PROPOSED / DRAFT Local Coverage Determination (LCD): Drugs of Abuse Testing (DL34754)

[PROPOSED/DRAFT]

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Contractor Information

Contractor Name	Contract Number	Contract Type
Noridian Healthcare Solutions, LLC opens in new window	03602	MAC - Part B

Back to Top

Proposed / Draft LCD Information

Document Information

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DL34754

Proposed LCD Title
Drugs of Abuse Testing

Jurisdiction
Wyoming

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 clearly 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, to some degree, drug overdose, the treatment of neonates, addiction medicine and the medical management of patients using chronic opioid therapy (COT). However, the nature of drugs of abuse testing for each of these groups is somewhat different because treatment goals and timelines generally vary.

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	Generally used to determine the presence or absence of drug or drug metabolite in the sample. The test result is expressed in non-numerical terms, with a negative or positive result.
Quantitative Drug Testing	Generally 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 numerical terms.
Confirmation Testing	Generally used to evaluate initial qualitative screening results to minimize the potential of a clinician relying on a false negative or positive result. Confirmation testing is often recommended when initial screening involves a CLIA-waived or moderate immunoassay screening, but is not medically necessary in all patient cases. A confirmation test order must be medically necessary and reasonable and patient self-report may, in some cases, reduce the need for confirmation of screen results. Confirmation tests may be expressed in qualitative (CPT 80102) or quantitative (codes within the Therapeutic or Chemistry sections of the CPT) values. The use of qualitative versus quantitative confirmation testing depends upon the individual patient's case and medical necessity therefore.

More detailed information about medical necessity for test orders, indications and exclusions is set forth below:

Specific Test Methods

Clinical laboratories of all types use a variety of test methods to perform qualitative drug analysis, including enzyme immunoassays (EIA and IA), thin-layer chromatography, and spectrometry. In-office and onsite testing generally involves chemical "spot" tests, including dipstick, cassettes and cup methods (generally classified as CLIA-waived), and bench-top chemistry analyzers (classified under CLIA as moderately complex). In either case, EIA and IA drug screening are limited in several ways because:

- they generally screen for drug classes rather than specific drugs;
- they cannot provide information on many specialty drugs; and
- these methods may produce false positives and cross-react with other drug analytes.

These drug screen methods are also unable to identify specific drugs within many drug classes, including the amphetamines, barbiturates, benzodiazepines, and opiate/opioids. Due to these limitations, confirmatory testing with a more specific method such as GC-MS, LC-MS/MS may be medically necessary and reasonable within the confines of the clinical criteria and coverage indications set forth below. However, confirmatory testing should ONLY be ordered and performed on a patient/drug specific basis, within the parameters outlined in this policy, and documented in the patient record.

Confirmatory tests either verify or refute the result of the screening assay. With recent improvements in technology, some laboratories may bypass screening tests and submit all specimens for analysis by what have traditionally been referred to as confirmatory test methods, such as gas or liquid chromatography, mass spectrometry. Confirmatory tests use a more specific, and usually more sensitive, method than do screening tests and are usually performed in an independent laboratory.

Confirmatory tests usually:

- Provide quantitative concentrations (e.g., ng/mL) of specific substances or their metabolites in the specimen;
- Have high specificity and sensitivity;
- Require a trained technician to perform the test and interpret the results;
- Can identify specific drugs within drug classes

In clinical situations, confirmation is not always necessary and should be based on provider choice to allow for the proper evaluation of medical necessity. Clinical correlation is appropriate. For example, if the patient or a family member affirms that drug use occurred, a confirmation drug test is not usually needed.

The terms "drug screening" and "drug testing" are somewhat misleading because they may be interpreted that all drugs will be identified by ordered test panels. In reality, the drug or drug metabolites detected by a test depend on the testing method and the device or test method cutoff concentrations. In the clinical care of patients, the need for testing each drug ordered must be documented and the connection between the test order and clinical decision-making following test results must be reasonable and medically necessary to the ongoing care of the patient.

