SUPERSEDED Local Coverage Determination (LCD): Controlled Substance Monitoring and Drugs of Abuse Testing (L36029)

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Please Note: This version is not currently in effect.

Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
CGS Administrators, LLC	MAC - Part A	15101 - MAC A	J - 15	Kentucky
CGS Administrators, LLC	MAC - Part B	15102 - MAC B	J - 15	Kentucky
CGS Administrators, LLC	MAC - Part A	15201 - MAC A	J - 15	Ohio
CGS Administrators, LLC	MAC - Part B	15202 - MAC B	J - 15	Ohio

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LCD Information

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

Title XVIII of the Social Security Act, §1833(e). Prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

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, 80.2. Clinical Laboratory services.

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

b> Purpose

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

This policy details:

1. The appropriate indications and expected frequency of testing for safe medication management of prescribed substances in risk stratified pain management patients and/or in identifying and treating substance use disorders.
2. 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;
3. Provides an overview of presumptive urine drug testing (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) - Used when medically necessary to determine the presence or absence of drugs or drug classes in a urine sample; results expressed as negative or positive or as a numerical result; includes competitive immunoassays (IA) and thin layer chromatography.
2. **Definitive/Quantitative/Confirmation** (hereafter called "definitive" UDT) - Used when medically necessary to identify specific medications, illicit substances and metabolites; reports the results of analytes absent or present typically in concentrations such as ng/mL; definitive methods include, but are not limited to GC-MS and LC-MS/MS testing methods.
3. **Specimen Validity Testing** - Urine specimen testing to ensure that it is consistent with normal human urine and has not been adulterated or substituted, may include, but is not limited to pH, specific gravity, oxidants and creatinine.
4. **Immunoassay (IA)** - Ordered by clinicians primarily to identify the presence or absence of drug classes and some specific drugs; biochemical tests that measure the presence above a cutoff level of a substance (drug) with the use of an antibody; read by photometric technology.
5. **Point of Care Testing (POCT)** - Used when medically necessary by clinicians caring for the beneficiary for immediate test results for the immediate management of the beneficiary; available when the beneficiary and physician are in the same location; IA test method that primarily identifies drug classes and a few specific drugs; platform consists of cups, dipsticks, cassettes, or strips; read by the human eye, or read by instrument assisted direct optical observation.
6. **Standing Orders** - Test request for a specific patient representing repetitive testing to monitor a condition or disease for a limited number of sequential visits; individualized orders for certain patients for pre-determined tests based on historical use, risk and community trend patient profiles; clinician can alter the standing order.

   Note: A "profile" differs from a "panel" in that a profile responds to the clinical risks of a particular patient, whereas a panel may encourage unnecessary or excessive testing when no clinical cause exists for many of the tests

1. **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.
2. **Reflex Testing** - Laboratory testing that is performed "reflexively" after initial test results to identify further diagnostic information essential to patient care. This testing is not based on a specific physician's order. Testing performed as a step necessary to complete a physician's order is not considered reflex testing.

Drug Test Methods.

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

A. **Presumptive Testing Methods:**

1. **Presumptive UDT:**

Presumptive UDT consist of various platforms including cards, dipsticks, cassettes and cups based on qualitative competitive immunoassay methodology with one or more analytes in the test. A presumptive IA test detects the presence of the amount of drug/substance present in urine above a predetermined "cut-off" value, and may be read by direct optical observation or by instrument assisted direct optical observation.

A positive test result is reported when the concentration of drug is above the cutoff; a negative is reported when the concentration of drug is below the cut-off. Positive test results are presumptive but not necessarily definitive due to sensitivity and cross-reactivity limitations. Negative test results do not necessarily indicate the absence of a drug or substance in the urine specimen. The accuracy of the results of a presumptive UDT will depend on the testing environment, type of test, and training of the individual conducting the test.

This type of test should only be used when results are needed immediately.

2. **Presumptive UDT by Instrumented Chemistry Analyzers:**

Chemistry analyzers with IA UDT technology can be used in an office or clinical laboratory setting. This test may be used when less immediate test results are required. At no time is IA technology by chemistry analyzer analysis considered confirmatory (definitive) testing.

A presumptive positive IA test detects the presence of a drug/substance in urine at or above the "cut-off" value. If the concentration of the drug is below the cut-off, the result will be negative. Presumptive positive tests are not always true positives due to sensitivity, specificity, and cross-reactivity limitations. Negative test results do not necessarily indicate the absence of a drug or substance in the urine specimen.

FDA approved/cleared test platforms are available in the marketplace as well as, laboratory developed tests (LDTs) such as modified FDA approved/ cleared and non-FDA approved/cleared platforms and/or reagents. LDTs generally have been modified to test at a lower cutoff in order to detect substances that would have been missed at a higher cutoff. For example, a FDA labeled cutoff may be 300 ng/mL and the LDT cutoff for the same drug may be a 100 ng/mL

Presumptive UDT can be carried out at any validated cut-off concentration. Lowering of the cut-off concentration provides more stringent cutoffs for illicit drugs. LDTs may include non-FDA cleared tests not available in CLIA-waived or moderate complexity tests (e.g. tramadol, tapentadol, carisoprodol, fentanyl, zolpidem). Lowering the cutoff increases the possibility of detecting a drug when the test has been modified from the recipe of the manufacturer

1. **Limitations of Presumptive UDT**

Presumptive UDT testing is limited due to:

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

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

An IA involves an antibody that reacts best with the stimulating drug, and reacts to a lesser extent (cross-reactive) or not at all with other drugs in the drug class. While presumptive tests vary in their ability to detect

illicit drugs such as tetrahydrocannabinol (THC), cocaine, 3,4-methylenedioxy-N-methylamphetamine (MDMA; "ecstasy"), and phencyclidine (PCP), they may not be optimal tests for many prescription drugs, such as: opiates, barbiturates, benzodiazepines and opioids.

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

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

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

In summary, presumptive IA UDT is often unable to identify specific drugs within many drug classes, particularly within the amphetamine, barbiturate, benzodiazepine, tricyclic antidepressants, and opiate/opioid drug classes. Drugs such as buprenorphine, amphetamines, benzodiazepines, and cocaine/heroin yield false negative IA results due to low cross-reactivity or non-reactivity and drugs such as fentanyl, carisoprodol, tramadol, tapentadol and synthetic designer drugs cannot be detected by presumptive IA. Therefore, it may be medically necessary for clinicians to utilize definitive UDT when the presumptive tests for these drugs are negative.

B. **Definitive UDT:**

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

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

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

1. **GC-MS**
   GC-MS can only be performed on molecules that are volatile. If the test drug is not volatile in its own right, it must be modified or derivatized to a volatile form. To derivatize, the test drug must be extracted from the urine, eluted from the extraction device, concentrated, and then reacted with a chemical reagent to make a volatile product. Each drug class may require a different derivatizing agent. For patients on multiple classes of medications, laboratories using GC procedures must make different volatile derivatives in order to perform comprehensive testing. Since a GC column may not be able to separate more than one class of compounds, multiple chromatographic runs on different column types may be required to monitor multiple drug classes. Newer GC-MS instruments often use tandem systems. GC-MS methodology allows for the testing of multiple substances but differs in ease of run.

