LCD L32050 - Qualitative Drug Testing

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Contractor Information

Contractor Name:	Contractor Number(s):	Contractor Type:
Novitas Solutions, Inc.	12102, 12202, 12302, 12501, 12301, 12201, 12401, 12402, 12101, 12502, 12901	MAC Part A & B

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LCD Information

Document Information

LCD ID Number

L32050

LCD Title

Qualitative Drug Testing

Contractor's Determination Number

L32050

AMA CPT/ADA CDT Copyright Statement

Primary Geographic Jurisdiction

Pennsylvania, Maryland, District of Columbia, New Jersey, Delaware

Oversight Region

Central Office

Original Determination Effective Date

For services performed on or after 11/11/2011

Original Determination Ending Date

N/A

Revision Effective Date

For services performed on or after 05/15/2012

Revision Ending Date

N/A

CMS National Coverage Policy

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.

Code of Federal Regulations (CFR) Title 42, Part 410.32 indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements) who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the

management of the beneficiary's specific medical problem. Tests not ordered by the physician (or other qualified non-physician provider) who is treating the beneficiary are not reasonable and necessary (see section 411.15 (k)(1) of this chapter).

Medicare regulations at 42 CFR 410.32(a) state in part, that "…diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." Thus, except where other uses have been authorized by statute, Medicare does not cover diagnostic testing used for routine screening or surveillance.

CMS Internet-Only Manual (IOM) Publication 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 130.6, Treatment of drug abuse

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

Indications and Limitations of Coverage and/or Medical Necessity

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

A qualitative 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 broad qualitative 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 qualitative testing. A qualitative test may be followed by confirmation with a second method, only if there is a positive inconsistent finding from the qualitative test in the setting of a symptomatic patient, as described below. Typically, the above "spot" chemical tests (referred to above) are urine dipsticks or multiple drug cup devices, which are coded via G0434, whereas G0431 comprises those chemical analyzers that are designed for office-based use. Techniques in the 80xxx series are most appropriately performed in independent laboratories where there is an adequate quality control infrastructure to guarantee the viability and proficiency of such quantitative confirmation testing.

Examples of drugs or classes of drugs that are commonly assayed by qualitative tests, followed by confirmation with a second method, are: alcohols, amphetamines, barbiturates/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.

Covered Indications:

"Although technology has provided the ability to measure many toxins, most toxicological diagnoses and therapeutic decisions are made based on historical or clinical considerations: (1) laboratory turnaround time can often be longer than the critical intervention time course of an overdose; (2) the cost and support of maintaining the instruments, staff training, and specialized labor involved in some analyses are prohibitive; (3) for many toxins there are no established cutoff levels of toxicity, making interpretation of the results difficult." "Although comprehensive screening is unlikely to affect emergency management, the results may assist the admitting physicians in evaluating the patient if the diagnosis remains unclear." Qualitative screening panels should be used when the results will alter patient management or disposition.(Richardson et al, 2007).

List of Indications:

1. A qualitative drug test may be indicated for a symptomatic patient when the history is unreliable, when there has been a suspected multiple-drug ingestion, to determine the cause of a patient in delirium or coma, or for the identification of specific drugs that may indicate when antagonists may be used. The clinical utility of drug tests in the emergency setting may be limited because patient management decisions are unaffected, since most therapy for drug poisonings is symptom directed and supportive.

2. Medicare will consider performance of a qualitative drug test reasonable and necessary when a patient presents with suspected drug overdose and one or more of the following conditions:

- 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.

3. A qualitative drug test may be reasonable and necessary for patients with known substance abuse or dependence, when the results of such testing may impact their ongoing treatment.

4. A qualitative drug test may be reasonable and necessary for patients with symptoms of schizophrenia suspected to be secondary to drug or substance intoxication.

5. A qualitative drug test may be reasonable and necessary for chronic pain patients:

- In whom other illicit drug use is suspected, when there has been an acute change in physical or mental status that meets the indications above.
- To demonstrate abnormal findings, including the presence or absence of prescribed drugs, presence of nonprescribed substances, detection of illicit substances and adulterated urine samples.

Drugs or drug classes for which testing is performed should reflect only those likely to be present, based on the patient's medical history or current clinical presentation. Drugs for which specimens are being tested must be indicated by the referring provider in a written order.

Confirmation of drug testing *(80102*) is indicated when the result of the drug test is different than that suggested by the patient's medical history, clinical presentation or patient's own statement AND there is a positive inconsistent finding from the previously performed qualitative test. This test may also be used, when the coverage criteria of the policy are met AND there is no qualitative test available, locally and/or commercially, as may be the case for certain synthetic or semi-synthetic opioids. Frequent use of this code will be monitored for appropriateness.

Limitations of Coverage:

It is considered not reasonable or necessary to test for the same drug with both a blood and a urine specimen simultaneously.

Drug screening for medico-legal purposes (e.g., court-ordered drug screening) or for employment purposes (e.g., as a pre-requisite for employment or as a requirement for continuation of employment) is not covered.

