Skip to Main Content

Main Menu

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Back to Local Coverage Proposed/Draft LCD Status Report Results

Local Coverage Determination (LCD): Controlled Substance Monitoring and Drugs of Abuse Testing (DL35105)

[PROPOSED/DRAFT]

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Proposed/Draft LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Proposed/Draft LCDs are not necessarily a reflection of the current policies or practices of the contractor.

- Contractor Information

Contractor Name	Contract Number	Contract Type
Palmetto GBA	11502	MAC - Part B

- Proposed/Draft LCD Information

Document Information

[PROPOSED/DRAFT]

Source LCD ID
N/A

Proposed LCD ID
DL35105

Proposed LCD Title
Controlled Substance Monitoring and Drugs of Abuse Testing

Jurisdiction
North Carolina

AMA CPT/ADA CDT Copyright Statement

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

This policy provides an overview of distinctions between qualitative, confirmation and quantitative drugs of abuse testing, and indicates that coverage is dependent on proper documentation of clinical decision-making and test orders that are tailored to the individual patient's medical needs. This policy addresses drugs of abuse testing for Medicare patients. It does not address neonatal testing for suspected prenatal drug exposure.

Drugs of Abuse testing may be useful in the clinical setting because it may provide objective information to assist the provider in diagnosing and making treatment decisions. Clinicians use qualitative and quantitative drugs of abuse testing to look for the presence (or absence) of drugs in the body. In general, drug testing can be helpful in the medical disciplines of emergency medical care for drug-drug interactions and drug overdose, addiction medicine and the medical management of patients using chronic opioid therapy (COT).

By way of definition and as used in this document, the following terminology relates to the basic forms of drugs of abuse testing:

Term	General Purpose in Clinical Drugs of Abuse Testing
Qualitative Drug Testing	Used to determine the presence or absence of drug or drug metabolite (drug class) in the sample. The test result may be expressed as negative or positive (non-numerical) or as a semi-quantitative result.

Quantitative Drug Testing	Used when it is medically necessary to determine the specific quantity of drug or drug metabolite present in the sample. The test result is expressed in concentration. Medicare considers this definitive testing.
Confirmation Testing	Used to confirm the presence of illicit drug(s) following an initial, presumptive positive, screening result. This confirmation prevents a clinician from relying on a false positive result.

Specific Test Methods

Clinical laboratories use a variety of test methods to perform qualitative drug analysis, including enzyme immunoassays (EIA and IA), thin-layer chromatography, and spectrometry. Point of care (POC) testing in physician office labs (POL) consists of CLIA-waived tests and bench-top chemistry analysis.

1. **CLIA-waived Drug Screening Tests:**

   CLIA-waived drug screening tests consist of cards, dipsticks, cassettes and cups based on qualitative competitive immunoassay methodology with one or more analytes in the test.

2. **Qualitative Drug Testing by FDA Approved/Cleared Immunoassay Analysis:**

   Most bench top chemistry analyzers with drugs of abuse screening immunoassays are classified as moderately complex test systems. The test platform and the reagents are FDA approved/cleared.

   A screening immunoassay detects the amount of drug present in urine above a predetermined “cut-off” value. Positive test results are reported when the concentration of drugs is above the cutoff. If the concentration of the drug is below the cut-off, the result will be negative. Positive test results are presumptive/not definitive due to sensitivity and cross-reactivity limitations.

   Drug screening by EIA and IA is limited due to the following reasons:

   - Screens for drug classes rather than specific drugs;
   - Unable to provide information on many specialty/designer drugs; and
   - May produce false positives, cross-react with other compounds, or miss a drug within a class of drugs.

   Because screening methods are unable to identify specific drugs within many drug classes, particularly within the amphetamine, barbiturate, benzodiazepine, and opiate/opioid drug classes, confirmatory testing may be medically reasonable and necessary within the confines of the clinical criteria and coverage indications set forth in this policy.

   Bench top analyzers may NOT be used to “confirm” results obtained by cups, dipsticks, cards and/or cassettes. Although bench top analyzers can provide semi-quantitative results (numerical results), the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (53 CFR 11979) mandates that a different technique must be used as stated in the following excerpt: A second analytical procedure to identify the presence of a specific drug or metabolite, which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. In other words, initial drug screening and any subsequent confirmatory procedures must be carried out by two separate

techniques employing different chemical principles (e.g. immunoassay followed by a chromatographic-mass spectral method).