Drug Test Panels

A drug test panel is a list (or menu) of drugs or drug classes that can be tested for in a specimen. These can be ordered to identify drugs of abuse or in pain management. No single drug panel is suitable for all clinical uses, and test options should be adapted to clinical needs through proper exercise of clinical decision-making. Panels must be related to the individual patient's medical history and treatment needs. Existing test panels in POCT devices and as marketed by independent clinical laboratories may result in medically unnecessary and unreasonable testing and should be carefully evaluated by the ordering practitioner.

Specimen Type

Urine may be the preferred biologic specimen for testing because of its ease of collection and storage, and cost-effectiveness. Urine is also believed to be the best source for broad qualitative drugs of abuse testing because blood is relatively insensitive for common drugs such as psychotropic agents, opioids, and stimulants. However, there may be clinical value in the limited use of other specimen types, such as saliva and serum, so long as clinical rationale therefore is clearly stated as described below. NOTE: Medicare excludes from coverage the testing of two different specimen types from the same patient on the same date of service.

Drugs of Abuse – Commonly Assayed Drugs/Drug Classes

The chart below provides insight into the more common drugs of abuse. Not all drugs of abuse are listed. This policy makes clear that clinicians must have choice in selecting which drugs to test and when, and all testing should be tailored to the individual patient under consideration and involve other documented clinical criteria as set forth below for each specific group. Thus, sometimes testing will be more basic than others depending on the patient, the demographics of drugs abused in a particular geographic area, and the relationship of the drugs tested to the ongoing care of the patient, whether by treatment in an emergency department, neonate unit, substance abuse treatment facility or physician's office where patients are managed with chronic opioid therapy. Medicare expects provider orders to reflect careful consideration of the drugs/drug classes to be tested. Routine testing for all of the drugs/drug classes listed in the chart below is excluded and reimbursement may be denied.

Parent Drugs and Metabolite Chart (Basic Drugs of Abuse*)

Drug Class/Drugs	Common Names	General Monitoring Possibilities Subject to Medical Necessity
Alcohol/Alcohol Metabolites Ethyl Alcohol EtG EtS	Ethyl Alcohol	Ethyl Alcohol* Ethyl Glucuronide Ethy Sulfate
Barbiturates Amobarbital Butabarbital Butalbital Pentobarbital Phenobarbital Secobarbital	Amytal Sodium&reg Butisol Sodium&reg, Butibel Fiorinal&reg, Fioricet&reg Nembutal&reg Belladona, Luminal&reg Seconal&reg	Amobarbital Butabarbital Butalbital Pentobarbital 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 A dumbran, 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
Muscle Relaxants Carisoprodol Meprobamate	Soma&reg, Soprodoal Equinal, Miltown&reg, Meprospan	Carisoprodol, Meprobamate Meprobamate

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

TABLE NOTES: 6-MAM= 6-monoacetylmorphine; **EDDP**= 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine; **EtG**=ethyl glucuronide; **EtS**= ethyl sulfate; **MDS**= methylenedioxyamphetamine; **MDMA**= methylenedioxymethamphetamine; **THC-COOH** = 11-nor-9-carboxy-delta-9-tetrahydrocannabinol

Covered Indications

Medicare has divided covered indications into the following four broad groups (A-C) and provides more detailed information on when qualitative drug testing is reasonable and medically necessary for each category:

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

A qualitative drug screen is performed as part of the evaluation and treatment of a patient who presents (usually to an emergency department) 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

This section and description of clinical criteria relates only to laboratory testing used in the initial assessment and ongoing monitoring of drug and alcohol treatment compliance. The assessment of continued drug use should be based on treatment interactions, behavioral observations as well as mental status and history and physical evaluation. Confrontation of findings consistent with drug use in many cases results in self-disclosure of ongoing substance use. However, the validity of patient's self-reported substance use is not always reliable and may require testing verification.