2. **LC-MS/MS**
LC-MS/MS is roughly 100 times more sensitive and selective, involves less human steps, provides quicker turn-around time, uses less specimen volume and can test for a larger number of substances simultaneously when compared to GC-MS. After sample preparation, it is injected into the LC-MS/MS. The sample has to undergo hydrolysis to break the glucuronide bond that frees the drug and drug metabolites. Hydrolysis is followed by multiple additional steps including protein precipitation, centrifugation and purification. Deuterium-labeled isotopic internal standards are added to quantify the drugs and drug metabolites.

The sample is injected when the mobile phase is flowing through the chromatographic column. Each drug and drug metabolite interacts with the mobile phase and stationary phase differently and moves at different speeds depending on their chemical properties. In other words, each analyte elutes at different times. Specific drugs and metabolites are identified by their retention time and quantified against isotopic internal standards for each drug and metabolite. Each drug peak has to be compared to drug standards (calibrators) in order to ensure identification.

CLIA-Certified Laboratories

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

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

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

Purpose of UDT:

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

Definitive UDT is reasonable and necessary for the following circumstances:

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

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

Drug Testing Panels

A. **Presumptive UDT Panels**

Presumptive UDT testing typically involves testing for multiple analytes based on the beneficiary's clinical history and risk assessment, and must be documented in the medical record.

B. **Definitive UDT Panels**

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

Specimen Type

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

Parent Drugs and Metabolite

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

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

Parent Drugs and Metabolite Chart

Drug Class/Drugs	Common Names	General Monitoring Possibilities Subject to Medical Necessity
Alcohol/Alcohol Metabolites Ethyl Glucuronide Ethyl Sulfate	Alcohol	Ethyl Glucuronide Ethyl Sulfate
Barbiturates Amobarbital Butabarbital Butalbital	Amytal Sodium&reg Butisol Sodium&reg, Butibel Fiorinal&reg, Fioricet&reg	Amobarbital Butabarbital Butalbital Pentobarbital

Parent Drugs and Metabolite Chart

Drug Class/Drugs	Common Names	General Monitoring Possibilities Subject to Medical Necessity
Pentobarbital Phenobarbital Secobarbital	Nembutal&reg Belladona, Luminal&reg Seconal&reg	Phenobarbital Secobarbital
Benzodiazepines Alprazolam Chlordiazepoxide Clonazepam Clorazepate Diazepam Lorazepam Oxazepam Temazepam	Xanax&reg, Niravam&reg, Xanor Librax&reg, Libritabs Klonopin&reg Tranxene&reg Valium&reg Ativan&reg, Lorax Adumbran, Alepam, Murelax, Serax, Serepax Restoril&reg, Tenox, Euhypnos	Alprazolam, Alpha-hydroxyalprazolam Nordiazepam, Oxazepam 7-Aminoclonazepam Nordiazepam, Oxazepam Diazepam, Nordiazepam, Temazepam, Oxazepam Lorazepam Oxazepam Temazepam, Oxazepam
Illicit Drugs Cocaine Heroin Marijuana MDA MDMA Methamphetamine Phencylclidine (PCP)	Blow, Coke, Crack, Snow Black Tar, Brown Sugar, Dragon, H, Horse, Tar Marinol, Pot, Reefer, Weed Ecstasy, X Ecstasy, X Crank, Crystal Meth, Didrex&reg, Eldepryl&reg, Ice Angel Dust	Benzoylecgonine 6-MAM, Morphine THC-COOH Methylenedioxyamphetamine Methylenedioxymethamphetamine, Methylenedioxyamphetamine Methamphetamine, Amphetamine Phencyclidine
Synthetic Cannabinoids	"K2"/"Spice"	
Cathinones	"Bath Salts" Kratom	
General Anesthetic Ketamine	Ketamine Norketamine	

Parent Drugs and Metabolite Chart

Drug Class/Drugs	Common Names	General Monitoring Possibilities Subject to Medical Necessity
Muscle Relaxants		
Carisoprodol	Soma&reg, Soprodoal	Carisoprodol, Meprobamate
Meprobamate	Equinal, Miltown&reg, Meprospan	Meprobamate
Neuroleptics		
Gabapentin	Neurontin&reg	
Pregabalin	Lyrica&reg	
Opiates		
Codeine	Tylenol&reg 3	Codeine, Morphine
Hydrocodone	Hycodan&reg, Lorcet&reg, Lortab&reg, Norco&reg Vicodin&reg, Vicoprofen&reg	Hydrocodone, Hydromorphone, Norhydrocodone
Hydromorphone	Dilaudid&reg, Exalgo&reg, Hymorphan	Hydromorphone
Morphine	Avinza&reg, Kadian&reg, MS Contin&reg, MSER, MSIR, Roxanol	Morphine
Oxycodone	OxyContin&reg, OxyIR&reg, Percocet&reg, Percodan&reg, Roxicodone&reg, Tylox&reg	Oxycodone, Oxymorphone, Noroxycodone
Oxymorphone	Numorphan&reg, Opana&reg ER, Opana&reg	Oxymorphone
Opioids		
Buprenorphine	Buprenex&reg, Butrans&reg, Suboxone&reg, Subutex&reg	Buprenorphine, Norbuprenorphine
Fentanyl	Actiq&reg, Duragesic&reg, Fentora&reg, Onsolis&reg Sublimaze	Fentanyl, Norfentanyl
Meperidine	Demerol&reg, Mepergan&reg	Meperidine, Normeperidine
Methadone	Dolophine&reg, Methadose&reg	Methadone, EDDP
Propoxyphene	Darvocet&reg, Darvon&reg	Propoxyphene, Norpropoxyphene
Tapentadol		Tapentadol, N-Desmethyltapentadol
Tramadol		Tramadol, O-Desmethyltramadol

Parent Drugs and Metabolite Chart

Drug Class/Drugs	Common Names	General Monitoring Possibilities Subject to Medical Necessity
	Nucynta&reg Ryzolt&reg, Ultracet&reg, Ultram&reg, Tramadol	
Stimulants Amphetamine Methylphenidate Nicotine	Adderall&reg, Benzedrine, Dexedrine&reg, Vyvanse&reg Concerta&reg, Focalin&reg, Methylin&reg, Ritalin&reg Nicoderm&reg, Nicorette&reg	Amphetamine Methylphenidate, Ritalinic Acid Cotinine

Covered Indications for UDT

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

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

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

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

Group B - Diagnosis and treatment for substance abuse or dependence

A patient in active treatment for substance use disorder (SUD) or monitoring across different phases of recovery may undergo medical management for a variety of medical conditions. A physician who is writing prescriptions for medications to treat either the SUD or other conditions may need to know if the patient is taking substances which can interact with prescribed medications or taking prescribed medications as expected. The risk of drug-drug interactions is inherent to the patient, and may be compounded by prescribed medications.UDT is a medically necessary and useful component of chemical dependency diagnosis and treatment. The UDT result influences treatment and level of care decisions. Ordered tests and testing methods (presumptive and/or definitive) must match the stage of screening, treatment, or recovery; the documented history; and Diagnostic and Statistical Manual of Mental Disorders (DSM V) diagnosis.For patients with no known indicators of risk for