3. **Qualitative Drug Testing by Laboratory Developed Test (LDT) Immunoassay Analysis:**

Subject to appropriate internal quality control and test validation, an immunoassay performed on a bench top chemistry analyzer becomes a high complexity test in the following two situations:

1. Test Assay Not Classified: Per CFR 493.17(c)(4), if a laboratory test system, assay and examination does not appear on the list of tests in the Federal Register notices, it is considered a test of high complexity until Public Health Service (PHS) reviews the matter and notifies the applicant of its decision. Examples of current tests that fall into this category are listed below:
    - Extended opioids such as fentanyl, meperidine, tramadol and tapentadol,
    - Muscle relaxants such as carisoprodol and meprobamate
    - Stimulants such as methylpenidate,
    - Sleep aids such as zolpidem
2. Lowering Cutoff for Detection: Modified FDA approved/cleared test platforms and/or reagents are considered laboratory developed tests (LDTs). Drug testing platforms and/or reagents that are not FDA approved/cleared are also considered LDTs. LDTs have presumably been modified to test at a lower cutoff in order to detect substances that would have been missed at a higher threshold. 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

Urine drug screening can be carried out at any validated cut-off concentration. Lowering of the cut-off concentration provides more stringent cutoffs for illicit drugs and compensates for cross reactivity differences. Additionally, urine drug screening panels have more flexibility as they can include non-FDA cleared tests (e.g. tramadol, tapentadol, carisoprodol, fentanyl, zolpidem, etc). It also allows the physician greater choice to select from panels of illicit and prescription medications.

High complexity laboratories must ensure that testing is carried out by qualified, trained personnel using validated, reliable methods compliant with regulatory procedures (42 CFR Part 493). This includes but is not limited to the following requirements:

- extensive initial training and continual monitoring
- compliance with regulations
- qualifications and experience of the laboratory director and staff
- regular monitoring of compliance
- staff training in the use and maintenance of equipment
- standard operating procedures

The laboratory director must demonstrate oversight and review of all lab functions, to include

quality assurance (QA) and quality control (QC), proficiency testing, initial training and retraining of technicians, accreditation documents, licenses and all day to day activities per CLIA requirements at the site of testing. It is not reasonable and necessary for a central facility to perform QC or proficiency testing and provide the information to physician office labs. Each physician's office lab must perform QC and proficiency testing on site.

A high complexity laboratory must maintain validation data for each assay that demonstrates accuracy and imprecision, sensitivity and specificity, carryover and interference, and method comparison. There must be a quality assurance (QA) policy and proof of commercially available proficiency testing being performed per CLIA requirements for each analyte assay where available. Machine QC records per run must be maintained for a minimum of 5 years. Manual QC logs are not acceptable.

4. **Confirmatory/Quantitative Drug Testing by LC-MS/MS or GC-MS (CPT code 80102 and the CPT Specific Drug/Methodology Code:**

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 and require the competency of highly trained experts in this technology and interpretation of results. Both GC-MS and LC-MS/MS techniques identify the presence of test molecules by detecting predetermined ion masses.

- **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 to a volatile form. This modification is termed derivitization. To derivitize, 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 derivitizing 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.

- **LC-MS/MS**

  Relying on a process of hydrolysis, LC-MS/MS is roughly 100 times more sensitive and selective than GC-MS. In a toxicology laboratory sample preparation often requires 4-6 hours prior to injection of the sample 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 prior to sample preparation 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.

  Different sample preparation and analytical runs may be required for multiple drugs and drug metabolites. For example, THC metabolite may need different hydrolyses and a different mode than opiates. K2/Spice compounds require higher sensitivity instruments. If a patient specimen requires identification of multiple drugs or metabolites, multiple profiles may be performed on different instruments. One profile may take 4 to 10 min.

  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. A minimum of 1-2 years of training is necessary before a technician is capable of interpreting MS data.

