

Local Coverage Determination (LCD): Controlled Substance Monitoring and Drugs of Abuse Testing (L35006)

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Contractor Information

| CONTRACTOR NAME | CONTRACT TYPE | CONTRACT NUMBER | JURISDICTION | STATE(S) |
|-------------------------|---------------|-----------------|--------------|---|
| Novitas Solutions, Inc. | A and B MAC | 04111 - MAC A | J - H | Colorado |
| Novitas Solutions, Inc. | A and B MAC | 04112 - MAC B | J - H | Colorado |
| Novitas Solutions, Inc. | A and B MAC | 04211 - MAC A | J - H | New Mexico |
| Novitas Solutions, Inc. | A and B MAC | 04212 - MAC B | J - H | New Mexico |
| Novitas Solutions, Inc. | A and B MAC | 04311 - MAC A | J - H | Oklahoma |
| Novitas Solutions, Inc. | A and B MAC | 04312 - MAC B | J - H | Oklahoma |
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| Novitas Solutions, Inc. | A and B MAC | 04412 - MAC B | J - H | Texas |
| Novitas Solutions, Inc. | A and B MAC | 04911 - MAC A | J - H | Colorado New Mexico Oklahoma Texas |
| Novitas Solutions, Inc. | A and B MAC | 07101 - MAC A | J - H | Arkansas |
| Novitas Solutions, Inc. | A and B MAC | 07102 - MAC B | J - H | Arkansas |
| Novitas Solutions, Inc. | A and B MAC | 07201 - MAC A | J - H | Louisiana |
| Novitas Solutions, Inc. | A and B MAC | 07202 - MAC B | J - H | Louisiana |
| Novitas Solutions, Inc. | A and B MAC | 07301 - MAC A | J - H | Mississippi |
| Novitas Solutions, Inc. | A and B MAC | 07302 - MAC B | J - H | Mississippi |
| Novitas Solutions, Inc. | A and B MAC | 12101 - MAC A | J - L | Delaware |
| Novitas Solutions, Inc. | A and B MAC | 12102 - MAC B | J - L | Delaware |
| Novitas Solutions, Inc. | A and B MAC | 12201 - MAC A | J - L | District of Columbia |
| Novitas Solutions, Inc. | A and B MAC | 12202 - MAC B | J - L | District of Columbia |
| Novitas Solutions, Inc. | A and B MAC | 12301 - MAC A | J - L | Maryland |
| Novitas Solutions, Inc. | A and B MAC | 12302 - MAC B | J - L | Maryland |
| Novitas Solutions, Inc. | A and B MAC | 12401 - MAC A | J - L | New Jersey |
| Novitas Solutions, Inc. | A and B MAC | 12402 - MAC B | J - L | New Jersey |
| Novitas Solutions, Inc. | A and B MAC | 12501 - MAC A | J - L | Pennsylvania |

| CONTRACTOR NAME | CONTRACT TYPE | CONTRACT NUMBER | JURISDICTION | STATE(S) |
|-------------------------|---------------|-----------------|--------------|--|
| Novitas Solutions, Inc. | A and B MAC | 12502 - MAC B | J - L | Pennsylvania |
| Novitas Solutions, Inc. | A and B MAC | 12901 - MAC A | J - L | Delaware District of Columbia Maryland New Jersey Pennsylvania |

LCD Information

Document Information

LCD ID

L35006

Original Effective Date

For services performed on or after 10/01/2015

LCD Title

Controlled Substance Monitoring and Drugs of Abuse Testing

Revision Effective Date

For services performed on or after 10/17/2019

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

DL35006

Retirement Date

N/A

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Notice Period Start Date

11/05/2015

Notice Period End Date

12/30/2015

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CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for drug testing. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for drug testing and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site.

IOM Citations:

- CMS Internet-Only Manual (IOM) Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1, Part 2, Section 130.6 Treatment of Drug Abuse (Chemical Dependency)

Change Request References:

- CMS Transmittal 653, Change Request 6852, Clinical Laboratory Fee Schedule (CLFS) - Special Instructions for Specific Test Codes (CPT Code 80100, CPT Code 80101, CPT Code 80101QW, G0430, G0430QW and G0431QW).
- CMS Transmittal 1905, Change Request 6800, February New Waived Tests.

