Comments

LCD Title
Qualitative Drug Testing

LCD Database ID Number
L32450

Contractor's Determination Number
PATH - 035

Note: The majority of comments received on this draft were related to the omission of overall coverage for patient monitoring of patients with chronic pain, patients abusing pain medications or other drugs. In short the policy did not reflect current practice guidelines. We have put together one response to all the comments at the end of the document..

1. Comment
It looks like if patients wish to continue with chronic opiate therapy, they will need to pay for the random urine screening out of pocket. In my experience, physicians are not ordering random urine testing enough. What this rule says is that we need to first accuse our patients of illicit behavior before ordering the test. Not the best for maintaining a therapeutic relationship. This rule will not have an impact on how I manage patients. Fortunately, most of my chronic opiate patients are at the VA which saves money by limiting the opiate formulary, not by interfering with the management of patients. Hopefully patients will push back against this as much as physicians. You are making physicians decide between accusing patients of illicit behavior and documenting it in the medical record vs. making the patient pay out of pocket to avoid having something of that nature placed in their record. Dumb idea!!

2. Comment
I have reviewed the DRAFT LCD and believe I have an ethical and professional responsibility to point out what I believe is a very serious disconnect between the medical necessity boundaries set forth in the DRAFT LCD and the current clinical and regulatory standards pertaining to drug screening in chronic pain management. Specifically, based on the resources I cite below, I am very concerned that the disconnect may increase the potential for my legal liability, present a threat to patient and public safety, and threaten my license to practice - all because the DRAFT LCD currently prevents me from offering the level of care to my patients as contemplated by the prevailing practice standards in my state.

The DRAFT LCD also seems to ignore recommendations for more risk assessment and patient monitoring, to include drug screening, as set forth in various recent publications citing growing abuse and diversion problems in the United States. For example, in November 2011, the Centers for Disease Control (CDC) published its newsletter, *Vital Signs*, wherein the CDC labels the problem of prescription drug abuse and diversion as a public health epidemic, stating:

“Deaths from prescription painkillers* have reached epidemic levels in the past decade. The number of overdose deaths is now greater than those of deaths from heroin and cocaine combined.” 1
The CDC’s article also contains suggestions about the steps health care providers can take to address the problem:

Health care providers can follow guidelines for responsible pain killer prescribing, including . . . Using patient-provider agreements *combined with urine drug tests for people using prescription painkillers long term*.2

I am most concerned by the fact that the DRAFT LCD proposes to limit coverage for qualitative drug testing to situations where the physician can document:
(1) *His/her suspicion that the patient is abusing drugs*, **AND**
(2) Specific findings that the patient is symptomatic in one of several ways defined by the DRAFT LCD**.3**

The current clinical or regulatory standard contain no such requirements, and thus illustrate a material disconnect as I cited above. Quite significantly, the DRAFT LCD overlooks the recognized clinical utility of baseline drug-testing of new patients in a chronic pain management setting; it likewise overlooks the need for the routine use of randomized drug testing of chronic pain patients based on patient risk levels (low, moderate, high risk) as contemplated by the clinical literature and developing body of state licensing board guidelines and rules. Moreover, the DRAFT LCD does not recognize drug testing for compliance or to help practitioners identify diversion, despite the fact that the literature cited herein recognizes the need for compliance testing and targeted testing to help the clinician make decisions about abuse, addiction, and diversion. In fact, the DRAFT LCD clearly rejects testing for these reasons, stating that Medicare does not cover or reimburse drug screening for, among other reasons, . . . patient compliance purposes, identifying diversion, or in asymptomatic patients." The DRAFT LCD is overly restrictive, placing the physician in the position where he/she cannot comply with generally accepted clinical and regulatory standards. The DRAFT LCD also represents a departure from final LCDs published by National Government Services and First Coast Service Options. 4 This makes no sense in light of a recent Report published by the Government Accountability Office (GAO) Identify Diversion in Medicare Part D.5

The GAO Report on Diversion in Medicare Part D makes clear: "prescription drug abuse is a serious and growing public health problem." Citing the CDC, the GAO report notes: "drug overdoses, including those from prescription drugs, are the second leading cause of deaths from unintentional injuries in the United States, exceeded only by motor vehicle fatalities. *Unlike addiction to heroin and other drugs that have no accepted medical use, addiction to some controlled substances can be unknowingly financed by insurance companies and public programs, such as MedicarePart D.*"

The GAO's analysis found that about 170,000 Medicare beneficiaries received prescriptions from five or more medical practitioners for the 12 classes of frequently abused controlled substances and 2 classes of frequently abused non-controlled substances in calendar year 2008. The GAO obtained additional information on 10 of the Medicare Part D beneficiaries that showed indications of doctor shopping. In each of the 10 cases, the GAO found evidence that the beneficiary was acquiring highly abused drugs through doctor shopping. The GAO Report refers to the CMS requirement that Part D plans perform retrospective drug utilization review (DUR) analysis to identify prior inappropriate or unnecessary medication use and provide education, such as alert letters, to the prescribers involved. The GAO believes that drug plans can identify individuals who are likely obtaining excessive amounts of highly abused drugs or potentially seeking such drugs from multiple medical practitioners. However, the GAO found that according to CMS Part D program officials, *federal law does not authorize Part D plans to restrict the access of these individuals, leaving little recourse for preventing known doctor shoppers from obtaining hydrocodone, oxycodone, and other highly abused drugs.*

The GAO thus recommended that the Administrator of CMS should review its findings, evaluate the existing DUR program, and consider additional steps, such as a restricted recipient program for Medicare Part D that would limit identified doctor shoppers to one prescriber, one pharmacy, or both for receiving prescriptions. While the GAO did not mention drug testing specifically, it is clear that drug testing is a viable step to guard against drug abuse, accidental poisoning, and diversion. In fact, it may be more expedient to use drug testing and state prescription drug monitoring profiles than to engage in a massive doctor shopping analysis based on DUR.
The DRAFT LCD also represents a serious departure from mainstream clinical literature specifically relating to drug testing in pain management, and the most recent opioid guidelines developed in connection with seven state agency medical directors, including the state's Medicaid program. See respectively, Gourlay et al, *Drug Testing in ClinicalPractice*6 and the Washington State Agency Medical Directors Group (AMDG) and the 2010 Opioid Guidelines. (AMDG Opioid Guidelines).7

A fair reading of both the drug testing monograph and the AMDG Opioid Guidelines is that drug testing in clinical practice is expected (1) at baseline during initial patient evaluation and risk assessment, (2) in a random fashion based on the patient's initial risk assessment level, and (3) as needed to address aberrant drug-related behaviors to determine compliance with the treatment plan, to ensure patient safety, and to guard against prescription drug abuse and diversion. The AMDG Opioid Guidelines summarizes these points as follows:

Urine drug testing (UDT)
The purpose of drug testing is to identify aberrant behavior, undisclosed drug use and/or abuse, and verify compliance with treatment. When used with an appropriate level of understanding, UDT can improve the prescriber's ability to safely and appropriately manage opioid therapy (see Appendix D – Using Urine Drug Testing to Monitor Opioid Therapy for Chronic Non-cancer Pain).
Urine drug testing is an important part of the baseline risk assessment, which prescribers should perform on all candidates for chronic opioid therapy (see Before you decide to prescribe opioids for chronic pain, page 5).