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 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 42CFR Part 493.1489 (Testing Personnel Qualifications). A GC-MS or LC-MS/MS laboratory must have a qualified laboratory director as provided in 42 CFR 493.1443 (Laboratory Director Qualifications).

In summary, confirmatory and quantitative testing by LC-MS/MS or GC-MS provide the following:

- Quantitative concentrations (e.g., ng/mL) of specific substances or their metabolites in the specimen;
- Definitive results with high specificity and sensitivity;
- Identification of specific drugs within drug classes

Drug Test Panels

The American Medical Association (AMA) has not assigned a code to report a “panel” for drugs of abuse testing. Because no single drug panel is suitable for all clinical uses, drug testing must be patient-specific and documented in the medical record.

1. **Physician-directed test panel(s):**

   Physician directed drug confirmation panel(s) are not reasonable and necessary. Every ordered test must be based on the elements identified and documented in the clinical assessment.

2. **Reference laboratory-directed panel(s):**

   A reference laboratory test requisition form must include the following items:

   - list individual drugs and/or drug classes
   - provide a physician reporting area for the following:
     - positive and negative qualitative office testing results
     - all prescribed medication

Medicare has determined that laboratory-created drug panels are not reasonable and necessary and will be denied because they prevent the ordering physician from making patient-specific test selection.

The ordering physician must maintain documentation of medical necessity for each ordered drug test.

Specimen Type

Urine or oral fluid is the preferred biologic specimen for testing because of the ease of collection, storage, and cost-effectiveness. Urine drug testing cannot detect the amount 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. Oral fluid testing has comparable drug detection patterns as compared with urine. Oral fluid provides a better reflection of plasma drug levels and a better indication of dosages and dose timing. Collection is easily witnessed with minimal invasiveness, which minimizes the possibility of substitution, dilution or adulteration. Immunoassay testing is available for all the illicit drugs in oral fluid.

Medicare will only reimburse one specimen type per patient per day.

Parent Drugs and Metabolite

Based on the patient-specific treatment, clinicians must select and order the specific drug(s) for testing. The rationale for this selection must be documented and available upon request in the patient record. Routine testing or nonspecific panel testing for all of the drugs/drug classes listed in the chart below is not considered reasonable and necessary and will be denied.

Although ethanol is a significant drug of abuse, testing is performed by serum and not urine. Alcohol metabolites, ethyl glucuronide and ethyl sulfate, are detected through LC-MS/MS.

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	Amytal Sodium®	Amobarbital
Butabarbital	Butisol Sodium®, Butibel	Butabarbital
Butalbital	Fiorinal®, Fioricet®	Butalbital
Pentobarbital	Nembutal®	Pentobarbital
Phenobarbital	Belladona, Luminal®	Phenobarbital
Secobarbital	Seconal®	Secobarbital

Benzodiazepines Alprazolam Chlordiazepoxide Clonazepam Clorazepate Diazepam Lorazepam Oxazepam Temazepam	Xanax®, Niravam®, Xanor Librax®, Libritabs Klonopin® Tranxene® Valium® Ativan®, Lorax Adumbran, Alepam, Murelax, Serax, Serepax Restoril®, 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®, Eldepryl®, 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	
Muscle Relaxants Carisoprodol Meprobamate	Soma®, Soprodoal Equinal, Miltown®, Meprospan	Carisoprodol, Meprobamate Meprobamate