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

Federal Register References:

- 42 CFR, Section 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.
- 42 CFR, Section 411.15(k)(1) Particular services excluded from coverage. Any services that are not reasonable and necessary.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

For purposes of clarification the term physician or clinician refers to a Physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements).

Urine drug testing (UDT) provides objective information to assist clinicians in identifying the presence or absence of drugs or drug classes in the body and making treatment decisions. A presumptive drug screen is used to detect the presence of a drug in the body. A blood or urine sample may be used. However, urine is the best specimen for presumptive screening, as blood is relatively insensitive for many common drugs, including psychotropic agents, opioids, and stimulants.

Common methods of drug analysis include chromatography, immunoassay, chemical ("spot") tests, and spectrometry. Analysis is comparative, matching the properties or behavior of a substance with that of a valid reference compound (a laboratory must possess a valid reference agent for every substance that it identifies). Drugs or classes of drugs are commonly assayed by presumptive testing. A presumptive test may be followed by definitive testing, when there is a positive inconsistent finding from the presumptive test in the setting of a symptomatic patient, as described below. Typically, the "spot" chemical tests (referred to above) are urine dipsticks or multiple drug cup devices.

Examples of drugs or classes of drugs that are commonly assayed by presumptive tests, followed by definitive testing, are: alcohols, amphetamines, barbituates/sedatives, benzodiazepines, cocaine and metabolites, methadone, antihistamines, stimulants, opioid analgesics, salicylates, cardiovascular drugs, antipsychotics, cyclic antidepressants, and others. Focused drug screens, most commonly for illicit drug use, may be more useful clinically.

There should be a direct correlation between those positive findings generated from presumptive testing and those requested definitive tests to specifically confirm such findings.

This policy provides:

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

Definitions:

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

1. Presumptive (Qualitative) Drug Testing (hereafter called "presumptive" UDT)
 - Used when medically necessary to determine the presence or absence of drugs or drug classes in a urine sample;
 - Results expressed as negative or positive or as a numerical result;
 - Includes competitive immunoassays (IA) and thin layer chromatography.
2. Definitive (Quantitative) Confirmation (hereafter called "definitive" UDT)
 - Used when medically necessary to identify specific medications, illicit substances and metabolites; Reports the results of drugs absent or present in concentrations of ng/ml;
 - Limited to GC-MS and LC-MS/MS testing methods only.
3. Specimen Validity Testing
 - Urine specimen testing to ensure that it is consistent with normal human urine and has not been adulterated or substituted;
 - May include pH, specific gravity, oxidants and creatinine.
4. Point of Care Testing (POCT)
 - Used when medically necessary by clinicians for immediate test results for the immediate management of the patient;
 - Available when the patient and physician are in the same location;
 - IA test method that primarily identifies drug classes and a few specific drugs;
 - Platform consists of cups, dipsticks, cassettes, or strips; read by the human eye.
5. Immunoassay (IA)
 - Ordered by clinicians primarily to identify the presence or absence of drug classes and some specific drugs;
 - Biochemical tests that measure the presence above a cutoff level of a substance (drug) with the use of an antibody;
 - Read by photometric technology.
6. Standing Orders
 - Test request for a specific patient representing repetitive testing to monitor a condition or disease for a limited number of sequential visits;
 - Individualized orders for certain patients for pre-determined tests based on historical use, risk and community trend patient profiles;
 - Clinician can alter the standing order.
Note: A "profile" differs from a "panel" in that a profile responds to the clinical risks of a particular patient, whereas a panel encourages unnecessary or excessive testing when no clinical cause exists.
7. Blanket Orders
 - Test request that is not for a specific patient; rather, it is an identical order for all patients in a clinician's practice without individualized decision making at every visit.
8. Reflex Testing
 - Laboratory testing that is performed reflexively after initial test results to identify further diagnostic information essential to patient care.
 - Testing Indications, performed as a step necessary to complete a physician's order is not considered reflex testing.

