute intoxication
K76.9	Liver disease, unspecified
G40.89	Other seizures
125.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
M25.50	Pain in the Unspecified Joint
J44.9	Chronic Obstructive Pulmonary Disease, Unspecified

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