Neuroleptics Gabapentin Pregabalin	 Neurontin® Lyrica®	
Opiates Codeine Hydrocodone Hydromorphone Morphine Oxycodone Oxymorphone	Tylenol® 3 Hycodan®, Lorcet®, Lortab®, Norco® Vicodin®, Vicoprofen® Dilaudid®, Exalgo®, Hymorphan Avinza®, Kadian®, MS Contin®, MSER, MSIR, Roxanol OxyContin®, OxyIR®, Percocet®, Percodan®, Roxicodone®, Tylox® Numorphan®, Opana® ER, Opana®	Codeine, Morphine Hydrocodone, Hydromorphone, Norhydrocodone Hydromorphone Morphine Oxycodone, Oxymorphone, Noroxycodone Oxymorphone
Opioids Buprenorphine Fentanyl Meperidine Methadone Propoxyphene Tapentadol Tramadol	Buprenex®, Butrans®, Suboxone®, Subutex® Actiq®, Duragesic®, Fentora®, Onsolis® Sublimaze Demerol®, Mepergan® Dolophine®, Methadose® Darvocet®, Darvon® Nucynta® Ryzolt®, Ultracet®, Ultram®, Tramadol	Buprenorphine, Norbuprenorphine Fentanyl, Norfentanyl Meperidine, Normeperidine Methadone, EDDP Propoxyphene, Norpropoxyphene Tapentadol, N-Desmethyltapentadol Tramadol, O-Desmethyltramadol
Stimulants Amphetamine Methylphenidate Nicotine	Adderall®, Benzedrine, Dexedrine®, Vyvanse® Concerta®, Focalin®, Methylin®, Ritalin® Nicoderm®, Nicorette®	Amphetamine Methylphenidate, Ritalinic Acid Cotinine

Parent Drugs and Metabolite Chart Abbreviations: 6-MAM= 6-monoacetylmorphine; **EDDP=**

2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine; **MDA=** methylenedioxyamphetamine; **MDMA=** methylenedioxymethamphetamine; **THC-COOH** = 11-nor-9-carboxy-delta-9-tetrahydrocannabinol

Covered Indications

Group A – Symptomatic patients, multiple drug ingestion and/or unreliable history

A qualitative drug screen should be performed as part of the evaluation and treatment of a patient who presents in an urgent care setting with any one of the following:

- Unexplained coma
- Unexplained 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;

Group B - Monitoring patient adherence and compliance during active treatment for substance abuse or dependence

Laboratory testing for drugs of abuse is a medically necessary and useful component of chemical dependency treatment. The drug screen result influences treatment and level of care decisions. Ordered tests must match treatment needs, the documented history and Diagnostic and Statistical Manual of Mental Disorders (DSM IV TR) or most current DSM diagnosis.

The clinician should test for a broad range of commonly abused drugs to screen a patient for substance use disorders. Decisions about screened substances must be documented, and based on the following criteria:

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

“Designer drugs” manufactured specifically to elude law enforcement require confirmatory testing for detection. Most commercially available POCT immunoassays fail to detect designer drugs, such as psychedelic phenethylamines, even at very high concentrations.

Criteria for Testing	• Patient evaluated by a licensed clinician • Ordered tests within the scope of ordering clinician’s

	authority • Rationale for order of each drug/drug class substantiated in medical record • Test results used in patient management and documented in treatment plan
Qualitative Screening Indications	A new patient screening immunoassay with confirmation or quantitative testing typically involves the following drugs/drug classes: • Alcohol/Ethanol – not part of a qualitative urine drug screen; alcohol testing is not performed by immunoassay • Amphetamines/Methamphetamine/MDMA (AMP, MAMP, MDMA) • Barbiturates (BAR) • Benzodiazepines (BZO) • Cannabinoids (THC) • Cocaine (COC without BE or CE) • Methadone (MTD) • Opiates (OPI) • Oxycodone (OXY) Depending on the patient's specific history regarding substances abused, confirmation/quantitation, specialty screening or direct to quantitative analysis for expanded benzodiazepines and opioid panels to determine the specific drugs in the patient's system may be necessary. Coverage depends upon the documentation of this history and rationale for such test orders. Ongoing patient monitoring with a qualitative screening immunoassay without confirmation or quantitative testing is typically sufficient in this patient population. Confirmation/quantitative testing or specialty testing may be necessary but requires specific documentation to substantiate testing. • Post initial facility admission, qualitative screenings are expected and may be approved at a frequency not to exceed three (3) every thirty (30) days. • Qualitative screening at a frequency greater than three (3) times in thirty (30) days requires rationale documented in medical record and must meet medical

	necessity. • Qualitative testing must be ordered in order to rapidly integrate treatment decisions and clinical assessment.
Specimen Validity Testing	Specimen validity testing (SVT), consisting of pH, specific gravity, oxidants, creatinine, or other test, is considered to be a quality measure and is statutorily excluded from the Medicare Benefit. Testing by GC-MS or LC-MS technology is not affected by adulterants and/or dilution.
Confirmation/Quantitative and Specialty Testing	All orders for confirmation/quantitation testing require a positive qualitative screening test and shall be performed only for the drug class represented by the positive qualitative screening. “Designer drugs”, not identified by POC immunoassays, require confirmatory testing for detection. • Documentation of medical necessity for quantitative testing is required in the medical record. • Quantitative testing exceeding three (3) procedure codes or drug classes every thirty (30) days requires rationale documented in the medical record and must meet medical necessity.