This baseline UDT should be performed on all transferring patients who are already using opioids and for those patients who you are considering for chronic opioid therapy (e.g. 3rd opioid prescription or >6 weeks after an acute injury). Prior to testing, the prescriber should inform the patient of the reason for testing, the expectation of random repeat testing and consequences of unexpected results. This gives the patient an opportunity to disclose drug use and allows the prescriber to modify drug testing for the individual's circumstances and more accurately interpret the results.
After opioid therapy has been initiated, the prescriber should randomly repeat testing at the approximate frequency determined by the patient's risk category based on the ORT or similar screening tools (see Table 2).

Although UDT and other screening tools are helpful in identifying aberrant behavior, it is also important for prescribers to use their clinical judgment in the development of a monitoring plan. Information from third parties, such as family and friends, can be helpful in evaluating behavior. Opioid prescribing should be avoided in patients with active alcohol or other substance abuse. Extreme caution should be used, and a consultation with an addiction specialist is strongly encouraged, prior to prescribing opioids for patients with a history of alcohol or other substance abuse.8
I recommend that the DRAFT LCD committee review the AMDG Opioid Guidelines, including the AMDG's Table on Urine Drug Testing and corresponding general algorithm for testing. 9

The DRAFT LCD fails to reference any of this current literature and fails to take into account recent revisions to the existing NGS LCD (#L 28145) that state qualitative drug screening is medically necessary and reasonable when:
(1) The patient is in pain management and the provider has a suspicion that the patient is misusing controlled substances;
(2) *The patient belongs to a select population that has a significant pre-test probability of drug interactions and side effects, such as those patients using multiple medications as part of their pain management treatment plan and to manage their combined health conditions*;

(3) T*here is a significant pre-test probability of non-adherence to the prescribed drug regimen as documented in the patient's medical record, such as in the instance of a new patient, a patient with a history of substance abuse,and a patient whose past interactions with this office have revealed one or more aberrant, drug-related behaviors as listed in clinical guidelines*; and/
or
(4) The patient is under treatment for substance abuse and the provider has a suspicion of continued substance abuse, such as when the patient is involved in the office-based treatment of opioid addiction through a Suboxone program.

The DRAFT LCD also limits use of confirmation and quantitative testing and once again presents a serious challenge to the practitioner who must verify that his/her patient's are in fact taking the medications prescribed to him/her. The clinical literature shows that drug testing is one of the more reliable ways to determine compliance with a treatment protocol and, while not 100% indicative of compliance, healthcare practitioners need to utilize confirmation and quantitative testing to differentiate and identify semi-synthetic and synthetic opioids as well as amongst the various benzodiazepines and other drugs that are only initially tested in a class rather than as a specific, individual drug at the point of care. The DRAFT LCD limits confirmation and quantitative testing to circumstances where
(1) 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
(2) there is a positive inconsistent finding *from the previously performed qualitative test*. This makes no sense because it fails to understand the realities of patient risk assessment and monitoring, as indicated in the cited resources.

I understand that Medicare does not cover diagnostic testing used for routine screening or medical surveillance. However, WPS's decision to limit coverage on qualitative drug testing to situations where a practitioner "suspects illicit drug use" in a chronic pain patient **AND** can point to (and document) an acute change in the patient's physical or mental status meeting one or more of the following conditions, appears to ignore the fact that there is a prescription drug abuse and diversion epidemic in our country, doctor shopping problems in Medicare Part D programs. Consequently, as written, the DRAFT LCD may actually contribute to the ongoing prescription drug abuse and diversion problem rather than enable physicians to take steps to minimize it and more safely treat patients with controlled medications.
The role of drug testing in pain management is to help pain practitioners ensure patient safety, detect abuse and diversion, as well as determine proper care, treatment options, and patient compliance with the treatment plan. Without it, practitioners will face yet another significant barrier in treating pain and minimizing the prescription drug abuse and diversion problem plaguing the nation. The use of in office drug screening and confirmatory testing by an outside laboratory is absolutely crucial to the safe and judicious practice of pain management.
I respectfully request that your enter my comments into the record for the DRAFT LCD and consider making changes to it based on the materials cited herein.

References:

1 CDC *Vital Signs*, Nov. 2011, available online at http://www.cdc.gov/vitalsigns.

2 CDC *Vital Sign*s, Nov. 2011.

3 The DRAFT LCD #DL32450 suggests one of five possible symptoms qualifying the patient under the second part of its medical necessity requirement: (1) unexplained coma, (2) unexplained altered mental status in the absence of a clinically defined toxic syndrome or toxidrome, (3) severe or unexplained cardiovascular instability (cardiotoxicity), (4) unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome, or (5) seizures with an undetermined history.

4 National Government Services (NGS) LCD L28145 and First Coast Service Options (FCSO) LCD L30574.

5 Government Accountability Office, Testimony Before the Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security, Committee on Homeland Security
and Governmental Affairs, U.S. Senate, MEDICARE PART D Instances of Questionable Access to Prescription Drugs, Statement of Gregory D. Kutz Director, Forensic Audits and Special Investigations, Released October 4, 2011. GAO-11-699.

6 Gourlay, D. et al, *Urine Drug Testing in Clinical Practice*, 4th Ed. (2010), CME accredited monograph available online at
http://issuu.com/cafamilydocs/docs/udtmonograph.
The needs statement for this monograph contains the following information: This document is designed to provide clinicians with an understanding of the appropriate uses of UDT in clinical practice, *with a primary goal of using UDT as a tool to improve the clinical care and outcomes for patients, especially those who are prescribed chronic opioids or other controlled substances as a part of their routine clinical care, and to assist in interpretation of clinical conundrum*s.

7 AMDG Opioid Guidelines available online at http://www.agencymeddirectors.wa.gov/.
State health officials and actively practicing physicians who specialize in pain management developed the guideline. Boards and commissions that set practice standards reviewed the guideline. The workgroup also received input from others in state government and the medical and scientific community. The Agency Medical Directors‘ Group (AMDG) that sponsored this guideline consists of the medical directors of five Washington State agencies: Corrections, Health, Health Care Authority, Labor and Industries, **and the state‘s Medicaid program**.