Ambulatory laboratory testing for drugs of abuse is a medically necessary and useful component of chemical dependency treatment. Drug test results are of importance in treatment programs and in outpatient chemical dependency treatment. The drug screen result can influence treatment and level of care decisions. It is important that ordered tests match treatment needs, the documented history and Diagnostic and Statistical Manual of Mental Disorders (DSM IV TR) or most current DSM diagnosis.

When using drug tests to screen a patient for substance use disorders, the practitioner should test for a broad range of commonly abused drugs. However, decisions about which substances to screen for should be well documented, and based on and tailored to:

- The patient, including his/her history, the results of any physical examination, and previous laboratory findings, if any;
- The substance suspected of being misused;
- Local information about substances commonly abused and misused, considering input from the Substance Abuse and Mental Health Services Administration's [SAMHSA's] Drug Abuse Warning Network compiles prevalence data on drug-related emergency department visits and deaths (available at http://www.samhsa.gov/data/DAWN.aspx) or similar information;
- The substances commonly abused/misused in the practitioner's patient population; and
- Substances that may present high risk for additive or synergistic interactions with prescribed medication (e.g., benzodiazepines, alcohol).

When making decisions about specific drug test panels and criteria therefore, it may be helpful to consult the forthcoming American Society of Addiction Medicine Clinical Guidelines, due out in late 2013 (www.asam.org) and the Federation of State Medical Boards' Model Policy for the Office Based Treatment of Opioid Addiction (www.fsmb.org).

Criteria for Testing	1. The patient has been evaluated by a licensed clinician, who has documented appropriate symptomology to support the need for a test and the test panel ordered. 2. The tests ordered are within the scope of the ordering clinician's authority.

	3. The rationale for the tests ordered is clearly documented and includes a statement of reasons for the drugs/drug classes to be screened with specific reference to any specialty tests ordered (those not available in CLIA-waived, moderate in-office immunoassay tests). 4. The test results are used in the management of the patient and documented in the treatment plan.
Qualitative Screening Indications	A new patient screening immunoassay with confirmation or quantitative testing typically involves the following drugs/drug classes: • Alcohol • 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, specialty screening or direct to chromatography 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 proper documentation of this history and rationale for such test orders. Additional discussion of Confirmation and Specialty testing is found below. *Ongoing patient monitoring with a screening immunoassay without confirmation or quantitative testing is typically sufficient in this patient population.* Once again, specialty testing may be necessary but requires specific documentation of clinical rationale for the same and should be tied to appropriate symptomology. 1. Post initial facility admission screenings are expected and may be approved at a frequency not to exceed three (3) every thirty (30) days. 2. Screening at a frequency greater than three (3) times in thirty (30) days requires rationale documented in medical record and must meet medical necessity. Routine testing at the upper end of these limits may result in audit and overpayment demands, or other intervention as provided for by Medicare regulations. 3. Onsite CLIA-waived testing is preferred as results can rapidly be integrated into treatment decisions and clinical assessment.
Specimen Validity Testing	Specimen validity testing is considered to be a quality control issue with urine drug testing only and should not be separately billed. Most basic urine immunoassays have specimen validity checks built into the screening process, and allow for a basic determination of potential urine sample tampering (dilution, substituted specimen, etc.). **Specimen validity testing is excluded from coverage.**
Confirmation,	