Group C - Chronic pain management drug testing for patients on chronic opioid therapy (COT).

Testing for drugs of abuse to monitor treatment compliance must be included in the treatment plan for pain management when chronic opioid therapy is involved.

COT Patient Management Testing Objectives

- Identifies absence of prescribed medication and potential for abuse, misuse, and diversion
- Identifies undisclosed substances, such as alcohol, unsanctioned prescription medication, or illicit substances
- Identifies substances that contribute to adverse events or drug-drug interactions
- Provides objectivity to the treatment plan
- Reinforces therapeutic compliance with the patient
- Provides additional documentation demonstrating compliance with patient evaluation and monitoring

Medical Necessity Guidance

The medical record must include the following information:

- Treatment plan adheres to appropriate state regulatory requirements
- Patient history and physical
- Current treatment plan
- Prescribed medication,
- Risk assessment plan
- Review of prescription drug monitoring data or pharmacy profile
- Use of a validated risk assessment interview or questionnaire tool, with appropriate risk stratification and monitoring protocols.

Prior to ordering a confirmation of drug screen results, the clinician must consider the following patient-specific elements:

- Illicit Drugs:
    - If the qualitative screen is positive for an illicit substance, quantitation for that specific drug may be medically indicated
    - If the qualitative screen is negative, not further testing is necessary
- Prescribed drugs:
    - If the qualitative screen is positive or negative for a prescribed drug, quantitation for that specific drug may be medically indicated
- Designer drugs:
    - Qualitative screening assays not commercially available
    - Quantitative testing required

National pain organizations and the Federation of State Medical Boards recommend a practical approach to confirmatory drug testing, and don't advocate routine and comprehensive drugs of abuse testing. Frequency of testing beyond the baseline drug screen must be based on individual patient needs substantiated by documentation in the medical record.

Additional clinical criteria, indications, special issues, and exclusions for the ordering of qualitative, confirmation, quantitative, and specialty testing for patients on COT are as follows:

Baseline Testing	Indicated for initial COT patient assessment. Drug testing may include

	the following drugs/drug classes: AMP, BAR, BZO, COC, MAMP, MTD, OPI, OXY, and THC. Used to: • Identify presence of illicit substances prior to prescribing controlled medications, • Confirm the presence or absence of prescribed drug/drug class
Monitoring and Testing Frequency	Random urine drug testing, at random visits with random selection of drugs may be preferred. Frequency based on medical necessity and a complete clinical assessment of the individual patient's risk potential for abuse and diversion using a validated risk assessment interview or questionnaire. In the absence of specific symptoms of medication aberrant behavior or misuse, qualitative drug testing is reasonable and necessary when titrated to patient risk potential.
Targeted Testing	Targeted testing may be medically reasonable and necessary based on the clinical information obtained from the patient and the clinical assessment such as suspicious behaviors, self-escalation of dose, doctor-shopping, indications/symptoms of illegal drug use, evidence of diversion, or other documented change in affect or behavioral pattern.
Confirmatory/ Quantitative Testing	Automatic confirmatory testing for any drug is not reasonable and necessary without patient specific indications. Medicare considers confirmatory/quantitative drug testing reasonable and necessary when the results of a qualitative screen are: • Cocaine confirmation to identify a chronic cocaine user • THC confirmation to document patient's discontinuation of THC use according to the treatment plan • Presumptive positive for stimulant (amphetamine), barbiturate, benzodiazepine and opiates/oxycodone class of drugs • Negative screen inconsistent with patient's medical history or current prescribed pain medications • Suspicion of a specific drug use such as but not limited to Fentanyl and Meperidine, or designer drugs Exceptions should be documented with the physician's rational for the confirmation testing order in the medical record.
Specimen Validity	Specimen validity testing (SVT), consisting of pH, specific gravity, oxidants, creatinine, or other test, is considered to be a quality measure and is statutorily excluded from the Medicare Benefit. Testing by GC-MS or LC-MS technology is not affected by adulterants and/or dilution.