Drug Test Methods

The Clinical Laboratory Improvement Amendments (CLIA) regulates laboratory testing and requires clinical labs to be certified by their State as well as the CMS before they can accept human samples for diagnostic testing. Multiple

types of CLIA certificates may be obtained based on the complexity of testing a lab conducts. CLIA levels of complexity (CLIA-waived, moderate complexity and high complexity) are addressed only as they relate to the HCPCS code description.

A. Presumptive Testing Methods:

1. CLIA-waived Presumptive UDT:

- CLIA-waived presumptive UDT consist of various platforms including cards, dipsticks, cassettes and cups based on qualitative competitive immunoassay methodology with one or more analytes in the test.
 - Positive test results are presumptive or not definitive due to sensitivity and cross-reactivity limitations.
 - Negative test results do not necessarily indicate the absence of a drug or substance in the urine specimen.
 - Presumptive UDT may be ordered when it is necessary to rapidly obtain and integrate results into clinical assessment and treatment decisions.
 - This type of test should only be used when results are needed immediately.

2. Presumptive UDT by FDA Approved/Cleared IA Analysis

- Chemistry analyzers with IA UDT technology are used in an office or clinical laboratory setting. When FDA approved/cleared platforms and reagents are used, testing is classified as moderately complex.
- This test may be used when less immediate test results are required.
- At no time is IA technology by chemistry analyzer analysis considered confirmatory (definitive) testing.
- Presumptive positive tests are not definitive due to sensitivity, specificity, and cross-reactivity limitations.
- Negative test results do not necessarily indicate the absence of a drug or substance in the urine specimen.

3. Presumptive UDT by Laboratory Developed Test (LDT) IA Analysis:

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

Limitations of Presumptive UDT:

Presumptive UDT testing is limited for the following reasons:

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

B. Definitive UDT:

Gas Chromatography coupled with Mass Spectrometry (GC-MS) and High Performance Liquid Chromatography coupled with Tandem Mass Spectrometry (LC-MS/MS) are complex technologies that use the separation capabilities of gaseous or liquid chromatography with the analytical capabilities of mass spectrometry.

Both methodologies require the competency of on-site highly trained experts in this technology and interpretation of results. While these tests require different sample preparation and analytical runs, they are quantitative tests that identify all specific drugs, metabolites, and most illicit substances and report the results as absent or present in

concentrations of ng/mL.

Quantification should not be used to determine adherence with a specific dosage or time of dose of a pain medication or illicit drug for clinical purposes. Rather, the use of quantitative drug data may be important for many reasons such as in a differential patient assessment.

For example, when several opioids are present in the urine of a patient prescribed a single opioid, quantification may help the clinician decide whether the presence of the other opioids is consistent with metabolism of the prescribed opioid, opioid contamination during manufacturing, or if more than one drug within a class is being used.

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

Definitive UDT is reasonable and necessary in order to:

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

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

Covered Indications for UDT

Group A – Symptomatic patients, multiple drug ingestion or patients with unreliable history.

A patient who presents in a variety of medical settings with signs or symptoms of substance use toxicity will be treated presumptively to stabilize the patient while awaiting rapid, then definitive testing to determine the cause(s) of the presentation.

The need for definitive UDT is based upon rapid test findings, responses to medical interventions, and treatment plan.

A presumptive UDT should be performed as part of the evaluation and management of a patient who presents in an urgent care setting with any one of the following:

- Coma
- Altered mental status in the absence of a clinically defined toxic syndrome or toxidrome
- Severe or unexplained cardiovascular instability (cardiotoxicity)
- Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome

- Seizures with an undetermined history
- To provide antagonist to specific drug

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

Group B - Diagnosis and treatment for substance abuse or dependence.

A patient in active treatment for substance use disorder (SUD) or monitoring across different phases of recovery may undergo medical management for a variety of medical conditions.

A physician who is writing prescriptions for medications to treat either the SUD or other conditions may need to know if the patient is taking substances which can interact with prescribed medications or taking prescribed medications as expected.