Quantitative and Specialty Testing	Most positive screening results are confirmed by the patient's self-disclosed admission of substance use. All orders for confirmation testing (qualitative result, CPT 80102) require a positive screening test and shall be performed only for the drug class represented by the positive screening. Example: A patient is screened at admission and the sample is positive for cocaine; negative for all other drug classes. A proper confirmation order would be to confirm the cocaine only if the patient does not admit use of this drug. All orders for quantitative testing of drugs of abuse require a positive screening test and shall be performed only for the drug class represented by the positive screening. 1. Documentation of medical necessity for quantitative testing is required in the medical record. 2. 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. Once again, routine testing at the upper end of these limits may result in audit and/or overpayment demands, among other available regulatory action.
Exclusions	Any of the following is sufficient criteria for exclusion: 1. Confirmation or Quantitative testing is excluded from coverage if performed for forensic or legal purposes. 2. Qualitative and Quantitative testing of blood and urine, saliva and blood or urine, or any multiple source specimens on the same date of service is excluded. 3. Quantitative testing requires a positive screening test and shall be performed only for the drug class represented by the positive screening. 4. Quantitative testing for negative screening results is excluded without written documentation of medical necessity.

Group C - Chronic pain management drug testing for patients on chronic opioid therapy (COT). AMP = Amphetamine; MAMP = Methamphetamine; MDMA = methylenedioxymethamphetamine

This section and description of clinical criteria relates only to laboratory testing used in the monitoring of patients on chronic (more than 90 consecutive days) opioid therapy. Testing for drugs of abuse and adherence to the treatment plan is a recognized as a "best-practices" component of proper pain management when chronic opioid therapy is involved. The table below provides basic information on the role of drug testing in the medical management of patients using COT. However, clinical guidelines and major pain regulatory policy is unsettled as to the frequency of testing and nature of drugs/drug classes to be tested. Therefore, provider decisions regarding drugs of abuse and adherence monitoring testing for patients on COT should be based on documented treatment interactions, behavioral observations as well as mental status and history and physical evaluation. Providers should also consider the relevance and value of discussing the findings of drug test results with the patient and whether and when the discussion and the patient's self-disclosures obviate the medical need for additional testing. While it is fair to say that the validity of patient's self-reported substance use is not always reliable and testing verification may be required, Medicare expects providers to carefully evaluate what they know about the patient in addition to the patient's self-disclosure when considering test orders. In the long run, well-documented patient evaluations and clinical judgment trumps non-legal recommendations for drug testing frequency.

Role of Drug Testing in the Clinical Management of Patients on COT
• May detect the absence of prescribed medication and potential for abuse, misuse, and diversion • May detect the use of undisclosed substances, such as alcohol, unsanctioned prescription medication, or illicit substances

- May detect the use of substances that contribute to adverse events or drug-drug interactions
- May provide objectivity to the treatment plan
- May reinforce therapeutic compliance with the patient
- May provide additional documentation demonstrating compliance with patient evaluation and monitoring

**In all cases, drug tests must be based on medical necessity and must be reasonable in the treatment of the patient based on their individual circumstances.*

Additional Medical Necessity Guidance

Clinical literature and State regulatory pain management policies are not uniform in the recommendations associated with drug testing. What can be gleaned from this literature is the trend toward the use of clinical drug testing of new patients (to assess the presence or absence of drugs in the patient system before initiating opioid therapy), as well as random follow-up testing used to monitor the patient's adherence to/compliance with the treatment plan. For these reasons, it is imperative that the ordering clinician must have freedom of choice in ordering laboratory tests and carefully assess an individual patient's situation and need for drug testing (drug classes and frequency of testing); this information must, according to this policy, be documented in the medical record so that medical necessity may be properly evaluated by the Medicare program. Appropriate documentation must follow current clinical guidelines and State pain regulations or policies governing the initial assessment of the patient and medical need for the use of controlled medications to treat pain, as well as a validated risk assessment process (interview or questionnaire), proper risk stratification, and patient monitoring, which should include use of prescription drug monitoring database information where available.