Sample Testing Frequency Based on Validated Risk Assessment and Stratification*

Targeted testing must be completed and reviewed by the clinician prior to prescribing/renewing a controlled substance for every risk group outlined below:

Risk Group	Baseline	Risk Level
Low Risk	Prior to Initiation of COT	Random testing every 6-12 months for prescription compliance and illicit drug identification (AMP, COC, MAMP, THC)
Moderate Risk	Prior to Initiation of COT	Random testing at least every 6 months for prescription compliance and illicit drug identification
High Risk	Prior to Initiation of COT	Random testing performed on random visits and on different drugs or drug classes

Confirmatory and/or Quantitative Drug Testing Note: Limitations of Coverage:

In summary, confirmatory/quantitative test is reasonable and necessary based on patient history for:

- Positive identification or when a quantitative concentration of the drug is needed to guide management
- Specific drug identification in a large family of drugs (benzodiagzepines, barbiturates, and opiates)
- Ruling out false positive screening test
- Testing for specialty/designer drugs not covered by chemistry analyzer immunoassay screens

Non-Covered

1. **LC-MS/MS and GC-MS at Point-of-Care Physician Office Labs (POC/POL):**
   GC-MS and LC-MS/MS/MS are not point of care testing technologies and not reasonable and necessary for the immediate care and management of patients. They require extensive knowledge of the technology, many months to validate individual assays, 4-8 hours of complex pre-analytic, analytic and post analytic specimen handling, and compliance with CLIA regulations.

   Palmetto GBA will no longer reimburse for drug confirmation testing, specific drug quantitation testing or nonspecific analyte testing at POC/POLs and physician partnered laboratories. Test services referred from one physician lab to another physician's lab will not be reimbursed. Only independent reference labs will be reimbursed for GC-MS or LC-MS/MS testing.

2. **Standing Orders**
   Only patient-specific orders documented in the medical record are considered reasonable and

necessary. Nonspecific orders, aka “standing orders,” are not considered reasonable and necessary for patient management and will be denied. When an unexpected drug(s) or metabolite(s) is observed on a single procedure (single solid/mobile phase procedure), the laboratory is required to contact the ordering physician to obtain a written order for confirmation/quantitative testing if the physician determines the drug/metabolite has clinical significance for the management of the given patient. Not all incidental drug(s) or metabolite(s) require confirmation/quantitation. Standing orders for identification of incidental drug(s) or metabolite(s) are not covered by Medicare. The revised order must be documented in the patient’s medical record.

Laboratories must have on record and available upon request a physician signed, patient-specific order for every test performed and reported for reimbursement.

3. **Patient drug testing performed to protect a physician from drug diversion charges**

4. **Semi-qualitative (numerical) EIA or IA screening tests billed as a confirmatory/quantitative /definitive test result**

5. **Confirmatory/quantitative drug testing panel(s) performed by a reference laboratory**

6. **Drug testing of two different specimen types from the same patient on the same date of service**

7. **Routine non-specific or comprehensive orders for drug qualitative screening, and/or confirmatory/quantitation testing**

8. **Drug screening for medico-legal and/or employment purposes**

9. **Specimen validity testing**

10. **Direct submission of specimens for confirmatory/quantitative testing without prior qualitative testing (EIA/IA)**

Documentation Requirements

- A signed and dated physician order for each ordered drug test
- Legible record that includes patient identification information
- Valid diagnosis and procedure codes supported by medical record
- Rational substantiating qualitative drug test performance
- Requisition form for confirmatory and/or quantitative testing indicating specific qualitative test results as well as specific drugs that are prescribed for the patient that test negative by qualitative screening
- Treatment agreement or patient “contract”

All documentation must be maintained in the patient's medical record and available to the contractor upon request.