8 AMDG Opioid Guidelines (2010), available online at
http://www.agencymeddirectors.wa.gov/.

9 AMDG Opioid Guidelines (2010), available online at
http://www.agencymeddirectors.wa.gov/default.asp.

3. Comment

There is substantial clinical evidence to support coverage which we will be happy to provide. In fact, our legacy contractor has recently issued a revised policy
expanding coverage for a qualitative drug screen in patients on chronic opioid therapy:

- in whom illicit drug use, non-compliance or a significant pre-test probability of nonadherence to the prescribed drug regimen is suspected and documented in the medical record
- In those that are at high risk for medication abuse due to psychiatric issues, who have engaged in aberrant drug-related behaviors, or who have a history of substance abuse

4. Comment

Our clinic has a policy that all patients receiving chronic narcotics have to have a pain contract; part of this pain contract states they agree to have qualitative drug testing when requested by physician, but has to have one at least once a year. This is done to ensure; 1) that we detect the presence of the prescribed drug (so we know they are taking it and not diverting); and 2) that no other illicit drugs are present.

My question is: on page 3 of the policy it is stated the test may be "reasonable and necessary for chronic pain patients in whom other illicit drug use is suspected, when there has been a acute change in physical or mental status that meets the indications above".

It seems that the pain contract requiring test is a reaonable use of the test, but it is not clearly authorized in the above statement.

5. Comment

Urine drug testing is an important component of adherence monitoring for my patients on opioid therapy for chronic pain; ensuring access to this tool is critical. As part of my treatment of patients suffering from chronic pain, I routinely use qualitative drug testing to ensure that patients are taking their prescribed pain medications, avoiding drugs that may cause dangerous interactions, and not diverting their drugs. My ability to effectively monitor these patients would be significantly limited if I were unable to use UDT.

6. Comment

This is indeed a nation-wide problem and we have been discussing it at our American Society of Interventional Pain Physicians (ASIPP) board meetings.

Urine tox screens have become more widespread because there is a U.S. epidemic of prescription opioid abuse, diversion and overdose deaths. As pain docs, we really only have two available tools to combat this – the states' prescription monitoring database (facilitated by NASPER legislation 2005) and urine drug screening. Unfortunately, it seems that a few bad apples have abused billing which now threatens to derail the good medical practice of drug screening patients on chronic opioids. I have attached a PDF with some slides which outline the problem from a PowerPoint I give on addiction issues in the pain clinic.

My brief take on the proposed LCD as written, is that it would prevent pain specialists (and other prescribing physicians) from drug testing their patients unless there is clear evidence for addiction. But many of these abusing or diverting patients are quite sophisticated and do not appear to be addicted. We had a nice elderly couple in our pain clinic that we discovered was selling our prescribed opioids to neighborhood teenagers!

Ideally the LCD would be written with fraud and abuse safeguards while allowing doctors who are prescribing chronic opioids to urine drug screen their patients at initiation of therapy and perhaps two or three times per year (randomly) thereafter. Along these lines, I have heard that Florida passed legislation mandating urine drug testing for chronic opioid patients.

7. Comments

Comments from CAP Toxicology and Chemistry Resource Committees

I. Indications and Limitations of Coverage and/or Medical Necessity

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.

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.

A. 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).

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.

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.

A qualitative drug test may be reasonable and necessary for patients with known substance abuse or dependence, only when the clinical presentation has changed unexpectedly and one of the above indications is met.

A qualitative drug test may be reasonable and necessary for patients with symptoms of schizophrenia suspected to be secondary to drug or substance intoxication. These diagnoses will be covered in the inpatient facility setting only.

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.

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.

Is it feasible to require the referring provider (I assume this means the ordering physician) to list drugs to be tested in a written order? Most labs have non-flexible panels with certain drugs to be tested—is it sufficient to just order the panel or does the physician have to specify individual drugs/classes. I'm ok with the wording if the implication is that by ordering an available panel the criteria above is met.

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.

In general, covered indications appear appropriate, but should be expanded to include, among other things, testing on neonates suspected of prenatal drug exposure. For the case of "chronic pain patients in whom other illicit drug use is suspected" above, routine testing to (initially) qualify a patient for opioid therapy and to (periodically) evaluate compliance with the therapeutic management plan for a patient is described in state and national practice guidelines, and within the FDA's REMS (risk evaluation and mitigation strategies). Currently the WPS Medicare document states that such testing is only indicated for "patients in whom other illicit drug use is suspected, when there has been an acute change in physical or mental status…" This is not consistent with current guidelines. That said, current guidelines are not as specific as they should be. WPS Medicare would likely want to impose limits on the frequency of such testing. Many pain clinics mandate testing with every office visit; others establish testing frequency based on the patient risk (e.g. SOAPP risk assessment tool) of aberrant behavior (e.g., monthly for high risk patients, quarterly for moderate risk patients, annually for low risk patients). WPS Medicare would also want to impose limits on the confirmation testing. Qualitative screens are inadequate for interpretation of opiate and benzodiazepine results; quantitative testing is required. As such, confirmation testing should also be covered, when medially indicated. However, confirmation testing is usually not required for drugs like methadone, wherein false positive results are rare.

B. Coverage Limitations

It is considered not reasonable or necessary to test for the same drug with both a blood and a urine specimen simultaneously.
Similarly, testing or confirmation of any drug using CPT codes *80150* through *80299* or *82000-84999* is governed by the coverage statements outlined in this policy.
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. Drug screening for compliance purposes, diversion, or in asymptomatic patients is not covered under the Program. This determination applies also to CPT codes *80102, 80150* through *80299* and *82000-84999*.

Coverage limitations generally appear appropriate.

II. CPT/HCPCS 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

III. ICD-9 Codes that Support Medical Necessity

List of Diagnoses for 80102, G0431, G0434

276.2	ACIDOSIS
295.00 - 295.30	SIMPLE TYPE SCHIZOPHRENIA UNSPECIFIED STATE - PARANOID TYPE SCHIZOPHRENIA UNSPECIFIED STATE
345.10 - 345.11	GENERALIZED CONVULSIVE EPILEPSY WITHOUT INTRACTABLE EPILEPSY - GENERALIZED CONVULSIVE EPILEPSY WITH INTRACTABLE EPILEPSY
345.3	GRAND MAL STATUS EPILEPTIC
345.90 - 345.91	EPILEPSY UNSPECIFIED WITHOUT INTRACTABLE EPILEPSY - EPILEPSY UNSPECIFIED WITH INTRACTABLE EPILEPSY
426.10 - 426.13	ATRIOVENTRICULAR BLOCK UNSPECIFIED - OTHER SECOND DEGREE ATRIOVENTRICULAR BLOCK
426.82	LONG QT SYNDROME
427.0 - 427.1	PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA - PAROXYSMAL VENTRICULAR TACHYCARDIA
780.01	COMA