SUDs, the clinician may screen for a broad range of commonly abused drugs using presumptive UDT. For patients with known indicators of risk for SUDs, the clinician may screen for a broad range of commonly abused drugs using definitive UDT. For patients with a diagnosed SUD, the clinician should perform random UDT, at random intervals in order to properly monitor the patient. Testing profiles must be determined by the clinician based on the following medical necessity guidance criteria:

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

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

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

The testing frequency must meet medical necessity and be documented in the clinician's medical record.

a. For patients with 0 to 30 consecutive days of abstinence, presumptive UDT is expected at a frequency of 1 to 3 presumptive UDT per week. More than 3 presumptive panels in one week is not reasonable and necessary and is not covered by Medicare.
b. For patients with 31 to 90 consecutive days of abstinence, presumptive UDT is expected at a frequency of 1 to 3 UDT per week. More than 3 presumptive UDT in one week is not reasonable and necessary and is not be covered by Medicare.
c. For patients with > 90 consecutive days of abstinence, presumptive UDT is expected at a frequency of 1 to 3 UDT in one month. More than 3 physician-directed UDT in one month is not reasonable and necessary and is not covered by Medicare.

2. Frequency of Definitive UDT for SUD

Depending on the patient's specific substance use history, definitive UDT to accurately determine the specific drugs in the patient's system may be necessary. Definitive testing may be ordered when accurate and reliable results are necessary to integrate treatment decisions and clinical assessment. The frequency and the rational for definitive UDT must be documented in the patient's medical record.

a. For patients with 0 to 30 consecutive days of abstinence, definitive UDT is expected at a frequency not to exceed 1 physician-directed testing profile in one week. More than 1 physician-directed testing profile in one week is not reasonable and necessary and is not covered by Medicare.
b. For patients with 31 to 90 consecutive days of abstinence, definitive UDT is expected at a frequency of 1-3 physician-directed testing profiles in one month. More than 3 UDT in one month is not reasonable and necessary and is not covered by Medicare.
c. For patients with > 90 day of consecutive abstinence, definitive UDT is expected at a frequency of 1-3 physician-directed testing profiles in three months. More than 3 definitive UDT in 3 months is not reasonable and necessary and is not covered by Medicare.

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

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

1. COT UDT Testing Objectives:

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

2. Medical Necessity Guidance:

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

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 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:

3. COT Baseline Testing:

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

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. 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
b. 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.
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 Validated Risk Assessment and Stratification*:

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

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

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

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

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

Other Covered Services

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

Non-Covered Services

1. Blanket Orders
2. Reflex definitive UDT is not reasonable and necessary when presumptive testing is performed at point of care because the clinician may have sufficient information to manage the patient. If the clinician is not satisfied, he/she must determine the clinical appropriateness of and order specific subsequent definitive testing (e.g., the patient admits to using a particular drug, or the IA cut-off is set at such a point that is sufficiently low that the physician is satisfied with the presumptive test result).
3. Routine standing orders for all patients in a physician's practice are not reasonable and necessary.
4. It is not reasonable and necessary for a physician to perform presumptive POCT and order presumptive IA testing from a reference laboratory. In other words, Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers.
5. It is not reasonable and necessary for a physician to perform presumptive IA testing and order presumptive IA testing from a reference laboratory with or without reflex testing. Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers.
6. It is not reasonable and necessary for a reference laboratory to perform and bill IA presumptive UDT prior to definitive testing without a specific physician's order for the presumptive testing.

7. IA testing, regardless of whether it is qualitative or semi-quantitative (numerical), may not be used to "confirm" or definitively identify a presumptive test result obtained by cups, dipsticks, cards, cassettes or other IA testing methods. Definitive UDT provides specific identification and/or quantification typically by GC-MS or LC-MS/MS.
8. Drug testing of two different specimen types from the same patient on the same date of service for the same drugs/metabolites/analytes.
9. UDT for medico-legal and/or employment purposes or to protect a physician from drug diversion charges.
10. Specimen validity testing including, but not limited to, pH, specific gravity, oxidants, creatinine.

Summary of Evidence

N/A

Analysis of Evidence
(Rationale for Determination)

N/A

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Coding Information

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.

N/A
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.

N/A
CPT/HCPCS Codes
Group 1 Paragraph:
The following codes are new and effective 01/01/2017: G0659, 80305, 80306 and 80307.