Proposed/Draft Process Information

Associated Information
N/A

Sources of Information and Basis for Decision
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Open Meetings/Part B MAC Contractor Advisory Committee (CAC) Meetings

MEETING DATE	MEETING TYPE	MEETING STATE(S)	MEETING INFORMATION
10/01/2013	Carrier Advisory Committee (CAC) Meeting	West Virginia	

Comment Period Start Date
03/20/2014

Comment Period End Date
05/05/2014

Released to Final LCD Date
N/A

Reason for Proposed LCD
- Other (Extend comment period)

Proposed Contact
Elaine Jeter, MD
PO Box 100190
Columbia, SC 29202
PO Box 100190
Columbia, SC 29202
J11B.policy@PalmettoGBA.com

- Coding Information

[PROPOSED/DRAFT]

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:

80102	DRUG CONFIRMATION, EACH PROCEDURE
80152	AMITRIPTYLINE
80154	BENZODIAZEPINES
80159	CLOZAPINE
80160	DESIPRAMINE
80166	DOXEPIN
80171	GABAPENTIN
80173	HALOPERIDOL
80174	IMIPRAMINE
80182	NORTRIPTYLINE
80183	OXCARBAZEPINE
80184	PHENOBARBITAL
80299	QUANTITATION OF DRUG, NOT ELSEWHERE SPECIFIED
82055	ALCOHOL (ETHANOL); ANY SPECIMEN EXCEPT BREATH
82101	ALKALOIDS, URINE, QUANTITATIVE
82145	AMPHETAMINE OR METHAMPHETAMINE
82205	BARBITURATES, NOT ELSEWHERE SPECIFIED

82520	COCAINE OR METABOLITE
82542	COLUMN CHROMATOGRAPHY/MASS SPECTROMETRY (EG, GC/MS, OR HPLC/MS), ANALYTE NOT ELSEWHERE SPECIFIED; QUANTITATIVE, SINGLE STATIONARY AND MOBILE PHASE
82646	DIHYDROCODEINONE
82649	DIHYDROMORPHINONE
83805	MEPROBAMATE
83840	METHADONE
83925	OPIATE(S), DRUG AND METABOLITES, EACH PROCEDURE
83992	PHENCYCLIDINE (PCP)
G0431	DRUG SCREEN, QUALITATIVE; MULTIPLE DRUG CLASSES BY HIGH COMPLEXITY TEST METHOD (E.G., IMMUNOASSAY, ENZYME ASSAY), PER PATIENT ENCOUNTER
G0434	DRUG SCREEN, OTHER THAN CHROMATOGRAPHIC; ANY NUMBER OF DRUG CLASSES, BY CLIA WAIVED TEST OR MODERATE COMPLEXITY TEST, PER PATIENT ENCOUNTER

Group 2 Paragraph:
The following CPT codes are Non-Covered by Medicare

Group 2 Codes:

80100	DRUG SCREEN, QUALITATIVE; MULTIPLE DRUG CLASSES CHROMATOGRAPHIC METHOD, EACH PROCEDURE
80101	DRUG SCREEN, QUALITATIVE; SINGLE DRUG CLASS METHOD (EG, IMMUNOASSAY, ENZYME ASSAY), EACH DRUG CLASS

ICD-9 Codes that Support Medical Necessity

Group 1 Paragraph:
N/A

Group 1 Codes:

276.2	ACIDOSIS
295.00 - 295.30	SIMPLE TYPE SCHIZOPHRENIA UNSPECIFIED STATE - PARANOID TYPE SCHIZOPHRENIA UNSPECIFIED STATE
303.90	OTHER AND UNSPECIFIED ALCOHOL DEPENDENCE UNSPECIFIED DRINKING BEHAVIOR
304.00	OPIOID TYPE DEPENDENCE UNSPECIFIED USE