Prior to ordering a drug screen, the clinician should consider the following patient-specific elements:

- History
- Current treatment plan and medication prescribed,
- Risk potential for abuse, misuse, and diversion, including a review of prescription drug monitoring data (if available) or pharmacy profile, and
- 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 should consider the following patient-specific elements:

- Whether the screen results show the presence or absence of an illicit drug. If the screen is positive for an illicit substance, then the clinician may consider ordering a qualitative confirmation (CPT 80102) prior to making a final treatment decision associated with the patient's ongoing treatment plan or termination of care, as appropriate to the individual patient circumstances. Of note here a quantitative test result may be necessary to support the patient's ongoing discontinuation of marijuana (THC) to support ongoing treatment with controlled substances. It is generally not appropriate to order confirmation testing of a drug screen result that is negative for an illicit substance. Any such orders must be accompanied by specific documentation of the clinician's rationale for ordering confirmation of negative drug screen results involving illicit substances (AMP, MAMP, COC, THC, PCP, MDMA etc.).
- Whether the screen results show the presence or absence of a prescribed drug class, in which case either result may warrant confirmation testing to identify the specific analyte causing the positive result or to ensure the specimen is truly negative given the differences in the cut-off values used for point of care screening and quantitative confirmation testing via chromatography.

- Prior to ordering specialty testing for drugs/drug classes for which there presently is no commercially available qualitative screening assay, the clinician should consider patient-specific elements as cited above and throughout this policy document. Orders for drugs/drug classes lacking commercially available qualitative in-office/onsite screening assays should be carefully documented and supported by specific reference to the patient's history and other relevant factors, including whether (a) the patient is currently being prescribed the specific drug (or was recently converted to another drug from it), and/or (b) the clinician is in possession of information suggesting the potential for the abuse of a particular drug/drug class.

- In general, national pain organizations and the Federation of State Medical Boards recommend a practical approach to drug testing for patients in this group, and to not advocate a routine or wholesale approach to drugs of abuse testing. Further, these organizations tend to tie the frequency of testing beyond the baseline drug screen to individual patient medical needs and documented provider choice and discretion.

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	When appropriate, the patient should undergo a baseline drug test. Some state professional licensing boards require baseline drug testing and recommend that the baseline test include the following drugs/drug classes: AMP, BAR, BZO, COC, MAMP, MTD, OPI, OXY, and THC Baseline testing should be used to: A. Identify the presence of illicit substances prior to initiating treatment involving controlled medications, and B. Confirm the presence or absence of the prescribed drug/drug class where possible and in accordance with the patient's documented treatment history.
Periodic Monitoring and Testing Frequency	

	Monitoring of compliance is a critical aspect of chronic opioid prescribing, using such tools as random urine drug screening among others. The frequency of the testing should be 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. Periodic monitoring contemplates random drug testing. Periodic monitoring should be performed on a random basis, meaning drug testing should be ordered in a way that minimizes the patient's ability to prepare for the test. The drugs/drug classes tested for in the monitoring phase of patient drug testing should be tailored to the individual patient and include those drugs that are prescribed and common drugs of abuse. If testing for other drugs/drug classes is ordered, the provider must document the clinical rationale for such test orders. Periodic monitoring is used to address proper monitoring of the following risk potentials:

		○ Abuse and diversion of controlled medications ○ Abuse of illicit drugs or drugs not prescribed as part of the treatment plan and obtained from an undisclosed/unsanctioned source. The frequency of drug testing should be based in part on the validated risk assessment process and the potential that the patient will engage in medication-aberrant behavior (or illicit drug use behavior). Patients assessed at a higher risk for medication misuse and illicit drug use may require more frequent testing than those assessed at a lower risk for such behavior. *In the absence of specific symptoms of medication aberrant behavior or misuse, qualitative drug testing is only reasonable and necessary when titrated to patient risk potential.*
Targeted Testing	Targeted and select testing of limited drugs of abuse may be medically necessary and reasonable in response to specific information related to the clinician regarding patient behavior; Clinical rationale for targeted testing must be clearly documented and may include suspicious behaviors, such as self-escalation of dose, doctor-shopping, indications/symptoms of illegal drug use, evidence of diversion, or other documented change in affect or behavioral pattern.	
Confirmation and Quantitative Testing	Medicare considers confirmatory and/or quantitative drug testing reasonable and necessary when the results of a qualitative screen are: **Presumptive positive drug(s) on a drug screen**	

Example: A patient has been prescribed oxycodone. The point-of-care drug screen is negative. Quantitative confirmation of the parent drug and metabolite(s) should be ordered. Significant lower levels of parent drug and metabolite(s) levels can be ascertained by quantitative testing compared to screening methodologies.