Group 1 Codes:
80305

	DRUG TEST(S), PRESUMPTIVE, ANY NUMBER OF DRUG CLASSES, ANY NUMBER OF DEVICES OR PROCEDURES (EG, IMMUNOASSAY); CAPABLE OF BEING READ BY DIRECT OPTICAL OBSERVATION ONLY (EG, DIPSTICKS, CUPS, CARDS, CARTRIDGES) INCLUDES SAMPLE VALIDATION WHEN PERFORMED, PER DATE OF SERVICE
80306	DRUG TEST(S), PRESUMPTIVE, ANY NUMBER OF DRUG CLASSES, ANY NUMBER OF DEVICES OR PROCEDURES (EG, IMMUNOASSAY); READ BY INSTRUMENT ASSISTED DIRECT OPTICAL OBSERVATION (EG, DIPSTICKS, CUPS, CARDS, CARTRIDGES), INCLUDES SAMPLE VALIDATION WHEN PERFORMED, PER DATE OF SERVICE
80307	DRUG TEST(S), PRESUMPTIVE, ANY NUMBER OF DRUG CLASSES, ANY NUMBER OF DEVICES OR PROCEDURES, BY INSTRUMENT CHEMISTRY ANALYZERS (EG, UTILIZING IMMUNOASSAY [EG, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), CHROMATOGRAPHY (EG, GC, HPLC), AND MASS SPECTROMETRY EITHER WITH OR WITHOUT CHROMATOGRAPHY, (EG, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) INCLUDES SAMPLE VALIDATION WHEN PERFORMED, PER DATE OF SERVICE
G0480	DRUG TEST(S), DEFINITIVE, UTILIZING (1) DRUG IDENTIFICATION METHODS ABLE TO IDENTIFY INDIVIDUAL DRUGS AND DISTINGUISH BETWEEN STRUCTURAL ISOMERS (BUT NOT NECESSARILY STEREOISOMERS), INCLUDING, BUT NOT LIMITED TO GC/MS (ANY TYPE, SINGLE OR TANDEM) AND LC/MS (ANY TYPE, SINGLE OR TANDEM AND EXCLUDING IMMUNOASSAYS (E.G., IA, EIA, ELISA, EMIT, FPIA) AND ENZYMATIC METHODS (E.G., ALCOHOL DEHYDROGENASE)), (2) STABLE ISOTOPE OR OTHER UNIVERSALLY RECOGNIZED INTERNAL STANDARDS IN ALL SAMPLES (E.G., TO CONTROL FOR MATRIX EFFECTS, INTERFERENCES AND VARIATIONS IN SIGNAL STRENGTH), AND (3) METHOD OR DRUG-SPECIFIC CALIBRATION AND MATRIX-MATCHED QUALITY CONTROL MATERIAL (E.G., TO CONTROL FOR INSTRUMENT VARIATIONS AND MASS SPECTRAL DRIFT); QUALITATIVE OR QUANTITATIVE, ALL SOURCES, INCLUDES SPECIMEN VALIDITY TESTING, PER DAY; 1-7 DRUG CLASS(ES), INCLUDING METABOLITE(S) IF PERFORMED
G0481	DRUG TEST(S), DEFINITIVE, UTILIZING (1) DRUG IDENTIFICATION METHODS ABLE TO IDENTIFY INDIVIDUAL DRUGS AND DISTINGUISH BETWEEN STRUCTURAL ISOMERS (BUT NOT NECESSARILY STEREOISOMERS), INCLUDING, BUT NOT LIMITED TO GC/MS (ANY TYPE, SINGLE OR TANDEM) AND LC/MS (ANY TYPE, SINGLE OR TANDEM AND EXCLUDING IMMUNOASSAYS (E.G., IA, EIA, ELISA, EMIT, FPIA) AND ENZYMATIC METHODS (E.G., ALCOHOL DEHYDROGENASE)), (2) STABLE ISOTOPE OR OTHER UNIVERSALLY RECOGNIZED INTERNAL STANDARDS IN ALL SAMPLES (E.G., TO CONTROL FOR MATRIX EFFECTS, INTERFERENCES AND VARIATIONS IN SIGNAL STRENGTH), AND (3) METHOD OR DRUG-SPECIFIC CALIBRATION AND MATRIX-MATCHED QUALITY CONTROL MATERIAL (E.G., TO CONTROL FOR INSTRUMENT VARIATIONS AND MASS SPECTRAL DRIFT); QUALITATIVE OR QUANTITATIVE, ALL SOURCES, INCLUDES SPECIMEN VALIDITY TESTING, PER DAY; 8-14 DRUG CLASS(ES), INCLUDING METABOLITE(S) IF PERFORMED
G0482	DRUG TEST(S), DEFINITIVE, UTILIZING (1) DRUG IDENTIFICATION METHODS ABLE TO IDENTIFY INDIVIDUAL DRUGS AND DISTINGUISH BETWEEN STRUCTURAL ISOMERS (BUT NOT NECESSARILY STEREOISOMERS), INCLUDING, BUT NOT LIMITED TO GC/MS (ANY TYPE, SINGLE OR TANDEM) AND LC/MS (ANY TYPE, SINGLE OR TANDEM AND EXCLUDING IMMUNOASSAYS (E.G., IA, EIA, ELISA, EMIT, FPIA) AND ENZYMATIC METHODS (E.G., ALCOHOL DEHYDROGENASE)), (2) STABLE ISOTOPE OR OTHER UNIVERSALLY RECOGNIZED INTERNAL STANDARDS IN ALL SAMPLES (E.G., TO CONTROL FOR MATRIX EFFECTS, INTERFERENCES AND VARIATIONS IN SIGNAL STRENGTH), AND (3) METHOD OR DRUG-SPECIFIC CALIBRATION AND MATRIX-MATCHED QUALITY CONTROL MATERIAL (E.G., TO CONTROL FOR INSTRUMENT VARIATIONS AND MASS SPECTRAL DRIFT); QUALITATIVE OR QUANTITATIVE, ALL SOURCES, INCLUDES SPECIMEN VALIDITY TESTING, PER DAY; 15-21 DRUG CLASS(ES), INCLUDING METABOLITE(S) IF PERFORMED
G0483	DRUG TEST(S), DEFINITIVE, UTILIZING (1) DRUG IDENTIFICATION METHODS ABLE TO IDENTIFY INDIVIDUAL DRUGS AND DISTINGUISH BETWEEN STRUCTURAL ISOMERS (BUT NOT NECESSARILY STEREOISOMERS), INCLUDING, BUT NOT LIMITED TO GC/MS (ANY TYPE, SINGLE OR TANDEM) AND LC/MS (ANY TYPE, SINGLE OR TANDEM AND EXCLUDING IMMUNOASSAYS (E.G., IA, EIA, ELISA, EMIT, FPIA) AND ENZYMATIC METHODS (E.G., ALCOHOL DEHYDROGENASE)), (2) STABLE ISOTOPE OR OTHER UNIVERSALLY RECOGNIZED INTERNAL STANDARDS IN ALL SAMPLES (E.G., TO CONTROL FOR MATRIX EFFECTS, INTERFERENCES AND VARIATIONS IN SIGNAL STRENGTH), AND (3) METHOD OR DRUG-SPECIFIC CALIBRATION AND MATRIX-MATCHED QUALITY CONTROL MATERIAL (E.G., TO CONTROL FOR INSTRUMENT VARIATIONS AND MASS SPECTRAL DRIFT); QUALITATIVE OR QUANTITATIVE, ALL SOURCES, INCLUDES SPECIMEN VALIDITY TESTING, PER DAY; 22 OR MORE DRUG CLASS(ES), INCLUDING METABOLITE(S) IF PERFORMED
G0659	DRUG TEST(S), DEFINITIVE, UTILIZING DRUG IDENTIFICATION METHODS ABLE TO IDENTIFY INDIVIDUAL DRUGS AND DISTINGUISH BETWEEN STRUCTURAL ISOMERS (BUT NOT NECESSARILY STEREOISOMERS), INCLUDING BUT NOT LIMITED TO GC/MS (ANY TYPE, SINGLE OR TANDEM) AND LC/MS (ANY TYPE, SINGLE OR TANDEM), EXCLUDING IMMUNOASSAYS (E.G., IA, EIA, ELISA, EMIT, FPIA) AND ENZYMATIC METHODS (E.G., ALCOHOL DEHYDROGENASE), PERFORMED WITHOUT METHOD OR DRUG-SPECIFIC CALIBRATION, WITHOUT MATRIX-MATCHED QUALITY CONTROL MATERIAL, OR WITHOUT USE OF STABLE ISOTOPE OR OTHER UNIVERSALLY RECOGNIZED INTERNAL STANDARD(S) FOR EACH DRUG, DRUG METABOLITE OR DRUG CLASS PER SPECIMEN; QUALITATIVE OR QUANTITATIVE, ALL SOURCES, INCLUDES SPECIMEN VALIDITY TESTING, PER DAY, ANY NUMBER OF DRUG CLASSES

ICD-10 Codes that Support Medical Necessity
Group 1 Paragraph: N/A

Group 1 Codes:

