

# MEDICARE UTILIZATION RULES FOR URINARY DRUG SCREEN COVERAGE GUIDANCE



## THIS POLICY PROVIDES:

- The appropriate indications and expected frequency of testing for safe medication management of prescribed substances in risk stratified pain management patients or in identifying and treating substance use disorders.
- Documentation requirements, by the clinician in the patient's medical record, to support the medical necessity for drug testing on an individual patient basis.
- An overview of presumptive urine drug testing (UDT) and definitive UDT testing by various methodologies.

## DEFINITIONS

By way of definition and 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 drugs absent or present in concentrations of ng/ml
- Limited to GC-MS and LC-MS/MS testing methods only

### 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 pH, specific gravity, oxidants and creatinine

### 4. **Point of Care Testing (POCT)**

- Used when medically necessary by clinicians for immediate test results for the immediate management of the patient
- Available when the patient 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

### 5. **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

## 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 encourages unnecessary or excessive testing when no clinical cause exists.

## 7. Blanket Orders

- Test request that is not for a specific patient; rather, it is an identical order for all patient’s 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
- Testing Indications, 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 relate to the HCPCS code description.

### A. Presumptive Testing Methods:

1. CLIA-waived Presumptive UDT: CLIA-waived 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.
  - Positive test results are presumptive or not 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.
  - Presumptive UDT may be ordered when it is necessary to rapidly obtain and integrate results into clinical assessment and treatment decisions.
  - This type of test should only be used when results are needed immediately.
2. Presumptive UDT by FDA Approved/Cleared IA Analysis
  - Chemistry analyzers with IA UDT technology are used in an office or clinical laboratory setting. When FDA approved/cleared platforms and reagents are used, testing is classified as moderately complex.
  - 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.

- Presumptive positive tests are not definitive 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. Presumptive UDT by Laboratory Developed Test (LDT) IA Analysis:

- Similar to #2 above except only performed in a clinical laboratory setting.

#### **Limitations of Presumptive UDT**

Presumptive UDT testing is limited for the following reasons:

- 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 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 a wrong assumption or clinical decision.

#### **B. Definitive UDT:**

Gas Chromatography coupled with Mass Spectrometry (GC-MS) and High Performance Liquid Chromatography coupled with Tandem 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.

Both 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 are quantitative tests that identify all specific drugs, metabolites, and most illicit substances and report the results as absent or present 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.

Definitive UDT is reasonable and necessary in order to:

- 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
- 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.

## COVERED INDICATIONS FOR UDT

**Group A** – Symptomatic patients, multiple drug ingestion 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 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.

### **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, efficacy, side effects, and patient safety in general.

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. The risk of addiction in this population is considered equivalent to the risk in the general population. In contrast to the population of individuals who have a history of SUD, in the cancer and non-cancer pain population the risk of SUD is inherent to the substance(s) to which the patient is exposed.

1. COT UDT Testing Objectives:
  - a. Identifies absence of prescribed medication and potential for abuse, misuse, and diversion
  - b. Identifies undisclosed substances, such as alcohol, 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
  - e. Reinforces therapeutic compliance with the patient

- f. Provides additional documentation demonstrating compliance with patient evaluation & monitoring
- 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 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) and
- 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:

- **COT Baseline Testing**

Initial presumptive or definitive COT patient testing may include amphetamine/methamphetamine, barbiturates, benzodiazepines, cocaine, methadone, oxycodone, tricyclic antidepressants, tetrahydrocannabinoid, opioids, opiates, heroin, and synthetic/analog or "designer" drugs.

- **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.

## **DRUG TESTING PANELS**

### **A. Presumptive UDT Panels**

Presumptive UDT testing may be ordered as a panel because the Medicare billing codes (G0431 and G0434) are defined on a "per patient encounter" basis regardless of the number of analytes tested.

Presumptive UDT orders should be individualized based on clinical history and risk assessment, and must be documented in the medical record.

## B. Definitive UDT Panels

At the current time, 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.