780.09	ALTERATION OF CONSCIOUSNESS OTHER
780.1	HALLUCINATIONS
780.39	OTHER CONVULSIONS
963.0	POISONING BY ANTIALLERGIC AND ANTIEMETIC DRUGS
965.00 - 965.09	POISONING BY OPIUM (ALKALOIDS) UNSPECIFIED - POISONING BY OTHER OPIATES AND RELATED NARCOTICS
965.1	POISONING BY SALICYLATES
965.4	POISONING BY AROMATIC ANALGESICS NOT ELSEWHERE CLASSIFIED
965.5	POISONING BY PYRAZOLE DERIVATIVES
965.61	POISONING BY PROPIONIC ACID DERIVATIVES
966.1	POISONING BY HYDANTOIN DERIVATIVES
967.0 - 967.9	POISONING BY BARBITURATES - POISONING BY UNSPECIFIED SEDATIVE OR HYPNOTIC
969.00 - 969.9	POISONING BY ANTIDEPRESSANT, UNSPECIFIED - POISONING BY UNSPECIFIED PSYCHOTROPIC AGENT
972.1	POISONING BY CARDIOTONIC GLYCOSIDES AND DRUGS OF SIMILAR ACTION
977.9	POISONING BY UNSPECIFIED DRUG OR MEDICINAL SUBSTANCE
V58.69	**LONG TERM (CURRENT) USE OF OTHER MEDICATIONS**
V71.09	**OBSERVATION OF OTHER SUSPECTED MENTAL CONDITION**

Patients receiving opioids and other analgesics for chronic non-cancer pain should be monitored by qualitative screening for possible illicit drug use or substitution when a change of symptoms or behavior indicates. Recommend adding V58.69 for monitoring of patients on methadone maintenance and chronic pain patients with opioid dependence, suspected of abusing other illicit drugs, and V71.09 for monitoring of patient compliance in a drug treatment program.

Reference: Hammet-Stabler CA, Magnani B, "Supporting the Pain Service", chapter 3 in Magnani B, Bissell MG, Kwong TC, Wu AHB. Clinical Toxicology Testing: A Guide for Laboratory Professionals 2012, CAP Press, Northfield IL, pp. 15-26.

8. Comment

Under the covered indications the sentences should read
A qualitative drug test may be reasonable and necessary for patients with known substance abuse or dependence, **or patients with chronic usage or the usage of opiods with chronic pain**

A qualitative drug test may be reasonable and necessary for patients with symptoms of schizophrenia suspected to be secondary to drug or substance intoxication. **Remove the statement that these diagnosis will be paid in the inpatient facility only.**

A qualitative drug test may be reasonable and necessary for chronic pain patients in whom other illicit drug use is suspected**~ Both compliance and suspected drug use should be included**

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.

Random infrequent drug screens should be part of the treatment regimen for most patients taking opioids.

A qualitative drug test may be indicated in the emergency department setting for patients presenting with agitation, confusion, altered mental status, intoxication, delirium, hallucinations, nonspecific weakness, inability to care for self.

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.
Similarly, testing or confirmation of any drug using CPT codes *80150* through *80299* or *82000-84999* is governed by the coverage statements outlined in this policy.
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. Remove this sentence "Drug screening for compliance purposes, diversion, or in asymptomatic patients is not covered under the Program."**
This determination applies also to CPT codes *80102, 80150* through *80299*and *82000-84999*.

Add the following under
ICD-9 Codes that Support Medical Necessity

Low blood pressure
Failed back syndrome
Neck spondylosis
Thoracic spondylosis
Reflex sympathetic dystrophy RSD
Osteoarthritis
Chronic Abdominal pain
Agitation

9. Comment
I suggest that the second to last sentence under the Limitations of coverage be removed. The sentence "Drug screening for compliance purposes, diversion, or in asymptomatic patients is not covered under the Program" does not seem appropriate.

10 Comment
Urine drug screening is an important part in a lot of pain practices. The points you made about first of all verifying they are taking their medications are true. You mentioned screening for addicted patients to be sure they are not taking anything else and I want to be sure that is not to tightly written. We don't consider the chronic pain patient to be an addict. Yet, we want to be sure they can be tested to be sure they are taking their medications for their three failed back surgeries and don't have additional drugs in their urine.

11. Comment
I am writing to express my concern with the draft Local Coverage Determination (LCD) DL32450 entitled Qualitative Drug Testing. Urine drug testing is an important component of adherence monitoring for my patients on opioid therapy for chronic pain to ensure that they are

taking their pain medications appropriately, avoiding dangerous drug interactions, not diverting their drugs to others, and achieving the intended pain relief. The draft LCD as written puts restrictions on the use of qualitative drug testing that will deprive me of an important tool for monitoring medication adherence. I strongly urge you to revise the draft LCD to cover all medically necessary qualitative drug monitoring tests for patients with chronic pain including for compliance purposes and diversion.

Millions of Americans suffer from debilitating chronic pain. Appropriate use of pain medications, including opiods, often provides patients with the relief they need to lead productive lives. Unfortunately, the use of prescription pain medication is associated with an increased risk for drug abuse, addiction, diversion and overdose in chronic pain patients. Thus, adherence to the plan of care is central to optimal chronic pain management. Medication monitoring using periodic urine drug testing provides me with critical insights into the use of pain medication, as well as identifying other legal and illicit drugs possibly being used by my patients especially in light of the national prescription drug abuse epidemic in the United States.

However, the draft LCD specifically excludes coverage of qualitative drug testing for patients with chronic pain who are not suspected drug abusers. Periodic monitoring of chronic pain patients regardless of suspicion of illicit drug use is consistent with professional standards and clinical practice guidelines in the treatment of chronic pain patients. WPS' policy should remain consistent with this standard.

The American Pain Society (APS), the American Academy of Pain Medicine (AAPM), the American Society of the Interventional Pain Physicians (ASIPP) , The Institute for Clinical Systems Improvement (ICSI) , and the Veterans Affairs (VA) and Department of Defense all have recommended the use of urine drug testing for compliance monitoring for patients on an opioid regimen.

Further, studies show that patient self-reports and physician assessment of non-adherence through identification of the signs of medication misuse are not reliable. According to a review by Michna, prescription medication use was underestimated in up to 32% of patient when assessed by patient questioning, compared with urine drug tests.

In light of the clinical importance of medication monitoring tests to patients and providers, I urge you to revise the LCD to enable me to use qualitative drug tests to provide optimal pain relief to my patients suffering from chronic pain.

12. Comment

On September 6, 2006, the Department of Justice, Drug Enforcement Administration (DEA), published in the Federal Register (21 CFR Part 1306) a discussion regarding the dispensing of controlled substances for the treatment of pain. This notice was to address the DEAs role in the oversight and management of the improper use of controlled substance prescriptions for pain and to address the medical communities concern regarding that oversight. This notice further clarifies the responsibility of physicians who prescribe controlled substances and who must take reasonable measures to detect and prevent inappropriate diversion or use. One of the mechanisms that physicians can utilize to manage the appropriate use of schedule II drugs is to require qualitative urine drug testing to validate and monitor patient compliance, and to detect inappropriate use or misuse of these potent controlled substances. The policy, as presented in the present draft form, does not allow for the physician's ability to validate and monitor patient compliance, as well as detect possible drug diversion, abuse or misuse.