ICD-10 Codes	Description
E87.2	Acidosis
F10.11	Alcohol abuse, in remission
F10.20	Alcohol dependence, uncomplicated
F11.11	Opioid abuse, in remission
F11.20	Opioid dependence, uncomplicated
F11.220	Opioid dependence with intoxication, uncomplicated
F11.221	Opioid dependence with intoxication delirium
F11.222	Opioid dependence with intoxication with perceptual disturbance
F11.229	Opioid dependence with intoxication, unspecified
F11.23	Opioid dependence with withdrawal
F11.24	Opioid dependence with opioid-induced mood disorder
F11.250	Opioid dependence with opioid-induced psychotic disorder with delusions
F11.251	Opioid dependence with opioid-induced psychotic disorder with hallucinations
F11.259	Opioid dependence with opioid-induced psychotic disorder, unspecified
F11.281	Opioid dependence with opioid-induced sexual dysfunction
F11.282	Opioid dependence with opioid-induced sleep disorder
F11.288	Opioid dependence with other opioid-induced disorder
F11.29	Opioid dependence with unspecified opioid-induced disorder
F12.11	Cannabis abuse, in remission
F13.11	Sedative, hypnotic or anxiolytic abuse, in remission
F14.11	Cocaine abuse, in remission
F15.11	Other stimulant abuse, in remission
F16.11	Hallucinogen abuse, in remission
F18.10	Inhalant abuse, uncomplicated
F18.11	Inhalant abuse, in remission
F18.120	Inhalant abuse with intoxication, uncomplicated
F18.90	Inhalant use, unspecified, uncomplicated
F19.11	Other psychoactive substance abuse, in remission
F19.20	Other psychoactive substance dependence, uncomplicated
F20.0	Paranoid schizophrenia
F20.1	Disorganized schizophrenia
F20.2	Catatonic schizophrenia
F20.89	Other schizophrenia
F55.0	Abuse of antacids
F55.1	Abuse of herbal or folk remedies
F55.2	Abuse of laxatives
F55.3	Abuse of steroids or hormones
F55.4	Abuse of vitamins
F55.8	Abuse of other non-psychoactive substances
G40.301	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, with status epilepticus
G40.309	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, without status epilepticus
G40.311	Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus
G40.319	Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.401	Other generalized epilepsy and epileptic syndromes, not intractable, with status epilepticus
G40.409	Other generalized epilepsy and epileptic syndromes, not intractable, without status epilepticus
G40.411	Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus
G40.419	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.901	Epilepsy, unspecified, not intractable, with status epilepticus
G40.909	Epilepsy, unspecified, not intractable, without status epilepticus
G40.911	Epilepsy, unspecified, intractable, with status epilepticus
G40.919	Epilepsy, unspecified, intractable, without status epilepticus
G89.29	Other chronic pain
G89.4	Chronic pain syndrome
I44.0	Atrioventricular block, first degree

ICD-10 Codes	Description
I44.1	Atrioventricular block, second degree
I44.30	Unspecified atrioventricular block
I45.81	Long QT syndrome
I47.0	Re-entry ventricular arrhythmia
I47.1	Supraventricular tachycardia
I47.2	Ventricular tachycardia
I49.2	Junctional premature depolarization
M25.50	Pain in unspecified joint
M47.21	Other spondylosis with radiculopathy, occipito-atlanto-axial region
M47.22	Other spondylosis with radiculopathy, cervical region
M47.23	Other spondylosis with radiculopathy, cervicothoracic region
M47.26	Other spondylosis with radiculopathy, lumbar region
M47.27	Other spondylosis with radiculopathy, lumbosacral region
M47.28	Other spondylosis with radiculopathy, sacral and sacrococcygeal region
M47.811	Spondylosis without myelopathy or radiculopathy, occipito-atlanto-axial region
M47.812	Spondylosis without myelopathy or radiculopathy, cervical region
M47.813	Spondylosis without myelopathy or radiculopathy, cervicothoracic region
M47.816	Spondylosis without myelopathy or radiculopathy, lumbar region
M47.817	Spondylosis without myelopathy or radiculopathy, lumbosacral region
M47.818	Spondylosis without myelopathy or radiculopathy, sacral and sacrococcygeal region
M47.891	Other spondylosis, occipito-atlanto-axial region
M47.892	Other spondylosis, cervical region
M47.893	Other spondylosis, cervicothoracic region
M47.896	Other spondylosis, lumbar region
M47.897	Other spondylosis, lumbosacral region
M47.898	Other spondylosis, sacral and sacrococcygeal region
M51.14	Intervertebral disc disorders with radiculopathy, thoracic region
M51.15	Intervertebral disc disorders with radiculopathy, thoracolumbar region
M51.16	Intervertebral disc disorders with radiculopathy, lumbar region
M51.17	Intervertebral disc disorders with radiculopathy, lumbosacral region
M51.36	Other intervertebral disc degeneration, lumbar region
M51.37	Other intervertebral disc degeneration, lumbosacral region
M54.14	Radiculopathy, thoracic region
M54.15	Radiculopathy, thoracolumbar region
M54.16	Radiculopathy, lumbar region
M54.17	Radiculopathy, lumbosacral region
M54.18	Radiculopathy, sacral and sacrococcygeal region
M54.2	Cervicalgia
M54.5	Low back pain
M60.811	Other myositis, right shoulder
M60.812	Other myositis, left shoulder
M60.821	Other myositis, right upper arm
M60.822	Other myositis, left upper arm
M60.831	Other myositis, right forearm
M60.832	Other myositis, left forearm
M60.841	Other myositis, right hand
M60.842	Other myositis, left hand
M60.851	Other myositis, right thigh
M60.852	Other myositis, left thigh
M60.861	Other myositis, right lower leg
M60.862	Other myositis, left lower leg
M60.871	Other myositis, right ankle and foot
M60.872	Other myositis, left ankle and foot
M60.88	Other myositis, other site
M60.89	Other myositis, multiple sites
M60.9	Myositis, unspecified
M79.1	Myalgia
M79.2	Neuralgia and neuritis, unspecified

