# FUTURE DRAFT Local Coverage Determination (LCD) for Drugs of Abuse Testing (DL32597)


Please note: This is a Draft policy.
Draft LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Draft LCDs are not necessarily a reflection of the current policies or practices of the contractor.


Please note: This is a Future Draft LCD.

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## Contractor Information

Contractor Name
Palmetto GBA opens in new window

Contractor Number
01302

Contractor Type
MAC - Part B

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## LCD Information

Document Information



LCD ID Number
DL32597

LCD Title
Drugs of Abuse Testing

Contractor's Determination Number
J1B-12-0001

Primary Geographic Jurisdiction opens in new window
Nevada

Oversight Region
Region X

Original Determination Effective Date
For services performed on or after 11/26/2012

Original Determination Ending Date

Revision Effective Date

Revision Ending Date

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
Clinicians order qualitative drug screens to detect the presence of a drug in the body. Urine is the best source for broad qualitative drugs of abuse testing because blood is insensitive for common drugs such as psychotropic agents, opioids, and stimulants.

Clinical laboratories use enzyme immunoassays (EIA and IA), thin-layer chromatography, and spectrometry to perform qualitative drug analysis. Point-of-care providers use chemical "spot" tests, including dipstick, cassettes and cup methods, and bench-top (considered moderate complexity) enzyme immunoassays.

EIA and IA drug screening are limited by the potential for false positives and cross-reactivity. 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 necessary. 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.

Examples of drugs or drug classes that are commonly assayed by qualitative tests include, but are not limited to, the following: amphetamines (AMP), barbiturates/sedatives(BAR), benzodiazepines(BENZ), cocaine and metabolites (COC), cannabinoids(THC), methadone(METH), antihistamines, stimulants, opioid analgesics(OP), salicylates, cardiovascular drugs, antipsychotics, and cyclic antidepressants.

Qualitative drug testing depends on an individual patient's situation and must, according to this policy, be documented in the medical record. Documentation must follow current clinical guidelines and validated risk assessment, stratification, and monitoring tools. Prior to ordering a drug screen or a confirmatory drug test, the clinician should consider the following patient specific elements:

- history
- current treatment plan
- risk potential for abuse
- diversion of controlled medications

**Covered Indications:**

**I. Qualitative Drug Testing-** Medicare considers qualitative drug testing reasonable and necessary for:
**A.** The symptomatic patient suspected of multi-drug ingestion and/or unreliable history to determine the cause of:

- 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, or
- To provide antagonist to specific drug;

**B.** Testing neonates suspected of prenatal drug exposure;

**C.** Monitoring patient adherence and compliance during active treatment for substance abuse or dependence; and

**D.** Chronic pain management testing protocols for chronic opioid therapy(COT).

**Baseline Testing -** for evaluation of patients when they seek treatment involving controlled medication to identify the following situations:

a. Presence of illicit substances prior to initiating treatment involving controlled medications, and
b. Presence of illicit drugs

**Periodic Testing-**to monitor treatment plan compliance with a validated risk assessment, stratification, and monitoring protocol to document the following risk potential:

a. Abuse and diversion of controlled medications
b. Abuse of illicit drugs or drugs not prescribed as part of the treatment plan

The frequency of drug testing should be based in part on the assessed risk 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 require more frequent testing than chronic pain patients assessed at a lower risk. 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.

Patients with the following behaviors may require more frequent testing:

a. History of aberrant drug-related behaviors,
b. Psychiatric co-morbidities
c. History of substance abuse

**Targeted Testing -** to identify patients with the following suspicious noncompliance behaviors:

a. Documented aberrant drug-related or change in behavioral pattern,
b. Illicit drug use, or
c. Use of prescription drugs not included in the current treatment plan