Exception 1: Medicare considers the need for cocaine confirmation to be rare but appropriate to identify the patient is a chronic cocaine user.

Exception 2: Medicare considers the need for THC confirmation to be rare but appropriate to document that the patient is discontinuing THC use according to the treatment plan.

Presumptive positive for stimulant (amphetamine), barbiturate and benzodiazepine class of drugs. Point-of-care drug testing cannot differentiate all the drugs in the stimulant (amphetamine), barbiturate and benzodiazepine class of drugs. A positive qualitative screen may require confirmation in the absence of reliable validation (patient self-report, prescription drug monitoring data, pharmacy profile, communication from prescribing clinician).

Negative screen, and the negative finding is inconsistent with the patient's medical history or current documented chronic pain

	Example: Drugs such as Fentanyl and Meperdine are not identified by point-of-care testing. It may be reasonable for the physician to order a separate initial drug test for one or both of these drugs and their metabolites at baseline or to address risk issues. These orders are subject to the criteria and indications in this document. Automatic confirmatory testing for Fentanyl and Meperdine are not reasonable and necessary without patient specific indications. **Note:** When the initial screen is negative, Medicare would not expect to see claims for confirmatory testing on COC, THC, AMP and methamphetamine except in rare, documented situations, i.e. when a patient is receiving a prescription for AMP for attention deficit (ADD) or other documented medical condition. Exceptions should be documented with the physician's rational for the confirmation testing order in the medical record. **When the coverage criteria of this policy are met AND there is no qualitative test available (locally or commercially).** **Example:** Selected synthetic or semi-synthetic opioids.
Specimen Validity	

	Urine for clinical drug testing is the specimen of choice because of its high drug concentrations and well-established testing procedures. Nevertheless, urine is one of the easiest specimens to adulterate. Urine samples can be diluted, swapped for another individual's, or tampered with using commercially available (or homemade) products that change the chemical profile of the urine. If the clinician suspects that a sample has been adulterated, substituted, swapped, or otherwise altered in attempt to defeat evaluation and monitoring, the clinician may choose to evaluate specimen validity using built-in validity tests such as temperature, creatinine, and pH readings. However, as a general rule specimen validity testing is considered to be a quality control issue and should not be separately billed. Most basic urine immunoassays have specimen validity checks built into the screening process, and allow for a basic determination of potential urine sample tampering (dilution, substituted specimen, etc.).

	In general, clinical laboratories do not conduct the same validity testing as is required for Federal workplace testing. Pain management laboratories may have specimen validity testing protocols that involve creatinine with reflexive specific gravity, pH, and/or oxidants in place. Once again, these are deemed quality control measures. If the physician believes the patient has produced adulterated or substituted urine, and no alternative matrix sampling is available (ie., blood or saliva), the treating provider should consider witnessed urine collection. Standardized Quality Control Measures in Urine Characteristic/Property	
		○ Temperature ○ pH ○ Creatinine ○ Specific Gravity **Specimen validity testing is excluded from coverage.**
Exclusions	SEE BELOW UNDER NON-COVERED INDICATIONS.	

Sample Testing Frequency Based on Validated Risk Assessment and Stratification*

Risk Group	Baseline	Risk Level	Target Testing
Low Risk	Prior to Initiation of COT	Randomly every six months to a year (depending on state licensing board requirements) for Rx Compliance and Commonly Abuse Illicit Drugs (AMP, COC, MAMP, THC)	On documented evidence or one or more of the behaviors listed for this category.
Moderate Risk	Prior to Initiation of COT	Randomly at least every 6 months (depending on state licensing board requirements) for Rx Compliance and Commonly Abused Illicit and	On documented evidence of one or more of the behaviors listed for this

Risk Group	Baseline	Risk Level	Target Testing
		Other Prescribed Drugs based on the Individual Patient's Case	category.
High Risk	Prior to Initiation of COT	Randomly but not necessarily at each scheduled office visit and not necessarily the same drug panel for each testing event.	On documented evidence of one or more of the behaviors listed for this category.