In the section of the Draft LCD, DL32450, describing Covered Indications, the policy clarifies the situations where it is medically reasonable and necessary to order qualitative drug testing "for the monitoring of chronic pain patients in whom other illicit drug usage is suspected when there has been an acute change in physical or mental status that meets the indications above." This language removes the appropriate management of these prescription drugs as cited in the DEA Notice— monitoring for patient compliance is not covered under this policy in its present draft form.

The treatment of chronic noncancer pain (CNCP) with opioids such as oxycodone, morphine, methadone, other potent analgesics and psychoactive drugs is becoming more frequent among all groups, including Medicare beneficiaries, and the cost to the nation is reported to exceed that of heart disease. The increased usage of analgesics with a high potential for addiction, abuse, misuse and diversion has placed a significant burden on physicians caring for these patients. The patient being treated for CNCP often experiences comorbid mood, anxiety or somatization disorders.
The presence of these disorders increases the likelihood that patients will exhibit substance-use disorders or aberrant drug-taking behavior as a result of their illness. Reports have suggested significant incidence of such disorders in patients being treated for CNCP. Although the behavior may in some instances be deemed illegal, the underlying condition is still medical.

The responsible physician treating CNCP is required to evaluate their patient's potential for the above-noted aberrant behaviors. In fact, many physicians do not have adequate training or a well-developed skill set in this area. In addition, the Food and Drug Administration, though its proposed risk evaluation mitigation strategy (REMS) for opioid drugs, is placing additional burdens on harried practitioners who treat CNCP. This all has the potential to limit the availability of CNCP therapy to Medicare beneficiaries.

This draft policy penalizes Medicare beneficiaries whom the physician is monitoring for appropriate prescription drug use that do not present with an obvious adverse drug reaction or signs that suggest illicit drug use. The draft policy, as presently written, indicates that these situations do not qualify as medically reasonable and necessary. The caring physician who, in the spirit of a DEA registrant, monitors patients for medication compliance would therefore have to require the patient to pay out of pocket as an excluded service under this policy, unless the physician suspected aberrant or illicit drug use.

Guidelines have been developed to manage CNCP patients by numerous professional societies including the American Medical Association, American Pain Society, American Academy of Pain Medicine, the American Academy of Family Practice, the American Society of Interventional Pain Physicians, the Department of Veterans Affairs/Department of Defense and the American Society of Anesthesiologists. These guidelines include developing a treatment agreement or contract, regular patient monitoring to evaluate the effectiveness of therapy, and reducing or eliminating the continued need for potent analgesics when appropriate. Periodic urine-based qualitative drug testing is a part of these guidelines. The purpose is to verify compliance, as well as identify the occurrence of abuse or misuse, if they should occur. Suggested frequency is every 2-3 months, unless there is suspicion of abuse or manipulation. Copies of relevant documents are enclosed.

In patients whose urine tests positive for various classes of drugs, confirmation with identification of metabolites is also important. The treating physician needs to compare the drugs being prescribed with the parent drug and metabolites identified in the qualitative drug test to be sure

that they are consistent. For example, a patient being prescribed morphine may also be abusing other opiates, such as oxymorphone.

This would only be identified by confirmatory qualitative drug testing. In my experience, many nonspecialist physicians are not aware of the metabolism of these drugs and can make a wrong decision based on misunderstanding the results. For example, oxycodone is partially metabolized to oxymorphone.

If oxymorphone is present in a lower concentration than the parent drug, it is consistent; if not, it suggests abuse of oxymorphone. Conversely, many physicians do not realize that some opiate class qualitative urine drug tests do not detect oxycodone at the usual therapeutic levels. A patient taking oxycodone with a negative opiate qualitative drug test, which cannot detect the drug, may be incorrectly accused of noncompliance or drug diversion.

I have personally been aware of patients being refused appropriate additional analgesic prescriptions when the presence of expected metabolites was misinterpreted by their treating physicians. The clinical laboratory, which uses interpretive pain management profiles and pathologist consultation, provides invaluable assistance to physicians who may need help in interpreting results.

In the interest of maintaining the physician's ability to prescribe and manage appropriate medications for Medicare beneficiaries, I recommend that the draft LCD DL32450 be modified to include qualitative urine drug testing for monitoring patients being treated for CNCP, even if illicit drug use is not suspected. In addition, I recommend the inclusion of the following ICD-9 codes to be considered as medically appropriate:

V58.69 Long term (current) use of other medications
724.2 Lumbago
338.4 Chronic pain syndrome
305.51 Nondependent opioid abuse continuous use
338.29 Other chronic pain
304.01 Opioid type dependence continuous use
304.00 Opioid type dependence unspecified use
724.5 Backache unspecified
715.09 Osteoarthrosis generalized involving multiple sites
304.60 Other specified drug dependence unspecified use
304.90 Unspecified drug dependence unspecified use
305.90 Other mixed or unspecified drug abuse unspecified use

13. Comment

As we discussed when we met with you several weeks ago, National Government Services (NGS) currently serves as Medicare Administrative Contractor for Indiana, but we understand that WPS will assume responsibility for our jurisdiction in the near future. We are being paid for qualitative drug testing performed in our lab under NGS's LCD L28145 – Qualitative Drug Screening, which explicitly provides AIT with reimbursement for its prescription drug monitoring services. AIT is concerned that the draft WPS LCD, as currently written, would significantly restrict the use of qualitative drug testing and would limit physicians' access to the only objective tool available to them to help manage their Medicare patients with chronic pain and reduce the risk of abuse or diversion of prescription pain medications. Qualitative drug testing can help protect against both under- and over- prescribing of pain medications and identify potential abuse, misuse, or diversion of prescription drugs.

The evidence presented in detail below and in the attached material demonstrates that qualitative drug testing is the standard of care for medication monitoring of patients on opioid therapy for chronic pain. Qualitative drug testing is the only objective method to ensure compliance with a patient's plan of care. **Accordingly, we urge WPS to revise the draft LCD to explicitly cover all medically necessary qualitative drug monitoring tests for patients with chronic pain, including testing for compliance purposes and to prevent diversion.**
We also recognize the importance of protecting against potential overutilization of qualitative drug testing and identify below several medical professional society treatment guidelines that provide consensus-based recommendations for the appropriate utilization and frequency of qualitative drug testing. Our detailed comments also recommend specific coverage strategies to address these areas, such as confirmation. AIT is committed to enabling physicians and Medicare beneficiaries to employ qualitative drug testing in the most appropriate manner possible.
Attachment A to this letter provides a side-by-side analysis which details: 1) the relevant draft LCD language (DL 32450); 2) specific alternative language proposed to replace or modify the draft policy; and 3) an explanatory justification for the recommended changes in the language. All reference material cited is identified either in the footnotes to this letter or at the bottom of Attachment A.