**Frequency of Drug Testing Based on Validated Risk Assessment**

| Risk Group | Baseline | Risk Level Testing | Targeted Testing |
|---|---|---|---|
| Low Risk | Prior To Initiation of COT | Every 6 months | On documented evidence or suspicion of aberrant drug-related behavior |
| Moderage Risk | Prior To Initiation of COT | Every 3 months | On documented evidence or suspicion of aberrant drug-related behavior |
| High Risk | Prior To Initiation of COT | Regularly, but not necessarily every drug at every visit | On documented evidence or suspicion of aberrant drug-related behavior |

**II. Confirmatory and/or Quantitative Drug Testing** Medicare considers confirmatory and/or quantitative drug testing reasonable and necessary when the results of a qualitative screen are:
**A.** 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:** Palmetto GBA considers the need for cocaine confirmation to be rare but appropriate to identify the patient is a chronic cocaine user.

**Exception 2:** Palmetto GBA considers the need for THC confirmation to be rare but appropriate to document that the patient is in the process to discontinue THC use.

**B.** Presumptive positive for stimulant (amphetamine), barbiturate and benzodiazepine class of drugs.

**Note:** Point-of-care drug testing can not differentiate all the drugs in the stimulant (amphetamine), barbiturate and benzodiazepine class of drugs. A positive qualitative screen requires mandatory confirmation.

**C.** Negative screen, and the negative finding is inconsistent with the patient's medical history or current documented chronic pain medication list;

**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. Automatic confirmatory testing for Fentanyl and Meperdine are not reasonable and necessary without patient specific indications.

**Note:** When the initial screen is negative, Palmetto GBA 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.

**D.** 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

**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. Drugs for which specimens are being tested must be indicated by the referring provider in a written order.

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 drugs screens with negative results is 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 drug screening
- Test for the same drug(s) using a blood and a urine specimen at the same time.

- 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 test sources such as saliva, oral fluids, and hair.

**Additional Information:**

**Parent Drug with Possible Urine Drug/Metabolites**

| Drug Used | Possible Results |
|---|---|
| Heroin | 6 MAM (monoacetylmorphine) only (<24 hours)<br>Morphine only<br>Codeine & morphine<br>6 MAM, morphine & codeine |
| Codeine<br>ex. Tylenol w/codeine&reg | Codeine only<br>Codeine & morphine<br>Morphine only<br>Hydrocodone (trace) when high concentration<br>of codeine present |
| Morphine<br>ex. Avinzo&reg<br>Embedda&reg<br>Kodine&reg<br>MSIR&reg<br>MS Contia&reg<br>Roxanol&reg | Morphine<br>Hydrocodone (trace) only when morphine<br>present |
| Hydrocodone<br>ex. Lorcet&reg<br>Lortab&reg<br>Norco&reg<br>Vicodin&reg<br>Vicoprofen&reg | Hydrocodone only<br>Hydromorphone only<br>Dydrocodone & hydromorphone |
| Hydromorphone<br>ex. Dilaudid&reg | Hydromorphone only |
| Oxycodone<br>ex. Oxycontin&reg<br>Oxylr&reg<br>Percocet&reg<br>Percodan&reg<br>Roxicodone&reg<br>Tylox&reg | Oxycodone only<br>Oxymorphone only<br>Oxycodone & morphone |
| Oxymorphone<br>ex. Numorphan&reg | Oxymorphone |

| Drug Used | Possible Results |
|---|---|
| Opana ER&reg<br>Opana IR&reg | |
| Carisoprodol<br>ex. CarisSoma&reg<br>Soma&reg<br>Somadril&reg | Meproamate |
| Methadone<br>ex. Dolophine&reg | EDDP (2-ethylidine-1, 5dimethyl-3, 3-diphenylpyrrolidine) |

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# Coding Information

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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.

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.

CPT/HCPCS Codes
GroupName
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 |

GroupName

**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
Note: ICD-9 codes must be coded to the highest level of specificity.