The risk of drug-drug interactions is inherent to the patient, and may be compounded by prescribed medications.

UDT is a medically necessary and useful component of chemical dependency diagnosis and treatment. The UDT result influences treatment and level of care decisions.

Ordered tests and testing methods (presumptive or definitive) must match the stage of screening, treatment, or recovery; the documented history; and Diagnostic and Statistical Manual of Mental Disorders (DSM V) diagnosis.

For patients with no known indicators of risk for SUDs, the clinician may screen for a broad range of commonly abused drugs using presumptive UDT.

For patients with known indicators of risk for SUDs, the clinician may screen for a broad range of commonly abused drugs using definitive UDT.

For patients with a diagnosed SUD, the clinician should perform random UDT, at random intervals in order to properly monitor the patient. Testing profiles must be determined by the clinician based on the following medical necessity guidance criteria:

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

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

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

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

A broad cross section of the general population will develop either cancer pain syndrome or non-cancer pain which

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

1. COT UDT Testing Objectives:

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

2. Medical Necessity Guidance:

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

- Patient history, physical examination and previous laboratory findings;
- Current treatment plan;
- Prescribed medication(s); and
- Risk assessment plan.

National pain organizations, physician societies, and the Federation of State Medical Boards recommend a practical approach to definitive UDT for COT.

Frequency of testing beyond the baseline presumptive UDT must be based on individual patient needs substantiated by documentation in the patient's medical record. Recommendations for the ordering of presumptive and definitive UDT for patients on COT are as follows:

- COT Baseline Testing:

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

- COT Monitoring Testing:

Ongoing testing may be medically reasonable and necessary based on the patient history, clinical assessment, including medication side effects or inefficacy, suspicious behaviors, self-escalation of dose, doctor-shopping, indications/symptoms of illegal drug use, evidence of diversion, or other clinician documented change in affect or behavioral pattern.

The frequency of testing must be based on a complete clinical assessment of the individual's risk potential for abuse and diversion using a validated risk assessment interview or questionnaire and should include the patient's response to prescribed medications and the side effects of medications.

The clinician should perform random UDT at random intervals, in order to properly monitor a patient. UDT testing does not have to be associated with an office visit.

Drug Testing Panels

1. Presumptive UDT Panels

Presumptive UDT testing may be ordered as a panel because the Medicare billing codes are defined on a “per patient encounter” basis regardless of the number of analytes tested.

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

2. Definitive UDT Panels

At the current time, physician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient based upon historical use and community trends. However, the same physician-defined profile is not reasonable and necessary for every patient in a physician’s practice.

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

Specimen Type

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

Other Covered Services

1. Reflex Testing by Reference Laboratories – since reference laboratories do not have access to patient-specific data, reflex testing under the following circumstances is reasonable and necessary:

- To verify a presumptive positive UDT using definitive UDT (GC-MS or LCMS/MS) before reporting the presumptive finding to the ordering clinician and without an additional order from the clinician;
- Or
- To confirm the absence of prescribed medications when a negative result is obtained by presumptive UDT in the laboratory for a prescribed medication listed by the ordering clinician.

2. Direct to definitive UDT without a presumptive UDT is reasonable and necessary, when individualized for a particular patient, in the following circumstances:

- To identify a specific substance or its metabolite that is in a large class of drugs, or that is inadequately detected or not detected by presumptive UDT, such as fentanyl, meperidine, synthetic cannabinoids, and other synthetic/analog drugs;
- For use in a differential assessment of medication efficacy, side effects, or drug-drug interactions;
- To identify non-prescribed medication or illicit substance use for ongoing safe prescribing of controlled substances, where clinician has documented concerns related to safety risks attendant to failure to identify specific substances suspected based upon clinical review and judgment; or
- To identify drugs when a definitive concentration of a drug is needed to guide management (e.g., discontinuation of THC use according to a treatment plan).