BACKGROUND
Laboratories provides laboratory testing, analysis, and research services to healthcare professionals. As an employee-owned company headquartered in Indianapolis with more than 450 employees nationwide, we specialize in prescription drug compliance monitoring, forensic toxicology, pharmaceutical testing and other clinical laboratory services. We are a leader in monitoring patient use of prescription drugs for chronic pain through compliance testing. Physicians use our services to verify patient compliance, quickly identify potential drug misuse and diversion, and make objective, informed decisions regarding patient care. We provide timely, objective data to inform clinical decision-making and help ensure appropriate patient care. Physicians frequently order drug testing for a patient they are treating for chronic pain to help determine whether a patient is using illicit drugs that may interfere with the prescribed drug regimen, to ensure that the patient is adherent to the prescribed drug regimen, and, in some cases, to quantify the level of prescribed drugs a patient has taken.

Care for Medicare beneficiaries with chronic pain
As many as one in four Americans live with chronic pain,1 meaning that more Americans are affected by chronic pain than by diabetes, cardiovascular disease and cancer combined. Appropriate care for chronic pain patients frequently includes the therapeutic use of opioids and other prescription drugs that can provide patients with the relief they need to lead productive lives. Regrettably, a recent GAO report2 underscored the growing rate of abuse, misuse, and diversion of these drugs in the Medicare population, resulting in insufficient pain management, increased risk of morbidity and mortality, and increased cost of care.
Lack of adherence to chronic pain drug therapy increases utilization of costly acute inpatient hospitalizations. A recent report released by the Agency for Healthcare Research and Quality's (AHRQ's) Healthcare Cost and Utilization Project (H-CUP)3 confirms that drug-induced delirium and poisoning associated with opiate-based pain medications is a serious and growing problem, especially among the elderly. The authors observed that the number of US hospital stays for drug-related conditions rose rapidly from 1997-2008 and concluded that the principal causes of this increase were a rapid growth in drug-induced delirium and in poisonings by opiate-based pain medications. In 2008 alone, these conditions accounted for 78 percent of drug related hospital stays and 89 percent of the increase in drug-related stays for the oldest patients

(> 85 years of age).4 Drug-induced delirium and poisonings by opiate-based pain medications were also responsible for 60 percent of drug-related admissions among Medicare beneficiaries 65 to 84 years of age.

Figure 1: Growth in US Hospitalizations Related to Pain Medications

These facts demonstrate the critical need for appropriate, routine access to qualitative drug testing to support effective treatment for Medicare beneficiaries with chronic pain.

COMMENTS

Clinicians must balance the need for pain medication with the risk of use. Primary care physicians write the majority of prescriptions for chronic pain. However, doctors' judgments regarding which patients are adherent to drug therapy are frequently wrong.5 Because of the potentially serious harm that may result from misuse and abuse of chronic pain medications, periodic compliance monitoring using qualitative drug testing has become a critical tool for physicians and has been endorsed by medical professional organizations.

Qualitative drug testing (also known as urine drug testing) is a standard of care for medication monitoring in the interest of patient safety

A number of medical professional societies and provider networks are developing treatment guidelines for the use of qualitative drug testing to monitor chronic opioid therapy.

1. American Pain Society/American Academy of Pain Medicine Guidelines

The American Pain Society (APS) and the American Academy of Pain Medicine (AAPM), in their Opioid Treatment Guidelines,6 state that "(a)lthough evidence on accuracy of urine drug screening to identify aberrant drug-related behaviors or diversion is lacking, and no evidence exists that demonstrates that screening improves clinical outcomes, absence of prescribed opioids or presence of unprescribed opioids or illicit drugs can be a marker for problematic issues that would not be apparent without urine drug screening."7 APS and AAPM recommend that:

- in patients on chronic opioid therapy (COT) who are at high risk or who have engaged in aberrant drug-related behaviors, clinicians should periodically obtain urine drug screens or other information to confirm adherence to the COT plan of care (strong recommendation; low-quality evidence)
- in patients on COT not at high risk and not known to have engaged in aberrant drug related behaviors, clinicians should consider periodically obtaining urine drug screens or other information to confirm adherence to the COT plan of care (weak recommendation; low-quality evidence).

The December 2011 Issue of Pain Medicine News included an article called "The APS/AAPM Opioid Treatment Guidelines Revisited."8 Several of the authors of the 2009 guidelines were asked a series of questions about the guidelines. One of the questions was "Are there any areas you feel didn't go far enough? Meaning, you addressed it, but perhaps could have worded the recommendations more strongly/differently?"

Two of the authors provided the following responses:

Professor of psychiatry, professor of anesthesiology,
Vanderbilt Medical Center, Vanderbilt University

“I believe that various aspects of risk management practice have progressed beyond the guidelines because there was such a grave need; for example, the frequency and timing of urine drug screening was left vague (in the original guidelines). It has become commonplace and much more frequently used than was alluded to in the guidelines. This has been due, in part, to new data to support the practice, but more than anything to a developing community standard of care in response to the need to protect patients and practices against abuse, misuse and diversion.”

Director, Pain Management Center, Dartmouth- Hitchcock Medical Center

"My own bias was for more intensive monitoring of all opioid patients. I would have included urine toxicology testing as a recommendation for all opioid patients with chronic noncancer pain."

Further, guidelines from the American Society of the Interventional Pain Physicians (ASIPP) state that "(i)n chronic pain management, UDT should be used with an appropriate level of understanding (which can improve a physician's professional ability to manage therapeutic prescription drugs with controlled substance), and to diagnose substance abuse or appropriate intake of drugs, thereby leading to proper treatment. They should be random, well-organized, and synchronized with a well-understood testing lab. The lab understands you, and you understand what they are testing. False positives, negatives, and the scope of testing should also be understood."9

2. Institute for Clinical Systems Improvement

The Institute for Clinical Systems Improvement (ICSI) is a nonprofit organization comprised of 55 medical groups in Minnesota, Wisconsin, and South Dakota whose mission is to improve the quality and value of health care. Its guideline10 for the assessment and management of chronic pain states: "Random drug screens are one tool to monitor compliance with the opioid regimen. Random urine drug screens are used: (1) to check for diversion, seeking evidence the patient is taking the medication being prescribed, (2) to check for drugs of abuse, and (3) to test for the presence of the prescribed drug. Any evidence of street drug use indicates non-compliance with the opioid contract." The sample opioid agreement form includes the following: "I agree to abstain from all illegal and recreational drugs (including alcohol) and will provide urine or blood specimens at the doctor's request to monitor my compliance."