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Coding Information

Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

012x	Hospital Inpatient (Medicare Part B only)
013x	Hospital Outpatient
014x	Hospital - Laboratory Services Provided to Non-patients
021x	Skilled Nursing - Inpatient (Including Medicare Part A)
022x	Skilled Nursing - Inpatient (Medicare Part B only)
023x	Skilled Nursing - Outpatient
071x	Clinic - Rural Health
072x	Clinic - Hospital Based or Independent Renal Dialysis Center
073x	Clinic - Freestanding
077x	Clinic - Federally Qualified Health Center (FQHC)
085x	Critical Access Hospital

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.

0300	Laboratory - General Classification
0301	Laboratory - Chemistry
0309	Laboratory - Other Laboratory
0971	Professional Fees - Laboratory

CPT/HCPCS Codes

Italicized and/or quoted material is excerpted from the American Medical Association, *Current Procedural Terminology (CPT)* codes.

80102	DRUG CONFIRMATION, EACH PROCEDURE
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

The following CPT codes are Non-Covered by Medicare

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

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-9-CM code book appropriate to the year in which the service is

rendered for the claim(s) submitted.

NOTE: Report monitoring of patient compliance in a drug treatment program using V71.09 as the primary diagnosis and the specific drug dependence diagnosis as the secondary diagnosis.

Report monitoring of patients on methadone maintenance and monitoring of chronic pain patients with opioid dependence suspected of abusing other illicit drugs, using V58.69 as the primary diagnosis.

276.2	ACIDOSIS
295.00	SIMPLE TYPE SCHIZOPHRENIA UNSPECIFIED STATE
295.10	DISORGANIZED TYPE SCHIZOPHRENIA UNSPECIFIED STATE
295.20	CATATONIC TYPE SCHIZOPHRENIA UNSPECIFIED STATE
295.30	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	GENERALIZED CONVULSIVE EPILEPSY WITHOUT INTRACTABLE EPILEPSY
345.11	GENERALIZED CONVULSIVE EPILEPSY WITH INTRACTABLE EPILEPSY
345.3	GRAND MAL STATUS EPILEPTIC
345.90	EPILEPSY UNSPECIFIED WITHOUT INTRACTABLE EPILEPSY
345.91	EPILEPSY UNSPECIFIED WITH INTRACTABLE EPILEPSY
426.10	ATRIOVENTRICULAR BLOCK UNSPECIFIED
426.11	FIRST DEGREE ATRIOVENTRICULAR BLOCK
426.12	MOBITZ (TYPE) II ATRIOVENTRICULAR BLOCK
426.13	OTHER SECOND DEGREE ATRIOVENTRICULAR BLOCK
426.82	LONG QT SYNDROME

427.0	PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA
427.1	PAROXYSMAL VENTRICULAR TACHYCARDIA
780.01	COMA
780.09	ALTERATION OF CONSCIOUSNESS OTHER
780.1	HALLUCINATIONS
780.39	OTHER CONVULSIONS
780.97	ALTERED MENTAL STATUS
963.0	POISONING BY ANTIALLERGIC AND ANTIEMETIC DRUGS
965.00	POISONING BY OPIUM (ALKALOIDS) UNSPECIFIED
965.01	POISONING BY HEROIN
965.02	POISONING BY METHADONE
965.09	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	POISONING BY BARBITURATES
967.1	POISONING BY CHLORAL HYDRATE GROUP
967.2	POISONING BY PARALDEHYDE
967.3	POISONING BY BROMINE COMPOUNDS
967.4	POISONING BY METHAQUALONE COMPOUNDS
967.5	POISONING BY GLUTETHIMIDE GROUP
967.6	POISONING BY MIXED SEDATIVES NOT ELSEWHERE CLASSIFIED

967.8	POISONING BY OTHER SEDATIVES AND HYPNOTICS
967.9	POISONING BY UNSPECIFIED SEDATIVE OR HYPNOTIC
969.00	POISONING BY ANTIDEPRESSANT, UNSPECIFIED
969.01	POISONING BY MONOAMINE OXIDASE INHIBITORS
969.02	POISONING BY SELECTIVE SEROTONIN AND NOREPINEPHRINE REUPTAKE INHIBITORS
969.03	POISONING BY SELECTIVE SEROTONIN REUPTAKE INHIBITORS
969.04	POISONING BY TETRACYCLIC ANTIDEPRESSANTS
969.05	POISONING BY TRICYCLIC ANTIDEPRESSANTS
969.09	POISONING BY OTHER ANTIDEPRESSANTS
969.1	POISONING BY PHENOTHIAZINE-BASED TRANQUILIZERS
969.2	POISONING BY BUTYROPHENONE-BASED TRANQUILIZERS
969.3	POISONING BY OTHER ANTIPSYCHOTICS NEUROLEPTICS AND MAJOR TRANQUILIZERS
969.4	POISONING BY BENZODIAZEPINE-BASED TRANQUILIZERS
969.5	POISONING BY OTHER TRANQUILIZERS
969.6	POISONING BY PSYCHODYSLEPTICS (HALLUCINOGENS)
969.70	POISONING BY PSYCHOSTIMULANT, UNSPECIFIED
969.71	POISONING BY CAFFEINE
969.72	POISONING BY AMPHETAMINES
969.73	POISONING BY METHYLPHENIDATE
969.79	POISONING BY OTHER PSYCHOSTIMULANTS
969.8	POISONING BY OTHER SPECIFIED PSYCHOTROPIC AGENTS
969.9	POISONING BY UNSPECIFIED PSYCHOTROPIC AGENT
970.81	POISONING BY COCAINE
970.89	POISONING BY OTHER CENTRAL NERVOUS SYSTEM