3. Definitive testing to confirm a negative presumptive UDT result, upon the order of the clinician, is reasonable and necessary in the following circumstances:

- The result is inconsistent with a patient’s self-report, presentation, medical history, or current prescribed medication plan (should be present in the sample);
- Following a review of clinical findings, the clinician suspects use of a substance that is inadequately detected or not detected by a presumptive UDT; or
- To rule out an error as the cause of a negative presumptive UDT result.

4. Definitive testing to confirm a presumptive UDT positive result, upon the order of the clinician, is reasonable and necessary when the result is inconsistent with the expected result, a patient’s self-report, presentation, medical history, or current prescribed medication plan.

Limitations

Non-Covered Services

1. Blanket Orders.
2. Reflex definitive UDT is not reasonable and necessary when presumptive testing is performed at point of care because the clinician may have sufficient information to manage the patient. If the clinician is not satisfied, he/she must determine the clinical appropriateness of and order specific subsequent definitive testing (e.g., the patient admits to using a particular drug, or the IA cut-off is set at such a point that is sufficiently low that the physician is satisfied with the presumptive test result).
3. Routine standing orders for all patients in a physician's practice are not reasonable and necessary.
4. It is not reasonable and necessary for a physician to perform presumptive POCT and order presumptive IA testing from a reference laboratory. In other words, Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers.
5. It is not reasonable and necessary for a physician to perform presumptive IA testing and order presumptive IA testing from a reference laboratory with or without reflex testing. Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers.
6. It is not reasonable and necessary for a reference laboratory to perform and bill IA presumptive UDT prior to definitive testing without a specific physician's order for the presumptive testing.
7. IA testing, regardless of whether it is qualitative or semi-quantitative (numerical), may not be used to "confirm" or definitively identify a presumptive test result obtained by cups, dipsticks, cards, cassettes or other IA testing methods. Definitive UDT provides specific identification or quantification by GC-MS or LCMS/MS.
8. Drug testing of two different specimen types from the same patient on the same date of service for the same drugs/metabolites/analytes.
9. UDT for medico-legal or employment purposes or to protect a physician from drug diversion charges.
10. Specimen validity testing including, but not limited to, pH, specific gravity, oxidants, creatinine.

This LCD imposes frequency limitations. For frequency limitations please refer to the Utilization Guidelines section below.

Notice: Services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules. Refer to Billing and Coding: Controlled Substance Monitoring and Drugs of Abuse Testing, A56645, for applicable CPT codes and diagnosis codes.

The redetermination process may be utilized for consideration of services performed outside of the reasonable and necessary requirements in this LCD.

Summary of Evidence

N/A

Analysis of Evidence

(Rationale for Determination)

N/A

General Information

Associated Information

Refer to the Local Coverage Article: Billing and Coding: Controlled Substance Monitoring and Drugs of Abuse Testing, A56645, for all coding information.

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The medical record documentation must support the medical necessity of the services as stated in this policy.
4. 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. All tests must be ordered in writing by the treating provider and all drugs/drug classes to be tested must be indicated in the order.
5. When a definitive/quantitative test is performed, the record must show that an inconsistent positive finding was noted on the presumptive testing or that there was no available, commercially or otherwise, presumptive test except when not medically necessary to perform presumptive testing in the COT patient subset.
6. 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 test. The physician must include the clinical indication/medical necessity in the order for the test.

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

1. The contractor will consider presumptive UDT testing in excess of 12 per Calendar year not reasonable and necessary.

NOTE: An exception to the above limitation will be made when patients have documented diagnoses consistent with a substance abuse disorder (SUD), for which patients presumptive UDT shall not occur more than 3 times within a seven-day period, based upon the following guidelines for monitoring abstinence.

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

is not covered by Medicare.

- For patients with more than 90 consecutive days of abstinence, presumptive UDT is expected at a frequency of 1 to 3 UDT in one month. More than 3 physician-directed UDT in one month is not reasonable and necessary and is not covered by Medicare.
2. The contractor will only pay for one presumptive UDT test per patient per date of service regardless of the number of billing providers.
 3. For chronic opioid therapy (COT), the contractor will consider up to 12 definitive tests (i.e., definitive UDT) per Calendar year reasonable and necessary. This would correspond to random testing performed 1-3 times every 3 months for prescribed medications, non-prescribed medications that may pose a safety risk if mixed with prescribed and illicit substances based on patient history, clinical presentation or community usage.