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

In all cases, drugs or drug classes for which testing is performed, should reflect only those likely to be present, based on the patient's medical history, current clinical presentation, and illicit drugs that are in common use. In other words, it is NOT medically necessary or reasonable to routinely test for substances (licit or illicit), which are not used in the patient treatment population or, in the instance of illicit drugs, in the community at large. The ordering/referring provider must issue a written order for all drugs to be tested.

Focused drug screens, most commonly for illicit drug use may be more useful for immediate or temporary clinical decision making to support continuation or discontinuation of a treatment plan. In addition routine confirmation (quantitative) of drug screens with negative results are not deemed medically necessary and are not covered by Medicare. Confirmatory testing is covered for a negative drug/drug class screen when the negative finding is inconsistent with the patient's medical history or current documented chronic pain medication list.

Non-Covered

Routine nonspecific or wholesale orders for drug screening (qualitative), confirmation, and quantitative drugs of abuse testing.

Test for the same drug(s) using a blood and a urine specimen at the same time on the same date of service.

Drug screening for medico-legal purposes (e.g., court-ordered drug screening) and for employment purposes (e.g., as a pre-requisite for employment or as a requirement for continuation of employment)

Unvalidated specimen sources.

Specimen Validity testing

Documentation

A signed and dated physician order for clinical drug screening and/or testing is a key element the medical record and the clinical decision-making based thereon. Documentation is important to the billing and claims for reimbursement of clinical laboratory services. Copies of the test results alone without a proper clinician order for the test are not sufficient documentation to support a claim for the testing services.

The physician order must specifically match the number, level, and complexity of the testing panel components performed. Orders for "custom profiles", "standing orders" or "orders to conduct additional testing as needed" are typically not sufficiently detailed and thus cannot be used to verify the medical necessity for the specific tests the ordering clinician intended to be performed.

From a post drug testing payment review prospective, an order from a non-qualified person (i.e. lab technician, front office personnel, sales rep), or one lacking the documentation required to verify that the billed tests were specifically ordered and medical necessary and reasonable may result in overpayment.

All documentation must be maintained in the patient's medical record and available to the contractor upon request. The following additional documentation requirements apply:

1. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The record must include the identity of the physician or non-physician practitioner responsible for and providing the care of the patient

2. The submitted medical record should support the use of the selected ICD-9-CM/ICD-10-CM code(s). The submitted CPT/HCPCS code should accurately describe the service performed.

3. Medical record documentation (e.g., history and physical, progress notes) maintained by the ordering physician/treating physician must indicate the medical necessity for performing a qualitative drug test.

4. The treating provider must reduce all testing orders to written form and must indicate all drugs/drug classes to be tested in the test order.

    - The treatment agreement (sometimes called a "contract") notifying the patient of his or her responsibility to provide urine/serum samples upon request is not sufficient by itself to support medical necessity.

    - The treating provider performing in-office/onsite POCT should use a CLIA-waived device or CLIA-approved test (FDA cleared/approved) containing specimen validity components to measure pH, specific gravity and temperature. Results of the drug test must be read according to the manufacturer's instructions. Specimen validity is not a covered service and should be used as a quality control measure to ensure a valid specimen. If the treating provider has a concern about the validity of the specimen, the provider should document these concerns and take steps to obtain a valid specimen for testing. Inability to obtain a valid specimen should be factored into the ongoing management of the patient.

    - Patient drug testing should be conducted and reviewed prior to the initial issuance or dispensing of a controlled substance prescription.