ICD-10 Codes	Description
M79.7	Fibromyalgia
R40.0	Somnolence
R40.1	Stupor
R40.20	Unspecified coma
R40.2110	Coma scale, eyes open, never, unspecified time
R40.2111	Coma scale, eyes open, never, in the field [EMT or ambulance]
R40.2112	Coma scale, eyes open, never, at arrival to emergency department
R40.2113	Coma scale, eyes open, never, at hospital admission
R40.2114	Coma scale, eyes open, never, 24 hours or more after hospital admission
R40.2120	Coma scale, eyes open, to pain, unspecified time
R40.2121	Coma scale, eyes open, to pain, in the field [EMT or ambulance]
R40.2122	Coma scale, eyes open, to pain, at arrival to emergency department
R40.2123	Coma scale, eyes open, to pain, at hospital admission
R40.2124	Coma scale, eyes open, to pain, 24 hours or more after hospital admission
R40.2210	Coma scale, best verbal response, none, unspecified time
R40.2211	Coma scale, best verbal response, none, in the field [EMT or ambulance]
R40.2212	Coma scale, best verbal response, none, at arrival to emergency department
R40.2213	Coma scale, best verbal response, none, at hospital admission
R40.2214	Coma scale, best verbal response, none, 24 hours or more after hospital admission
R40.2220	Coma scale, best verbal response, incomprehensible words, unspecified time
R40.2221	Coma scale, best verbal response, incomprehensible words, in the field [EMT or ambulance]
R40.2222	Coma scale, best verbal response, incomprehensible words, at arrival to emergency department
R40.2223	Coma scale, best verbal response, incomprehensible words, at hospital admission
R40.2224	Coma scale, best verbal response, incomprehensible words, 24 hours or more after hospital admission
R40.2310	Coma scale, best motor response, none, unspecified time
R40.2311	Coma scale, best motor response, none, in the field [EMT or ambulance]
R40.2312	Coma scale, best motor response, none, at arrival to emergency department
R40.2313	Coma scale, best motor response, none, at hospital admission
R40.2314	Coma scale, best motor response, none, 24 hours or more after hospital admission
R40.2320	Coma scale, best motor response, extension, unspecified time
R40.2321	Coma scale, best motor response, extension, in the field [EMT or ambulance]
R40.2322	Coma scale, best motor response, extension, at arrival to emergency department
R40.2323	Coma scale, best motor response, extension, at hospital admission
R40.2324	Coma scale, best motor response, extension, 24 hours or more after hospital admission
R40.2340	Coma scale, best motor response, flexion withdrawal, unspecified time
R40.2341	Coma scale, best motor response, flexion withdrawal, in the field [EMT or ambulance]
R40.2342	Coma scale, best motor response, flexion withdrawal, at arrival to emergency department
R40.2343	Coma scale, best motor response, flexion withdrawal, at hospital admission
R40.2344	Coma scale, best motor response, flexion withdrawal, 24 hours or more after hospital admission
R41.82	Altered mental status, unspecified
R44.0	Auditory hallucinations
R44.2	Other hallucinations
R44.3	Hallucinations, unspecified
R45.850	Homicidal ideations
R45.851	Suicidal ideations
R56.9	Unspecified convulsions
T39.011A	Poisoning by aspirin, accidental (unintentional), initial encounter
T39.012A	Poisoning by aspirin, intentional self-harm, initial encounter
T39.013A	Poisoning by aspirin, assault, initial encounter
T39.014A	Poisoning by aspirin, undetermined, initial encounter
T39.091A	Poisoning by salicylates, accidental (unintentional), initial encounter
T39.092A	Poisoning by salicylates, intentional self-harm, initial encounter
T39.093A	Poisoning by salicylates, assault, initial encounter
T39.094A	Poisoning by salicylates, undetermined, initial encounter
T39.1X1A	Poisoning by 4-Aminophenol derivatives, accidental (unintentional), initial encounter
T39.1X2A	Poisoning by 4-Aminophenol derivatives, intentional self-harm, initial encounter
T39.1X3A	Poisoning by 4-Aminophenol derivatives, assault, initial encounter

ICD-10 Codes	Description
T39.1X4A	Poisoning by 4-Aminophenol derivatives, undetermined, initial encounter
T39.2X1A	Poisoning by pyrazolone derivatives, accidental (unintentional), initial encounter
T39.2X2A	Poisoning by pyrazolone derivatives, intentional self-harm, initial encounter
T39.2X3A	Poisoning by pyrazolone derivatives, assault, initial encounter
T39.2X4A	Poisoning by pyrazolone derivatives, undetermined, initial encounter
T39.311A	Poisoning by propionic acid derivatives, accidental (unintentional), initial encounter
T39.312A	Poisoning by propionic acid derivatives, intentional self-harm, initial encounter
T39.313A	Poisoning by propionic acid derivatives, assault, initial encounter
T39.314A	Poisoning by propionic acid derivatives, undetermined, initial encounter
T39.391A	Poisoning by other nonsteroidal anti-inflammatory drugs [NSAID], accidental (unintentional), initial encounter
T39.392A	Poisoning by other nonsteroidal anti-inflammatory drugs [NSAID], intentional self-harm, initial encounter
T39.393A	Poisoning by other nonsteroidal anti-inflammatory drugs [NSAID], assault, initial encounter
T39.394A	Poisoning by other nonsteroidal anti-inflammatory drugs [NSAID], undetermined, initial encounter
T40.0X1A	Poisoning by opium, accidental (unintentional), initial encounter
T40.0X2A	Poisoning by opium, intentional self-harm, initial encounter
T40.0X3A	Poisoning by opium, assault, initial encounter
T40.0X4A	Poisoning by opium, undetermined, initial encounter
T40.1X1A	Poisoning by heroin, accidental (unintentional), initial encounter
T40.1X2A	Poisoning by heroin, intentional self-harm, initial encounter
T40.1X3A	Poisoning by heroin, assault, initial encounter
T40.1X4A	Poisoning by heroin, undetermined, initial encounter
T40.2X1A	Poisoning by other opioids, accidental (unintentional), initial encounter
T40.2X2A	Poisoning by other opioids, intentional self-harm, initial encounter
T40.2X3A	Poisoning by other opioids, assault, initial encounter
T40.2X4A	Poisoning by other opioids, undetermined, initial encounter
T40.3X1A	Poisoning by methadone, accidental (unintentional), initial encounter
T40.3X2A	Poisoning by methadone, intentional self-harm, initial encounter
T40.3X3A	Poisoning by methadone, assault, initial encounter
T40.3X4A	Poisoning by methadone, undetermined, initial encounter
T40.4X1A	Poisoning by other synthetic narcotics, accidental (unintentional), initial encounter
T40.4X2A	Poisoning by other synthetic narcotics, intentional self-harm, initial encounter
T40.4X3A	Poisoning by other synthetic narcotics, assault, initial encounter
T40.4X4A	Poisoning by other synthetic narcotics, undetermined, initial encounter
T40.601A	Poisoning by unspecified narcotics, accidental (unintentional), initial encounter
T40.602A	Poisoning by unspecified narcotics, intentional self-harm, initial encounter
T40.603A	Poisoning by unspecified narcotics, assault, initial encounter
T40.604A	Poisoning by unspecified narcotics, undetermined, initial encounter
T40.691A	Poisoning by other narcotics, accidental (unintentional), initial encounter
T40.692A	Poisoning by other narcotics, intentional self-harm, initial encounter
T40.693A	Poisoning by other narcotics, assault, initial encounter
T40.694A	Poisoning by other narcotics, undetermined, initial encounter
T40.7X1A	Poisoning by cannabis (derivatives), accidental (unintentional), initial encounter
T40.7X2A	Poisoning by cannabis (derivatives), intentional self-harm, initial encounter
T40.7X3A	Poisoning by cannabis (derivatives), assault, initial encounter
T40.7X4A	Poisoning by cannabis (derivatives), undetermined, initial encounter
T40.8X1A	Poisoning by lysergide [LSD], accidental (unintentional), initial encounter
T40.8X2A	Poisoning by lysergide [LSD], intentional self-harm, initial encounter
T40.8X3A	Poisoning by lysergide [LSD], assault, initial encounter
T40.8X4A	Poisoning by lysergide [LSD], undetermined, initial encounter
T40.901A	Poisoning by unspecified psychodysleptics [hallucinogens], accidental (unintentional), initial encounter
T40.902A	Poisoning by unspecified psychodysleptics [hallucinogens], intentional self-harm, initial encounter
T40.903A	Poisoning by unspecified psychodysleptics [hallucinogens], assault, initial encounter
T40.904A	Poisoning by unspecified psychodysleptics [hallucinogens], undetermined, initial encounter
T40.991A	Poisoning by other psychodysleptics [hallucinogens], accidental (unintentional), initial encounter
T40.992A	Poisoning by other psychodysleptics [hallucinogens], intentional self-harm, initial encounter