Sources of Information

Contractor is not responsible for the continued viability of websites listed.

Palmetto GBA LCD, L35105, Controlled Substance Monitoring and Drugs of Abuse Testing

JL ICD-9 LCD L32050, Qualitative Drug Testing

Original JH ICD-9 Source LCD L34352, Qualitative Drug Testing

Contractor Medical Directors

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Revision History Information

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION | REASON(S) FOR CHANGE |
|-----------------------|-------------------------|--|--|
| 10/17/2019 | R18 | LCD revised and published on 10/17/2019. Consistent with CMS Change Request 10901, the entire coding section has been removed from the LCD and placed into the related Billing and Coding Article, A56645. All CPT codes and coding information within the text of the LCD has been placed in the Billing and Coding Article. The following has been removed from the Documentation Requirements: The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed. | <ul style="list-style-type: none"> Other (CMS Change Request 10901) |
| 06/27/2019 | R17 | LCD revised and published on 06/27/2019. Consistent with Change Request (CR) 10901 CMS IOM language has been removed from the policy of the LCD. All CPT and ICD-10 codes have been removed from the LCD and placed in the related Billing and Coding Article, A56645. The references have been moved to the Bibliography section and links to A56645 and to NCD 130.6 have been added as related documents. There has been no change in coverage with this LCD revision. | <ul style="list-style-type: none"> Other (Change in LCD process per CMS CR 10901) |
| 10/01/2018 | R16 | LCD revised and published on 10/25/2018 effective for dates of service on and after 10/01/2018 to reflect the ICD-10-CM Annual Code Updates. The following ICD-10-CM code(s) have been deleted and therefore removed from Group 1 and Group 2 Codes of the LCD: M79.1. The following ICD-10-CM code(s) have been added to Group 1 Codes: M79.11, M79.12, M79.18, T43.641A, T43.642A, T43.643A, T43.644A. The following ICD-10-CM code(s) have been added to Group 2 Codes: F12.23, F12.93, M79.11, M79.12, M79.18, T43.641A, T43.641D, | <ul style="list-style-type: none"> Revisions Due To ICD-10-CM Code Changes Other (Clarification) |

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION | REASON(S) FOR CHANGE |
|-----------------------|-------------------------|---|--|
| | | <p>T43.642A, T43.642D, T43.643A, T43.643D, T43.644A, T43.644D. The following ICD-10-CM code(s) have undergone a descriptor change: R40.2331, R40.2332, R40.2333, R40.2334. Documentation Requirement #4 updated with standard policy language.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; therefore, not all the fields included on the LCD are applicable as noted in this policy.</p> | |
| 03/08/2018 | R15 | <p>LCD revised and published on 03/08/2018 to remove Bill Type 21x as that Bill Type is not for inpatient services claims; and to add an asterisk to the Group 1 Medical Necessity ICD-10 Codes Asterisk Explanation area. Statement that physicians are to select the most appropriate diagnosis code as labs are not to prepopulate requisition forms with diagnosis codes relocated from the Group 1 and 2 Asterisk Explanation areas to the Group 1 and 2 Paragraphs.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; therefore, not all the fields included on the LCD are applicable as noted in this policy.</p> | <ul style="list-style-type: none"> • Provider Education/Guidance • Typographical Error |
| 02/08/2018 | R14 | <p>LCD revised and published on 02/08/2018 effective for dates of service on and after 11/07/2017 to remove the following CPT codes from Group 2 codes: 80159, 80171, 80173, 80183, 80184, 83789, 83992, 84999. These CPT codes for individual drugs have been removed as the HCPCS codes for definitive drug testing incorporate all classes of drugs.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; therefore, not all the fields included on the LCD are applicable as noted in this policy.</p> | <ul style="list-style-type: none"> • Other (Clarification) |
| 01/01/2018 | R13 | <p>LCD revised and published on 01/25/2018 effective for dates of service on and after 01/01/2018 to reflect the annual CPT/HCPCS code updates. For the following CPT/HCPCS codes either the short description and/or the long description was</p> | <ul style="list-style-type: none"> • Revisions Due To CPT/HCPCS Code Changes |