3. Department of Veteran Affairs/Department of Defense

In addition, the joint Veteran Affairs (VA) and Department of Defense (DOD)'s Clinical guideline for the management of opioid therapy for chronic pain recommends the following:11

- A urine drug test (UDT) (also referred to as urine drug screen (UDS)) should be used to screen for the presence of illegal drugs, unreported prescribed medication, or unreported alcohol use prior to starting therapy.
- UDT or other laboratory tests should be part of a comprehensive patient assessment. Presence of illicit metabolites may warrant referral to a substance abuse/addiction consultant. Clinicians should be aware of the type of drugs tested, and the sensitivity and specificity of their facility's UDT assay because detection of synthetic opioids and newer benzodiazepines may not be part of routine screens. The goal should be to check for the presence of drugs in any amount. Most UDT, however, have cut-off levels below which the test result is reported as negative. Providers should be aware of the fact that positive results may occur and confirmation done by different methodology may be appropriate before clinical decisions are made.
- Understanding of lab methods for drug testing and reporting are necessary to interpret UDT results (*i.e.*, screen versus confirmatory test, substances tested, and cut-off levels for tests). Maintain a close working relationship with the clinical laboratory to answer any questions about the UDT or for confirming the results.

4. Expert consensus panel

Even more recently, a panel of eleven experts in the field of pain and addiction medicine was assembled to review current evidence and create consensus recommendations regarding the use of urine drug monitoring by primary care providers, pain specialists, and other providers who prescribe chronic opioid therapy. The panel's recommendations were presented in a poster session during the February 2012 annual meeting of the American Academy of Pain Medicine and have been submitted for publication in a peer-reviewed journal. The poster material is included as "Attachment B" to this letter and, among other things, recommends the following:

 Monitoring should consist of a comprehensive urine drug test. Such a test may include illicit drugs, commonly prescribed opioids, and other prescription drugs of potential abuse (e.g. benzodiazepines, barbiturates, carisoprodol, meprobamate, and tramadol). As part of this process, the physician may notify the laboratory as to what medications are prescribed and any concerns that may exist about specific nonprescribed medications being used.

 Given the difficulty in identifying safe and adherent drug use behaviors, all patients who are prescribed a short or long-acting opioid for long-term pain management (defined as > 3 months by the recommendations panel) should be tested.

 The initial test may be viewed as a component of risk assessment to aid in risk stratification and to evaluate the patient's therapeutic baseline (of currently prescribed substances) at this single point in time. Subsequent tests may be viewed as confirmatory or ongoing monitoring based on initial identified risk level and therapeutically prescribed medications. This initial test may be performed at the first visit when opioid therapy seems likely.

 The Screener and Opioid Assessment for People with Pain Revised (SOAPP-R) is recommended by this panel. The panel recognizes that there are other validated and useful screens, e.g., the Current Opioid Misuse Measure (COMM) and the Opioid Risk Tool (ORT). These tools are only a component of risk assessment, and screening for risk factors via patient interview or other data collection method is recommended. Risk factors which may be considered in determining the follow-up visit schedule, frequency of follow-up monitoring, and number of days opioid prescribed per prescription may include; findings from baseline test, smoking history, past medical history, history of psychiatric diagnosis that predisposes patient to abuse, history of prior opioid use and known misuse, personal and family history of substance abuse, and social environment that poses concern over misuse or diversion.

 Monitoring Frequency by Patient Risk Level
Low Risk of Misuse
- May be periodically eligible for monitoring at each visit, with a minimum of one test conducted every six months.
Moderate to High Risk of Misuse
- May be periodically eligible for monitoring at each visit, with a minimum of one test conducted every three months.

SUMMARY
Drug testing is a standard of care for patients who are taking opiates to manage chronic pain. Physicians depend on these tests to prevent misuse, diversion, and inappropriate combinations of therapies. Given the significant burden of chronic pain among the Medicare population and the associated therapeutic strategies, it is critical that the draft LCD be revised to include coverage of compliance monitoring through drug testing.

14. Comment
I offer some refinements to the proposed draft.

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 **or negative (please add)** inconsistent finding from the qualitative test in the setting of a symptomatic patient, as described below.

Some drug low levels may not be detected via urine qualitative testing and may require confirmation to correctly document patient compliance. This is addressed more specifically in later paragraphs. The paragraph above is not consistent with the later paragraph that discusses confirmation in more detail.

I am suggesting that the section below be removed from paragraph C.
Paragraph C "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:"
is an inappropriate section for dealing with these topics. These have nothing to do with overdose.

7. For monitoring patient compliance during active treatment for substance abuse or dependence.
8. A qualitative drug screen is considered medically reasonable and necessary in patients on chronic opioid therapy:
- In whom illicit dug use, non-compliance or a significant pre-test probability of non-adherence to the prescribed dug regimen is suspected and documented in the medical record; and/or
- In those who are at high risk for medication abuse due to psychiatric issues, who have engaged in aberrant drug-related behaviors, or who have a history of substance abuse.

9. Medicare will consider performance of a qualitative drug test reasonable and necessary in patients with chronic pain to:
- determine the presence of other substances prior to initiating pharmacologic treatment
- detect the presence of illicit drugs
- monitor adherence to the plan of care

I am recommending a new paragraph D that deals specifically with bullets 7-9 in paragraph C. I am recommending that Paragraph D state that

D. Medicare will consider performance of a qualitative drug test reasonable and necessary when a patient presents with one or more of the following conditions:
1. For monitoring patient compliance during active treatment for substance abuse or dependence.
2. A qualitative drug screen is considered medically reasonable and necessary in patients on chronic opioid therapy:
- In whom illicit dug use, non-compliance or a significant pre-test probability of non-adherence to the prescribed dug regimen is suspected and documented in the medical record; and/or
- In those who are at high risk for medication abuse due to psychiatric issues, who have engaged in aberrant drug-related behaviors, or who have a history of substance abuse.

3. Medicare will consider performance of a qualitative drug test reasonable and necessary in patients with chronic pain to:
- determine the presence of other substances prior to initiating pharmacologic treatment
- detect the presence of illicit drugs

- monitor adherence to the plan of care

Response to all comments:

We wish to thank all the commentors for their work in bringing to our attention the omissions in the draft policy.

We have updated the policy to include coverage of evaluating and monitoring patients with chronic pain. We have also added coverage for monitoring of patients addicted to prescription drugs and other substances.

In addition we have added ICD-9 codes that reflect these additions.
We have not added ICD-9 codes that specifically reflect the presenting cause of the pain such as Lumbago, Chronic pain syndrome, Other chronic pain, Failed back syndrome, Neck spondylosis Thoracic spondylosis, Reflex sympathetic dystrophy RSD, Osteoarthritis, Chronic Abdominal pain, Backache unspecified, Osteoarthrosis generalized involving multiple sites. These can be added to the claim but do not reflect the reason for the drug testing. Instead use

V58.69	Long-term (current) use of other medications
V15.81	Noncompliance with medical treatment
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. Or use another appropriate code as listed in the document.