	STIMULANTS
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

Diagnoses that Support Medical Necessity

Conditions that are listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

ICD-9 Codes that DO NOT Support Medical Necessity

All those not listed under the "ICD-9 Codes that Support Medical Necessity" section of this policy.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

Conditions that are not listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

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Other Information

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and 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 record must include the identity of the physician or non-physician practitioner responsible for and providing the care of the patient.
3. The submitted medical record should support the use of the selected ICD-9-CM code(s). The submitted CPT/HCPCS code should describe the service performed.
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 confirmatory test or a quantitative test is performed, the record must show that an inconsistent positive finding was noted on the qualitative testing or that there was no available, commercially or otherwise, qualitative test to evaluate the presence of a semi-synthetic or synthetic opioid in a patient who met the coverage criteria of this policy.
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 qualitative drug test. The physician must include the clinical indication/medical necessity in the order for the for the qualitative drug test.

Appendices

N/A

Utilization Guidelines

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

Sources of Information and Basis for Decision

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

AMA Report 2 of the Council on Science and Public Health I-08 Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction.

CDC Congressional Testimony. March 12, 2008. United States Senate Subcommittee on Crime & Drugs. Committee on the Judiciary and the Caucus on International Narcotics Control. 2009; Vol.58:42.

Chou R, Fanciullo GJ. Opioid Treatment Guidelines; Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. *The Journal of Pain*. Feb 2009 10(2): 113-130

Department of Health and Human Services. Morbidity and Mortality Weekly Report. Overdose deaths involving prescription opioids among enrollees- Washington, 2004-2007. Available at http://www.cdc.gov/mmwr/.

Federation of State Medical Boards of the United States. Model policy for the use of controlled substances for the treatment of pain. Available at http://www.fsmb.org/grpol_policydocs.html.

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http://www.toxicologyunit.com/drug_screen.htm retrieved from internet Septemper 2, 2009.

Jackman RP, Purvis JM. Chronic Nonmalignant Pain in Primary Care. *American Family Physician*. Nov 2008; 78(10): 1155-1162.

Melanson Stacy EF, Baskin LB. Interpretation and Utility of Drug of Abuse Immunoassays Lessons from Laboratory Drug Testing Surveys. *Arch Pathol Lab Med*. May 2010; 134: 736-739.

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

Nicholson B, Passik S. Management of chronic non-cancer pain in the primary care setting. *Southern Medical Journal* 2007;100(10)1028-1034.

Passik SD. Issues in long-term opioid therapy: unmet needs, risks, and solutions. *Mayo Clinic Proceedings*. July 2009;84(7):593-601.

Schneider J, Miller A. Urine drug tests in a private chronic pain practice (2008) *Practical Pain Management*. January/February 2008. Retrieved from http://www.tuft.edu/data/41/528854.pdf on Sept. 1, 2009.

Standridge JB, Adams SM. Urine Drug Screening: A Valuable Office Procedure. *American Family Physician*. March 1, 2010; 81(5):635-640.

Trescot AM, Standiford H. Opioids in the Management of Chronic Non-Cancer Pain: an update on American Society of the Interventional Pain Physicians' (ASIPP) guidelines. *Pain Physician* 2008;11:S5-S61 issn 1533-3159.

Other Contractor(s)' Policies

Novitas Solutions Contractor Medical Directors

Advisory Committee Meeting Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Directors. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from the appropriate specialty (ies).

CAC Distribution: 05/17/2011

Start Date of Comment Period

05/17/2011

End Date of Comment Period:

07/07/2011

Start Date of Notice Period

09/22/2011

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Revision History

Revision History Number

L32050

Revision History Explanation

Date	Policy #	Description
05/15/2012	L32050	LCD revised effective for dates of service on and after 01/27/2012 based on a reconsideration request to allow testing related to compliance and diversion when the results of such testing will used in the treatment of the patient. Diagnosis codes 304.01, 304.90, 305.90, 780.97, V15.81 and V58.69 added for coverage.
04/02/2012	L32050	LCD revised to reflect contractor name change from Highmark Medicare Services to Novitas Solutions, Inc.

09/22/2011	L32050	LCD revised to direct that CPT code *80100* is non-covered for Medicare. Final LCD re-posted for notice on 09/22/2011. LCD will become effective on 11/11/2011.
09/07/2011	L32050	Final LCD posted for notice on 09/07/2011. LCD will become effective on 10/27/2011
05/17/2011	DL32050	Draft LCD posted for comment.

Reason for Change

Other

Related Documents

This LCD has no related documents.

LCD Attachments

There are no attachments for this LCD.

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