5. Clinicians should exercise caution when relying on customized test panels and standing orders and ensure that medical necessity exists for the testing of all drugs/drug classes within the panel. Failure to back up customized test panels with medical necessity information for each individual patient and for each of the drug test panels ordered will be considered "routine test orders" and are excluded from coverage, resulting in the denial of the claim, audit, and/or overpayment request, among other program means for enforcing this policy.

6. Multiple ICD-9/ICD-10 codes should be assigned according to the individual patient case and used to justify the ordered testing. If the provider of the service is other than the ordering/referring physician, that provider must maintain hard copy documentation of the lab results, along with copies of the ordering/referring physician's order for the drug test. The ordering/referring physician must include the clinical indication/medical necessity in the order for the drug test.

Back to Top

Proposed / Draft Process Information

Associated Information

N/A

Sources of Information and Basis for Decision

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Carrier Advisory Committee (CAC) Meetings

Meeting Date	Meeting Information

Meeting Date	Meeting Information
01/07/2014	This medical policy was presented at the Medicare Part B Open Public Meeting held on 01/07/2014. It was again discussed at the following Carrier Advisory Committee meetings on the following dates: Alaska 01/09/2014 Arizona 01/21/2014 Idaho 01/22/2014 Montana 01/16/2014 North Dakota 01/15/2014 Oregon 01/11/2014 South Dakota 01/16/2014 Utah 01/23/2014 Washington 01/28/2014 Wyoming 01/16/2014

Comment Period Start Date
01/07/2014

Comment Period End Date
03/14/2014

Released to Final LCD Date
N/A

Reason for Proposed LCD
- Provider Education/Guidance

Proposed Contact
Noridian Healthcare Solutions, LLC JF Part B Contractor Medical Director(s)
Policy Development - Medicare Part B - Drafts
900 42nd Street S., PO Box 6704
Fargo, ND 58108
policyb.drafts@noridian.com
Back to Top

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
80154	BENZODIAZEPINES
80299	QUANTITATION OF DRUG, NOT ELSEWHERE SPECIFIED
82055	ALCOHOL (ETHANOL); ANY SPECIMEN EXCEPT BREATH
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
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 opens in new window	SIMPLE TYPE SCHIZOPHRENIA UNSPECIFIED STATE - PARANOID TYPE SCHIZOPHRENIA UNSPECIFIED STATE
304.01	OPIOID TYPE DEPENDENCE CONTINUOUS USE
304.90	UNSPECIFIED DRUG DEPENDENCE UNSPECIFIED USE
305.90	OTHER MIXED OR UNSPECIFIED DRUG ABUSE UNSPECIFIED USE
345.10 - 345.11 opens in new window	GENERALIZED CONVULSIVE EPILEPSY WITHOUT INTRACTABLE EPILEPSY - GENERALIZED CONVULSIVE EPILEPSY WITH INTRACTABLE EPILEPSY
345.3	GRAND MAL STATUS EPILEPTIC
345.90 - 345.91 opens in new window	EPILEPSY UNSPECIFIED WITHOUT INTRACTABLE EPILEPSY - EPILEPSY UNSPECIFIED WITH INTRACTABLE EPILEPSY
426.10 - 426.13 opens in new window	ATRIOVENTRICULAR BLOCK UNSPECIFIED - OTHER SECOND DEGREE ATRIOVENTRICULAR BLOCK
426.82	LONG QT SYNDROME
427.0 - 427.1 opens in new window	PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA - PAROXYSMAL VENTRICULAR TACHYCARDIA

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 opens in new window	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 opens in new window	POISONING BY BARBITURATES - POISONING BY UNSPECIFIED SEDATIVE OR HYPNOTIC
969.00 - 969.9 opens in new window	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
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 V58.69.

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

Back to Top

Associated Documents

Attachments
N/A

Related Local Coverage Documents
N/A

Related National Coverage Documents
N/A
Back to Top

Keywords

N/A
Back to Top
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