Quantitative Drug Testing

LCD ID L35920

Jurisdiction
Tennessee

Original Effective Date
For services performed on or after 10/01/2015

LCD Title
Pathology and Laboratory: Quantitative Drug Testing

CMS National Coverage Policy

- CMS On-Line Manual, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, §§80.0, 80.1.1, 80.2. Clinical Laboratory services.
- 42 CFR 410.32(a). Order diagnostic tests.
- 42 CFR 411.15(k)(1). Particular Services excluded from coverage.
- NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.
- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) allows coverage and payment for services considered medically reasonable and necessary.
- Title XVIII of the Social Security Act, Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Background:

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.

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.

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.

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.

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.

Definitive Urine Drug Testing (UDT): Gas Chromatography coupled with Mass Spectrometry (GC-MS) and High Performance Liquid Chromatography coupled with Tandem Mass Spectrometry (LC-MS/MS) use the separation capabilities of gaseous or liquid chromatography with the analytical capabilities of mass spectrometry. Both methodologies require on-site highly trained experts in this technology and interpretation of results. While these tests require different sample preparation and analytical runs, they 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.

GC-MS can only be performed on molecules that are volatile. If the test drug is not volatile, 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 use tandem systems. GC-MS methodology allows for the testing of multiple substances but differs in ease of run.

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 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 are identified by their retention time and mass spectrum of each peak, and quantified against isotopic internal standards for each drug and metabolite. Each drug peak has a minimum of two mass transitions, which the technician has to compare to drug standards (calibrators) in order to ensure identification.

Indications

Definitive UDT is reasonable and necessary for the following circumstances:

1.   Identify a specific substance or metabolite that is inadequately detected by a presumptive UDT screen;

2.   Definitively identify specific drugs in a large family of drugs;

3.	Identify a specific substance or metabolite that is not detected by presumptive UDT such as fentanyl, meperidine, synthetic cannabinoids and other synthetic/analog drugs;

4.	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);

5.	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;

6.	Rule out an error as the cause of an unexpected presumptive UDT result; Identify non-prescribed medication or illicit use for ongoing safe prescribing of controlled substances; and

7.	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 rational for the definitive UDT and the tests ordered must be documented in the patient's medical record.
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. Some labs offer comprehensive definitive drug testing panel (CDDP) of 40 or more drugs It is not reasonable and necessary to bill individual billing codes for this comprehensive testing.

Limitations

The following are non-covered services:

1.	Blanket Orders

2.	Reflex definitive UDT is not be reasonable and necessary when presumptive testing is performed at point of care because the physician may not need to order definitive testing (e.g., the patient admits to a particular drug and the clinician is satisfied that he or she knows everything he or she needs to know, or the IA cut-off is sufficiently low that the physician is comfortable with the test result).

3.	Routine standing orders for all patients in a physician's practice are not reasonable and necessary. Physician-defined standing orders for pre-determined drug panels according to specific patient profiles for a limited sequential period may be reasonable and necessary and must be documented in the patient's medical record.

4.	Individual definitive CPT codes when a CDDP is ordered

5.	Confirmation/definitive identification of a presumptive UDT negative result is not reasonable and necessary except when a patient on a prescribed medication should have had a presumptive positive result.

6.	IA testing, regardless of whether it is qualitative or semi-quantitative, may not be used to "confirm" or definitively identify a presumptive test result obtained by cups, dipsticks, cards, cassettes or other CLIA-waived methods. Semi-quantitative IA testing provides a presumptive test (numerical) result. Definitive UDT provides specific identification and/or quantification by GC-MS or LC-MS/MS.

7.	Drug testing of two different specimen types from the same patient on the same date of service for the same drugs/metabolites/analytes.

8.	UDT for medico-legal and/or employment purposes or to protect a physician from drug diversion charges.

9.	Specimen validity testing including, but not limited to, pH, specific gravity, oxidants, creatinine.

10.	CDDP panels are non-covered.

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: N/A
Group 1 Codes:

80159	CLOZAPINE
80171	GABAPENTIN, WHOLE BLOOD, SERUM, OR PLASMA
80173	HALOPERIDOL
80183	OXCARBAZEPINE
80184	PHENOBARBITAL
83789	MASS SPECTROMETRY AND TANDEM MASS SPECTROMETRY (MS, MS/MS), ANALYTE NOT ELSEWHERE SPECIFIED; QUANTITATIVE, EACH SPECIMEN
83992	PHENCYCLIDINE (PCP)
84999	UNLISTED CHEMISTRY PROCEDURE
G6030 - G6034	AMITRIPTYLINE - DOXEPIN
G6036	ASSAY OF IMIPRAMINE
G6037	NORTRIPTYLINE
G6040 - G6046	ALCOHOL (ETHANOL); ANY SPECIMEN EXCEPT BREATH - DIHYDROMORPHINONE
G6048	DIMETHADIONE
G6051 - G6054	FLURAZEPAM - METHSUXIMIDE
G6056	OPIATE(S), DRUG AND METABOLITES, EACH PROCEDURE
G6057	PHENOTHIAZINE

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: NA
There are numerous reasonable and necessary conditions that might warrant the use of these procedures but which are too many to list. However, an appropriate ICD-10-CM diagnosis must be submitted with each claim and failure to do so may result in denial or delay in claim processing.

ICD-10 codes must be coded to the highest level of specificity. Consult the 'Official ICD-10-CM Guidelines for Coding and Reporting' in the current ICD-10-CM book for correct coding guidelines. This LCD does not take precedence over the Correct Coding Initiative (CCI).

FUTURE

Group 1 Codes:

Group 1Codes	
ICD-10 CODE	**DESCRIPTION**
XX000	Not Applicable

Showing 1 to 1 of 1 entries in Group 1

Associated Information
Documentation Requirements

Documentation must support CMS 'signature guidelines, as described in the Medicare Program Integrity Manual (Pub. 100-08), Chapter 3.

Utilization Guidelines

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.

1.   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.

2.   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.

3.   For patients with > 90 day of consecutive abstinence, definitive UDT is expected at a frequency of 1-3 physician-directed testing profiles in one month. More than 3 definitive UDT in 3 months is not reasonable and necessary and is not covered by Medicare.

Sources of Information and Basis for Decision

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  - Nafziger AN, Bertino JS. Utility and application of urine drug testing in chronic pain management with opioids. Clin J Pain 2009;25(1)73-79.

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Please note: Most Revision History entries effective on or before 01/24/2013 display with a Revision History Number of "R1" at the bottom of this table. However, there may be LCDs where these entries will display as a separate and distinct row.

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
10/15/2015	R2	**What's New Posted Date: July, 2015** **Effective Date: October 1, 2015** This LCD has been updated. The 'Limitations' section is being updated to remove Limitation #5 which states: *'Direct to Definitive UDT without presumptive positive UDT – is not reasonable and necessary because this practice encourages excessive and unnecessary testing'.*	Other (This LCD has been updated. The 'Limitations' section is being updated to remove Limitation #5 which states: *'Direct to Definitive UDT without presumptive positive UDT – is not reasonable and necessary because this practice encourages excessive and unnecessary testing'.*)
10/15/2015	R1	Correction to link the Sources of Information and Basis for Decision section.	Typographical Error

Local Coverage Determination (LCD) Disclaimer

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