304.01	OPIOID TYPE DEPENDENCE CONTINUOUS USE
304.80	COMBINATIONS OF DRUG DEPENDENCE EXCLUDING OPIOID TYPE DRUG UNSPECIFIED USE
304.90	UNSPECIFIED DRUG DEPENDENCE UNSPECIFIED USE
305.90	OTHER MIXED OR UNSPECIFIED DRUG ABUSE UNSPECIFIED USE
338.29	OTHER CHRONIC PAIN
338.4	CHRONIC PAIN SYNDROME
345.10 - 345.11	GENERALIZED CONVULSIVE EPILEPSY WITHOUT INTRACTABLE EPILEPSY - GENERALIZED CONVULSIVE EPILEPSY WITH INTRACTABLE EPILEPSY
345.3	GRAND MAL STATUS EPILEPTIC
345.90 - 345.91	EPILEPSY UNSPECIFIED WITHOUT INTRACTABLE EPILEPSY - EPILEPSY UNSPECIFIED WITH INTRACTABLE EPILEPSY
426.10 - 426.13	ATRIOVENTRICULAR BLOCK UNSPECIFIED - OTHER SECOND DEGREE ATRIOVENTRICULAR BLOCK
426.82	LONG QT SYNDROME
427.0 - 427.1	PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA - PAROXYSMAL VENTRICULAR TACHYCARDIA
719.40	PAIN IN JOINT SITE UNSPECIFIED
721.0	CERVICAL SPONDYLOSIS WITHOUT MYELOPATHY
721.3	LUMBOSACRAL SPONDYLOSIS WITHOUT MYELOPATHY
722.52	DEGENERATION OF LUMBAR OR LUMBOSACRAL INTERVERTEBRAL DISC
723.1	CERVICALGIA
724.2	LUMBAGO
724.4	THORACIC OR LUMBOSACRAL NEURITIS OR RADICULITIS UNSPECIFIED
729.1	MYALGIA AND MYOSITIS UNSPECIFIED
729.2	NEURALGIA NEURITIS AND RADICULITIS UNSPECIFIED
780.01	COMA
780.09	ALTERATION OF CONSCIOUSNESS OTHER
780.1	HALLUCINATIONS

780.39	OTHER CONVULSIONS
963.0	POISONING BY ANTIALLERGIC AND ANTIEMETIC DRUGS
965.00 - 965.09	POISONING BY OPIUM (ALKALOIDS) UNSPECIFIED - POISONING BY OTHER OPIATES AND RELATED NARCOTICS
965.1	POISONING BY SALICYLATES
965.4	POISONING BY AROMATIC ANALGESICS NOT ELSEWHERE CLASSIFIED
965.5	POISONING BY PYRAZOLE DERIVATIVES
965.61	POISONING BY PROPIONIC ACID DERIVATIVES
966.1	POISONING BY HYDANTOIN DERIVATIVES
967.0 - 967.9	POISONING BY BARBITURATES - POISONING BY UNSPECIFIED SEDATIVE OR HYPNOTIC
969.00 - 969.9	POISONING BY ANTIDEPRESSANT, UNSPECIFIED - POISONING BY UNSPECIFIED PSYCHOTROPIC AGENT
972.1	POISONING BY CARDIOTONIC GLYCOSIDES AND DRUGS OF SIMILAR ACTION
977.9	POISONING BY UNSPECIFIED DRUG OR MEDICINAL SUBSTANCE
V15.81	PERSONAL HISTORY OF NONCOMPLIANCE WITH MEDICAL TREATMENT PRESENTING HAZARDS TO HEALTH
V58.69	LONG-TERM (CURRENT) USE OF OTHER MEDICATIONS
V58.83	ENCOUNTER FOR THERAPEUTIC DRUG MONITORING
V71.09*	OBSERVATION OF OTHER SUSPECTED MENTAL CONDITION

Group 1 Medical Necessity ICD-9 Codes Asterisk Explanation: *
*For monitoring of patient compliance in a drug treatment program, use ICD-9-CM code V71.09 as the primary diagnosis and the specific drug dependence diagnosis as the secondary diagnosis. For the monitoring of patients on methadone maintenance and chronic pain patients with opioid dependence, suspected of abusing other illicit drugs, use code V 58.69.

Physician are to select the most appropriate diagnosis code. Labs are not to pre-populate requisition forms with diagnosis codes.

ICD-9 Codes that DO NOT Support Medical Necessity
N/A

Associated Documents

Attachments

N/A

Related Local Coverage Documents

N/A

Related National Coverage Documents

N/A

Keywords

N/A

Read the **LCD Disclaimer**

78