## 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:
  - To verify a presumptive positive UDT using definitive UDT (GC-MS or LCMS/MS) before reporting the presumptive finding to the ordering clinician and without an additional order from the clinician OR
  - 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, in the following circumstances:
  - To identify a specific substance or its metabolite that is in a large class of drugs, or that is inadequately detected or not detected by presumptive UDT, such as fentanyl, meperidine, synthetic cannabinoids, and other synthetic/analog drugs;
  - For use in a differential assessment of medication efficacy, side effects, or drug-drug interactions;
  - To identify non-prescribed medication or illicit substance use for ongoing safe prescribing of controlled substances, where clinician has documented concerns related to safety risks attendant to failure to identify specific substances suspected based upon clinical review and judgment; or
  - To 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).
3. Definitive testing to confirm a negative presumptive UDT result, upon the order of the clinician, is reasonable and necessary in the following circumstances:
  - The result is inconsistent with a patient's self-report, presentation, medical history, or current prescribed medication plan (should be present in the sample);
  - 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
  - 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.

## LIMITATIONS

### 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 or quantification by GC-MS or LCMS/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 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.

As published in CMS IOM Pub. 100-08, Chapter 13, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under Section 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective.
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary).
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
  - » Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member.
  - » Furnished in a setting appropriate to the patient's medical needs and condition.
  - » Ordered and furnished by qualified personnel.
  - » One that meets, but does not exceed, the patient's medical needs.
  - » At least as beneficial as an existing and available medically appropriate alternative.

# MEDICARE UTILIZATION RULES FOR URINARY DRUG SCREEN COVERAGE GUIDANCE



## BILL TYPE CODES

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

<b>012X</b>	Hospital Inpatient (Medicare Part B only)
<b>013x</b>	Hospital Outpatient
<b>014x</b>	Hospital - Laboratory Services Provided to Non-patients
<b>021x</b>	Skilled Nursing - Inpatient (Including Medicare Part A)
<b>022x</b>	Skilled Nursing - Inpatient (Medicare Part B only)
<b>023x</b>	Skilled Nursing - Outpatient
<b>071x</b>	Clinic - Rural Health
<b>072x</b>	Clinic - Hospital Based or Independent Renal Dialysis Center
<b>073x</b>	Clinic - Freestanding
<b>077x</b>	Clinic - Federally Qualified Health Center (FQHC)
<b>085x</b>	Critical Access Hospital

## REVENUE CODES

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

Note: The contractor has identified the Bill Type and Revenue Codes applicable for use with the CPT/HCPCS codes included in this LCD. Providers are reminded that not all CPT/HCPCS codes listed can be billed with all Bill Type and/or Revenue Codes listed. CPT/HCPCS codes are required to be billed with specific Bill Type and Revenue Codes. Providers are encouraged to refer to the CMS Internet-Only Manual (IOM) Pub. 100-04, Claims Processing Manual, for further guidance.

<b>0300</b>	Laboratory - General Classification
<b>0301</b>	Laboratory - Chemistry
<b>0309</b>	Laboratory - Other Laboratory
<b>0971</b>	Professional Fees - Laboratory

## CPT/HCPCS CODES

Group 1 Paragraph: Note: Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book.  
Presumptive UDT

### GROUP 1 CODES:

<b>G0431</b>	Drug screen multiple class
<b>G0434</b>	Drug screen multi drug class

## CPT/HCPCS CODES

### Group 2 Paragraph: Definitive UDT

#### GROUP 2 CODES:

80159	Drug assay clozapine
80171	Drug screen quant gabapentin
80173	Assay of haloperidol
80183	Drug scrn quant oxcarbazepin
80184	Assay of phenobarbital
83789	Mass spectrometry quant
83992	Assay for phencyclidine
84999	Clinical chemistry test
G6030	Assay of amitriptyline
G6031	Assay of benzodiazepines
G6032	Assay of desipramine
G6034	Assay of doxepin
G6036	Assay of imipramine
G6037	Assay of nortriptyline
G6040	Assay of ethanol
G6041	Assay of urine alkaloids
G6042	Assay of amphetamines
G6043	Assay of barbiturates
G6044	Assay of cocaine
G6045	Assay of dihydrocodeinone
G6046	Assay of dihydromorphinone
G6048	Assay of dimethadione
G6051	Assay of flurazepam
G6052	Assay of meprobamate
G6053	Assay of methadone
G6056	Assay of opiates
G6057	Assay of phenothiazine
G6058	Drug confirmation