**80102, G0431, G0434**

| | |
|---|---|
| 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 |

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

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

Diagnoses that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

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

Diagnoses that DO NOT Support Medical Necessity

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# General Information


Documentations 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
- The physician shall discuss the risks and benefits of the use of controlled substances with the patient or patient's surrogate. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician must employ the use of a written agreement between the physician and the patient outlining patient responsibilities, including but not limited to:
    - Urine/serum medication levels screening when requested
    - Number and frequency of all prescription refills, and
    - Reasons for which drug therapy may be discontinued (ie: violation of agreement)
- The physician must use a CLIA-waived point-of-care test or CLIA-approved test (FDA cleared/approved) that uses a device to measure pH, specific gravity and temperature. Results of the drug test must be read according to the manufacturer's instructions.
- Patient drug testing must be conducted and reviewed prior to the initial issuance or dispensing of a controlled substance prescription, and thereafter on a random basis at least twice a year or when requested by the treating physician
- Physicians 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. Multiple ICD-9/ICD-10 codes should be used to justify testing of multiple drug classes.

5. 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.

Appendices

Utilization Guidelines

Sources of Information and Basis for Decision

1. 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.
http://www.ama-assn.org/resources/doc/csaph/csaph2i08.pdf

2. Centers for Disease Control and Prevention. Unintentional Drug Poisoning in the United States. July 2010.
http://www.cdc.gov/HomeandRecreationalSafety/pdf/poison-issue-brief.pdf

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

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

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

6. Gourlay DL, Heit HA,Caplan YH. Urine Drug testing in Clinical Practice. http://www.familydocs.org/files/UDTMonograph_for_web.pdf

7. Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain: An educational aid to improve care and safety with opioid therapy 2010 Update;
http://www.agencymeddirectors.wa.gov/Files/OpioidGdline.pdf

8. Institute for Clinical Systems Improvement (ICSI). Guideline for the assessment and management of chronic pain. November 2011. http://www.icsi.org/pain__chronic__assessment_and_management_of_14399/pain__chronic__assessment_and_management_of__guideline_.html

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12. Michna E,Jamison RN, Pham LD, et al. Urine toxicology screening among chronic pain patients of opioid therapy: frequency and predictability of abnormal findings. *Clin J Pain.* 2007;23(2):173-179

13. Moore TM, Jones T, Browder JH, Daffron S, Passik ST. A comparison of common screening methods for predicting aberrant drug-related behavior among patients receiving opioids for chronic pain management. Pain Med. Nov 2009;10:1426-1433.

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15. Nicholson B, Passik SD. Management of chronic non-cancer pain in the primary care setting. SMJ 2007;100(10):1028-1034.

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

17. Passik SD, Kirsh KL, Casper D. Addiction-related assessment tools and pain management: instruments for screening, treatment planning and monitoring compliance. *Pain Med.* 2008;9:S145-S166.

18. Schneider J, Miller A. Urine drug tests in a private chronic pain practice. *PPM.* January/February 2008. http://www.tuft.edu/data/41/528854.pdf.

19. Standridge JB, Adams SM. Urine drug screening: a valuable office procedure. *American Family Physician.* 2010;81(5):635-640.

20. Trescot AM, Standiford H,Hansen Hans, et al. Opioids in the management of chronic non-cancer pain: an update on American Society of the Interventional Pain Physicians' (ASIPP) guidelines. *AFP.* 2008;11:S5-S61.

21. Other CMS Contractor LCD - J11 B DL32552.
Advisory Committee Meeting Notes Advisory Committee Meeting Notes

This policy does not reflect the sole opinion of the contractor or

Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which include representatives from the affected provider community.

Contractor Advisory Committee meeting dates:
Hawaii: 07/13/2012
California: 07/18/2012
Nevada: 7/19/2012

Start Date of Comment Period 07/13/2012

End Date of Comment Period 09/04/2012

Start Date of Notice Period

Revision History Number

Revision History Explanation

Reason for Change Coverage Change (actual change in medical parameters)
Other

Related Documents
This LCD has no Related Documents.

LCD Attachments
There are no attachments for this LCD.

Draft Contact
Nita Collins
J1B.Policy@Palmettogba.com
Columbia, SC 29202
Nita.Collins@Palmettogba.com
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# All Versions

Updated on 06/08/2012 with effective dates 11/26/2012 - N/A
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