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION | REASON(S) FOR CHANGE |
|-----------------------|-------------------------|--|---|
| | | <p>changed: 80305, 80306, 80307. Depending on which description is used in this LCD there may not be any change in how the code displays in the document.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; therefore, not all the fields included on the LCD are applicable as noted in this policy.</p> | |
| 10/01/2017 | R12 | <p>LCD revised and published on 10/05/2017 effective for dates of service on and after 10/01/2017 to reflect the ICD-10 Annual Code Updates. The following ICD-10 code(s) have been added to Group 2 Codes: F10.11, F11.11, F12.11, F13.11, F14.11, F15.11, F16.11, F18.11, F19.11.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; therefore, not all the fields included on the LCD are applicable as noted in this policy.</p> | <ul style="list-style-type: none"> Revisions Due To ICD-10-CM Code Changes |
| 01/01/2017 | R11 | <p>LCD updated on 03/16/2017 to add HCPCS code G0659 to the CPT/HCPCS Group 2 list and to remove the following statement from the Group 2 Paragraph section: "Note: HCPCS code G0659 (Drug test def simple all cl) is hereby added to the Group 2 codes below effective for dates of service on or after 1/01/2017."</p> | <ul style="list-style-type: none"> Revisions Due To CPT/HCPCS Code Changes |
| 01/01/2017 | R10 | <p>LCD revised and published on 01/12/2017 effective for dates of service on and after 01/01/2017 to reflect the annual CPT/HCPCS code updates. The following CPT/HCPCS codes G0477, G0478, and G0479 have been deleted and therefore removed from group 1 of the LCD. The following CPT/HCPCS codes 80305, 80306, and 80307 have been added to group 1; CPT/HCPCS code G0659 has been added to group 2 of the LCD. For the following CPT/HCPCS codes either the short description and/or the long description was changed. Depending on which description is used in this LCD there may not be any change in how the code displays in the document: G0480, G0481, G0482, and G0483.</p> | <ul style="list-style-type: none"> Revisions Due To CPT/HCPCS Code Changes |
| 10/01/2016 | R9 | <p>LCD revised and published on 09/29/2016 effective for dates of service on and after 10/01/2016 to reflect the ICD-10</p> | <ul style="list-style-type: none"> Revisions Due To |

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION | REASON(S) FOR CHANGE |
|-----------------------|-------------------------|---|--|
| | | Annual Code Updates. The following ICD-10 codes have been deleted and therefore removed from the Group 2 list of the ICD-10 codes in the LCD: F32.8 and F34.8. The following ICD-10 codes have been added to the list of Group 1 diagnosis codes: R40.2410, R240.2411, R40.2412, R40.2413, R40.2414, R40.2420, R40.2421, R40.2422, R40.2423, R40.2424, R240.2430, R40.2431, R40.2432, R40.2433, R40.2434, R40.2440, R40.2441, R40.2442, R40.2443 and R40.2444. The following ICD-10 codes have been added to Group 2 diagnosis codes: F32.81, F32.89, F34.81, F34.89, R40.2410, R40.2411, R40.2412, R40.2413, R40.2414, R40.2420, R40.2421, R40.2422, R40.2423, R40.2424, R240.2430, R40.2431, R40.2432, R40.2433, R40.2434, R40.2440, R40.2441, R40.2442, R40.2443 and R40.2444. | ICD-10-CM Code Changes |
| 01/01/2016 | R8 | LCD revised and published on 02/19/16 effective for dates of service on or after 01/01/2016. New CPT/HCPCS codes added to the LCD on 12/31/15 in response to the 2016 annual CPT/HCPCS update have been placed into the appropriate CPT/HCPCS group 1 and group 2 coding sections. Language in CPT/HCPCS Group 1 Paragraph that was added on 12/31/15 has been deleted. Please refer to revision history R7 for detailed information regarding the code changes. | <ul style="list-style-type: none"> Revisions Due To CPT/HCPCS Code Changes |
| 12/31/2015 | R7 | 12/31/15 LCD revised to add the following ICD-10-CM codes to the ICD-10 code group 1 and group 2 as covered diagnoses: Z71.51*; Z91.120; Z91.128; Z91.130; Z91.138; Z91.14; Z91.19; Z79.891; Z79.899 effective for dates of service on and after 12/31/15. The following CPT/HCPCS codes have been added to the CPT/HCPCS code group 1 paragraph and will become group 1 codes effective for dates of service on or after 01/01/2016 to reflect the 2016 annual CPT/HCPCS update; G0477; G0478 and G0479. The following CPT/HCPCS codes will be deleted from the CPT/HCPCS code group 1 effective for dates of service on or after 01/01/2016 as a result of the 2016 annual code update; G0431 and G0434. The following CPT/HCPCS codes have been added to the group 1 paragraph and will become group 2 codes effective for dates of service on or after 01/01/2016 to reflect the 2016 annual CPT/HCPCS update; G04080; G0481; G0482 and G0483. The following CPT/HCPCS codes will be deleted from the CPT/HCPCS group 2 (currently listed in the group 1 paragraph) effective for dates of service on or after 01/01/2016 as a result of the 2016 annual code update; | <ul style="list-style-type: none"> Revisions Due To CPT/HCPCS Code Changes Other (Inquiry) |