ICD-10 Codes	Description
T40.993A	Poisoning by other psychodysleptics [hallucinogens], assault, initial encounter
T40.994A	Poisoning by other psychodysleptics [hallucinogens], undetermined, initial encounter
T42.0X1A	Poisoning by hydantoin derivatives, accidental (unintentional), initial encounter
T42.0X2A	Poisoning by hydantoin derivatives, intentional self-harm, initial encounter
T42.0X3A	Poisoning by hydantoin derivatives, assault, initial encounter
T42.0X4A	Poisoning by hydantoin derivatives, undetermined, initial encounter
T42.3X1A	Poisoning by barbiturates, accidental (unintentional), initial encounter
T42.3X2A	Poisoning by barbiturates, intentional self-harm, initial encounter
T42.3X3A	Poisoning by barbiturates, assault, initial encounter
T42.3X4A	Poisoning by barbiturates, undetermined, initial encounter
T42.4X1A	Poisoning by benzodiazepines, accidental (unintentional), initial encounter
T42.4X2A	Poisoning by benzodiazepines, intentional self-harm, initial encounter
T42.4X3A	Poisoning by benzodiazepines, assault, initial encounter
T42.4X4A	Poisoning by benzodiazepines, undetermined, initial encounter
T42.6X1A	Poisoning by other antiepileptic and sedative-hypnotic drugs, accidental (unintentional), initial encounter
T42.6X2A	Poisoning by other antiepileptic and sedative-hypnotic drugs, intentional self-harm, initial encounter
T42.6X3A	Poisoning by other antiepileptic and sedative-hypnotic drugs, assault, initial encounter
T42.6X4A	Poisoning by other antiepileptic and sedative-hypnotic drugs, undetermined, initial encounter
T42.71XA	Poisoning by unspecified antiepileptic and sedative-hypnotic drugs, accidental (unintentional), initial encounter
T42.72XA	Poisoning by unspecified antiepileptic and sedative-hypnotic drugs, intentional self-harm, initial encounter
T42.73XA	Poisoning by unspecified antiepileptic and sedative-hypnotic drugs, assault, initial encounter
T42.74XA	Poisoning by unspecified antiepileptic and sedative-hypnotic drugs, undetermined, initial encounter
T43.011A	Poisoning by tricyclic antidepressants, accidental (unintentional), initial encounter
T43.012A	Poisoning by tricyclic antidepressants, intentional self-harm, initial encounter
T43.013A	Poisoning by tricyclic antidepressants, assault, initial encounter
T43.014A	Poisoning by tricyclic antidepressants, undetermined, initial encounter
T43.021A	Poisoning by tetracyclic antidepressants, accidental (unintentional), initial encounter
T43.022A	Poisoning by tetracyclic antidepressants, intentional self-harm, initial encounter
T43.023A	Poisoning by tetracyclic antidepressants, assault, initial encounter
T43.024A	Poisoning by tetracyclic antidepressants, undetermined, initial encounter
T43.1X1A	Poisoning by monoamine-oxidase-inhibitor antidepressants, accidental (unintentional), initial encounter
T43.1X2A	Poisoning by monoamine-oxidase-inhibitor antidepressants, intentional self-harm, initial encounter
T43.1X3A	Poisoning by monoamine-oxidase-inhibitor antidepressants, assault, initial encounter
T43.1X4A	Poisoning by monoamine-oxidase-inhibitor antidepressants, undetermined, initial encounter
T43.201A	Poisoning by unspecified antidepressants, accidental (unintentional), initial encounter
T43.202A	Poisoning by unspecified antidepressants, intentional self-harm, initial encounter
T43.203A	Poisoning by unspecified antidepressants, assault, initial encounter
T43.204A	Poisoning by unspecified antidepressants, undetermined, initial encounter
T43.211A	Poisoning by selective serotonin and norepinephrine reuptake inhibitors, accidental (unintentional), initial encounter
T43.212A	Poisoning by selective serotonin and norepinephrine reuptake inhibitors, intentional self-harm, initial encounter
T43.213A	Poisoning by selective serotonin and norepinephrine reuptake inhibitors, assault, initial encounter
T43.214A	Poisoning by selective serotonin and norepinephrine reuptake inhibitors, undetermined, initial encounter
T43.221A	Poisoning by selective serotonin reuptake inhibitors, accidental (unintentional), initial encounter
T43.222A	Poisoning by selective serotonin reuptake inhibitors, intentional self-harm, initial encounter
T43.223A	Poisoning by selective serotonin reuptake inhibitors, assault, initial encounter
T43.224A	Poisoning by selective serotonin reuptake inhibitors, undetermined, initial encounter
T43.291A	Poisoning by other antidepressants, accidental (unintentional), initial encounter
T43.292A	Poisoning by other antidepressants, intentional self-harm, initial encounter
T43.293A	Poisoning by other antidepressants, assault, initial encounter
T43.294A	Poisoning by other antidepressants, undetermined, initial encounter