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION | REASON(S) FOR CHANGE |
|-----------------------|-------------------------|---|--|
| | | G6030; G6031; G6032; G6034; G6036; G6037; G6040; G6041; G6042; G6043; G6044; G6045; G6046; G6048; G6051; G6052; G6053; G6056; G6057; G6058. | |
| 12/31/2015 | R6 | LCD posted for notice on 11/05/2015 to become effective 12/31/2015. 05/14/2015 Draft LCD posted for comment. | <ul style="list-style-type: none"> • Creation of Uniform LCDs With Other MAC Jurisdiction |
| 10/01/2015 | R5 | LCD revised and published 10/29/2015 to add additional ICD-10 codes with higher specificity effective for dates of service 10/01/2015 and after. | <ul style="list-style-type: none"> • Other (Clarification) |
| 10/01/2015 | R4 | LCD published 01/23/2015 to correct the publication date of the annual CPT/HCPCS code updates incorrectly listed as 01/22/2015 in revision history below. The code updates remain as listed in the revision history below. | <ul style="list-style-type: none"> • Typographical Error |
| 10/01/2015 | R3 | LCD revised and published on 01-22-2015 to reflect the annual CPT/HCPCS code updates. CPT/HCPCS codes 80100, 80101, and 80102 have been deleted and therefore have been removed from the LCD. | <ul style="list-style-type: none"> • Revisions Due To CPT/HCPCS Code Changes |
| 10/01/2015 | R2 | LCD revised and published on 09/11/2014 to add ICD-10 diagnosis code Z71.51 to the covered diagnosis listing with an asterisk. Asterisks added to diagnosis codes Z79.891 and Z79.899. Asterisk explanation paragraph inserted for the above diagnosis codes. | <ul style="list-style-type: none"> • Other (Clarification) |
| 10/01/2015 | R1 | LCD revised to accommodate provider commentary on the relationship between qualitative and quantitative methods of urine drug testing effective for dates of service on or after 10/01/2014 (LCD updated 06/06/2014) | <ul style="list-style-type: none"> • Reconsideration Request |

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A56645 - Billing and Coding: Controlled Substance Monitoring and Drugs of Abuse Testing

Related National Coverage Documents

NCD(s)

130.6 - Treatment of Drug Abuse (Chemical Dependency)

Public Version(s)

Updated on 10/11/2019 with effective dates 10/17/2019 - N/A

Updated on 06/21/2019 with effective dates 06/27/2019 - 10/16/2019

Updated on 10/19/2018 with effective dates 10/01/2018 - 06/26/2019

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Keywords

N/A