ICD-10 Codes	Description
T43.3X1A	Poisoning by phenothiazine antipsychotics and neuroleptics, accidental (unintentional), initial encounter
T43.3X2A	Poisoning by phenothiazine antipsychotics and neuroleptics, intentional self-harm, initial encounter
T43.3X3A	Poisoning by phenothiazine antipsychotics and neuroleptics, assault, initial encounter
T43.3X4A	Poisoning by phenothiazine antipsychotics and neuroleptics, undetermined, initial encounter
T43.4X1A	Poisoning by butyrophenone and thiothixene neuroleptics, accidental (unintentional), initial encounter
T43.4X2A	Poisoning by butyrophenone and thiothixene neuroleptics, intentional self-harm, initial encounter
T43.4X3A	Poisoning by butyrophenone and thiothixene neuroleptics, assault, initial encounter
T43.4X4A	Poisoning by butyrophenone and thiothixene neuroleptics, undetermined, initial encounter
T43.501A	Poisoning by unspecified antipsychotics and neuroleptics, accidental (unintentional), initial encounter
T43.502A	Poisoning by unspecified antipsychotics and neuroleptics, intentional self-harm, initial encounter
T43.503A	Poisoning by unspecified antipsychotics and neuroleptics, assault, initial encounter
T43.504A	Poisoning by unspecified antipsychotics and neuroleptics, undetermined, initial encounter
T43.591A	Poisoning by other antipsychotics and neuroleptics, accidental (unintentional), initial encounter
T43.592A	Poisoning by other antipsychotics and neuroleptics, intentional self-harm, initial encounter
T43.593A	Poisoning by other antipsychotics and neuroleptics, assault, initial encounter
T43.594A	Poisoning by other antipsychotics and neuroleptics, undetermined, initial encounter
T43.601A	Poisoning by unspecified psychostimulants, accidental (unintentional), initial encounter
T43.602A	Poisoning by unspecified psychostimulants, intentional self-harm, initial encounter
T43.603A	Poisoning by unspecified psychostimulants, assault, initial encounter
T43.604A	Poisoning by unspecified psychostimulants, undetermined, initial encounter
T43.611A	Poisoning by caffeine, accidental (unintentional), initial encounter
T43.612A	Poisoning by caffeine, intentional self-harm, initial encounter
T43.613A	Poisoning by caffeine, assault, initial encounter
T43.614A	Poisoning by caffeine, undetermined, initial encounter
T43.621A	Poisoning by amphetamines, accidental (unintentional), initial encounter
T43.622A	Poisoning by amphetamines, intentional self-harm, initial encounter
T43.623A	Poisoning by amphetamines, assault, initial encounter
T43.624A	Poisoning by amphetamines, undetermined, initial encounter
T43.631A	Poisoning by methylphenidate, accidental (unintentional), initial encounter
T43.632A	Poisoning by methylphenidate, intentional self-harm, initial encounter
T43.633A	Poisoning by methylphenidate, assault, initial encounter
T43.634A	Poisoning by methylphenidate, undetermined, initial encounter
T43.691A	Poisoning by other psychostimulants, accidental (unintentional), initial encounter
T43.692A	Poisoning by other psychostimulants, intentional self-harm, initial encounter
T43.693A	Poisoning by other psychostimulants, assault, initial encounter
T43.694A	Poisoning by other psychostimulants, undetermined, initial encounter
T43.8X1A	Poisoning by other psychotropic drugs, accidental (unintentional), initial encounter
T43.8X2A	Poisoning by other psychotropic drugs, intentional self-harm, initial encounter
T43.8X3A	Poisoning by other psychotropic drugs, assault, initial encounter
T43.8X4A	Poisoning by other psychotropic drugs, undetermined, initial encounter
T43.91XA	Poisoning by unspecified psychotropic drug, accidental (unintentional), initial encounter
T43.92XA	Poisoning by unspecified psychotropic drug, intentional self-harm, initial encounter
T43.93XA	Poisoning by unspecified psychotropic drug, assault, initial encounter
T43.94XA	Poisoning by unspecified psychotropic drug, undetermined, initial encounter
T45.0X1A	Poisoning by antiallergic and antiemetic drugs, accidental (unintentional), initial encounter
T45.0X2A	Poisoning by antiallergic and antiemetic drugs, intentional self-harm, initial encounter
T45.0X3A	Poisoning by antiallergic and antiemetic drugs, assault, initial encounter
T45.0X4A	Poisoning by antiallergic and antiemetic drugs, undetermined, initial encounter
T46.0X1A	Poisoning by cardiac-stimulant glycosides and drugs of similar action, accidental (unintentional), initial encounter
T46.0X2A	Poisoning by cardiac-stimulant glycosides and drugs of similar action, intentional self-harm, initial encounter
T46.0X3A	Poisoning by cardiac-stimulant glycosides and drugs of similar action, assault, initial encounter
T46.0X4A	Poisoning by cardiac-stimulant glycosides and drugs of similar action, undetermined, initial encounter

ICD-10 Codes	Description
T50.901A	Poisoning by unspecified drugs, medicaments and biological substances, accidental (unintentional), initial encounter
T50.902A	Poisoning by unspecified drugs, medicaments and biological substances, intentional self-harm, initial encounter
T50.903A	Poisoning by unspecified drugs, medicaments and biological substances, assault, initial encounter
T50.904A	Poisoning by unspecified drugs, medicaments and biological substances, undetermined, initial encounter
Z51.81	Encounter for therapeutic drug level monitoring
Z79.3	Long term (current) use of hormonal contraceptives
Z79.891	Long term (current) use of opiate analgesic
Z79.899	Other long term (current) drug therapy

ICD-10 Codes that DO NOT Support Medical Necessity N/A
ICD-10 Additional Information Back to Top

General Information

Associated Information

N/A

Sources of Information

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Bibliography

N/A

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
10/01/2017	R9	R10 Revision Effective: 10/01/2017 Revision Explanation: Added F10.11, F11.11, F12.11, F13.11, f14.11, F15.11, F16.11, F18.11, F19.11 to ICD-10 codes that support medical necessity. Also corrected formatting. 10/26/2017:*At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.*	• Revisions Due To ICD-10-CM Code Changes
08/17/2017	R8	R9 Revision Effective: 08/17/2017 Revision Explanation: Added R41.82, R45.850, and R45.851 to ICD-10 codes that support medical necessity. Also corrected formatting.	• Reconsideration Request

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
		08/10/2017:*At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.*	
01/01/2017	R8	R8 Revision Effective N/A Revision Explanation: Annual review no changes made	
01/01/2017	R7	R7 Revision Effective: 01/01/2017 Revision Explanation: Database was updated to accept G0659 in the group list of codes. Added to the list and removed from the paragraph section above the list in group one.	• Revisions Due To CPT/HCPCS Code Changes
01/01/2017	R6	R6 Revision Effective: 01/01/2017 Revision Explanation: Added new codes for 2017 80305, 80306, 80307, and G6059. At this time G6059 is not accepted by the system even though it is a valid code Once added to the system G6059 will be moved from group 1 paragraph and added to the list. Codes G0477, G4078, and G4079 were deleted and are not effective after 12/31/2016.	• Revisions Due To CPT/HCPCS Code Changes
01/01/2016	R5	R5 Revision Effective N/A Revision Explanation: Annual review no changes made.	• Other (Annual Review)
01/01/2016	R4	R4 Revision Effective 01/01/2016 Revision Explanation: added new codes in HCPCS/CPT section and removed from paragraph	• Revisions Due To CPT/HCPCS Code Changes
01/01/2016	R3	R3 Revision Effective 01/01/2016 Revision Explanation: Added new HCPCS codes that will replace all old codes for 2016.	• Revisions Due To CPT/HCPCS Code Changes
01/01/2016	R2	R2 Revision Effective 01/01/2016 Revision Explanation: Added new coding and billing article for 2016 dates of service and updated the old one to show for dates of service prior to 01/01/2016.	• Revisions Due To CPT/HCPCS Code Changes
10/05/2015	R1	R1 Revision Effective 10/05/2015 Revision Explanation: Indications and Limitations section had some clarifying language added based on comments received.	• Provider Education/Guidance

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Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A54314 - Controlled Substance Monitoring and Drugs of Abuse Coding and Billing Guidelines A54315 - (MCD Archive Site) LCD(s) DL36029 - (MCD Archive Site)

Related National Coverage Documents N/A

Public Version(s) Updated on 07/02/2018 with effective dates 10/01/2017 - N/A Updated on 04/04/2018 with effective dates 10/01/2017 - N/A Updated on 10/26/2017 with effective dates 10/01/2017 - N/A Updated on 08/10/2017 with effective dates 08/17/2017 - 09/30/2017 Updated on 03/24/2017 with effective dates

Keywords

N/A Read the **LCD Disclaimer** Back to Top