Addendum (additional comment)

Revisions to WPS Draft LCD (DL32450) Language Proposed by Laboratories

Draft LCD language	Suggested Revision	Justification
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. (See Indications and Limitations of Coverage and/or Medical Necessity section of the draft LCD)	Substitute: A qualitative test may be followed by confirmation with a second method, as described below under the Covered Indications section.	See the justification in provisions 6 and 7 below.
A qualitative drug test may be	Substitute:	The clinical scenarios in

Draft LCD language	Suggested Revision	Justification
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. (See "Covered Indications" section of draft LCD)	A qualitative drug test may be indicated for a variety of reasons including the following: (1) a symptomatic patient when the history is unreliable, when there has been a suspected multiple-drug ingestion, to determine the cause of delirium or coma, or for the identification of specific drugs that may indicate when antagonists may be used; (2) for monitoring patient compliance during active treatment for substance abuse or dependence; or (3) to monitor for compliance/adherence to the treatment plan or illicit drug use in patients under treatment or seeking treatment for a chronic pain condition. 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.	which qualitative drug testing is appropriate for compliance monitoring of chronic opioid therapy are entirely different than the clinical scenarios for appropriate qualitative drug testing in emergency settings.
A qualitative drug test may be reasonable and necessary for patients with known substance abuse or dependence, only when the clinical presentation has changed unexpectedly and one of the above indications is met. (See "Covered Indications" section of draft LCD)	Substitute: Medicare will consider a qualitative drug test to be reasonable and necessary for patients with known substance abuse or dependence when the clinical presentation has changed unexpectedly and one of the above indications is met.	Qualitative drug testing is reasonable and necessary for patients without acute symptoms.
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. (See "Covered Indications" section of draft LCD)	Substitute: Medicare will consider performance of a qualitative drug test reasonable and necessary in patients with chronic pain to: • determine the presence of other substances prior to initiating pharmacologic	Urine drug testing for compliance monitoring for patients on chronic opioid therapy for both symptomatic/high risk patients and asymptomatic patients has the support of national physician specialty societies, both in pain management and

Draft LCD language	Suggested Revision	Justification
	treatment • detect the presence of illicit drugs • monitor adherence to the plan of care	in internal medicine, the Institute for Clinical Systems Improvement, which represents a large number of practitioners in WPS region, the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH).[i] [ii] [iii] [iv] [v] [vi] [vii] [viii] Also, recently a panel of eleven experts in the field of pain and addiction medicine was assembled to review current evidence and create consensus recommendations regarding the use of urine drug monitoring by primary care providers, pain specialists, and other providers who prescribe chronic opioid therapy. The panel's recommendations were presented in a poster session during the February 2012 annual meeting of the American Academy of Pain Medicine and have been submitted for publication in a peer-reviewed journal.[ix] The panel recommended: • Given the difficulty in identifying safe and adherent drug use behaviors, all patients who are prescribed a short or long-acting opioid for long-term pain management should be

Draft LCD language	Suggested Revision	Justification
		tested • The initial test may be viewed as a component of risk assessment to aid in risk stratification and to determine presence of other substances prior to starting therapy. Studies show that (1) patient self-report may be unreliable for determining amount of opioid use, functionality, or aberrant drug-related behaviors, and that urine drug testing can be useful in this context (2) primary care providers are often unable to identify substance abuse in their patients (3) a significant number of patients had positive urine drugs screens in the absence of obvious aberrant drug-taking behavior (in such cases urine drug testing is the only measure available to detect certain aberrant behaviors). [x] [xi] [xii] [xiii] [xiv]
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. (See "Covered Indications" section of draft LCD)	Substitute: 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. Drugs for which specimens are being tested must be indicated by the referring provider in a written order.	The NIH and the CDC recognize that three categories of drugs are commonly abused or misused and are likely to be present in a patient with a medical history of chronic pain: opioids, depressants, and stimulants.[xv] [xvi]
Confirmation of drug testing *(80102)* is indicated when the result of the drug test is different than that suggested by the	Substitute: Confirmation of drug testing *(80102)* is indicated when (1) the	The justification to confirm all presumptively positive results is strong:

Draft LCD language	Suggested Revision	Justification
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. (See "Covered Indications "section of draft LCD)	results of the qualitative screen are presumptively positive or (2) results of the qualitative screen are negative and this negative finding is inconsistent with the patient's medical history. 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.	1) all immunoassays (the methodology for qualitative screens) are subject to false positive results due to cross reactivity of other compounds with the test. The impact to patient care of a false positive result is severe, thus confirmatory testing of presumptive positives is always warranted, to eliminate the risk of a false positive.[xvii] [xviii] [xix] 2) There is language in the package inserts for the FDA approved immunoassay kits stating that confirmatory testing must be used.[xx] 3) Confirmatory testing must be performed in order to determine the specific drug(s) in the sample. For example, the qualitative screen will presumptively indicate the presence of opiates, however it cannot distinguish between the different opiates. There are situations in which a patient may be prescribed Hydrocodone (Vicodin), but divert/sell that medication to purchase Oxycodone (Oxycontin) for illicit use.[xxi] Justification to confirm negative qualitative screens, when the negative result is inconsistent with the patient's medical history: in order to minimize the

Draft LCD language	Suggested Revision	Justification
		risk of a false negative result, we recommend confirmation on samples that screen negative, but should be positive for a particular drug, based on a patient's medical history. While the incidence of false negatives is low, the potential risk to the patient of reporting a false negative is high enough to warrant additional testing.
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. (See "Covered Indications" section of draft LCD)	Substitute: When a confirmatory test or a quantitative test is performed, the record must show that the result of the qualitative test was positive, the result of the qualitative test was negative but was unexpected based on medical history or that there was no available qualitative test, commercially or otherwise, to evaluate the presence of a drug in a patient who met the coverage criteria of this policy.	Negative inconsistent results should be confirmed because the qualitative screen (lab based or point of care) can produce false negative results. Presumptive positive results should be confirmed because the qualitative screen can produce false positive results, can't distinguish between different drugs in a drug class (lack of specificity), and is recommended by the FDA. The justification for broadening language to "drug" instead of semi-synthetic or synthetic opioids is that there are other non-opioid synthetic drugs without a commercially available test such as tapentadol, pregabalin, and gabapentin.

Draft LCD language	Suggested Revision	Justification
Drug screening for compliance purposes, diversion, or in asymptomatic patients is not covered under the Program. This determination applies also to CPT codes *80102, 80150* through *80299* and *82000-84999*. (See "Limitations" section of draft LCD)	Remove this sentence.	Given the intent of the policy is not to limit access to routine qualitative drug testing for compliance monitoring of chronic pain patients for the purposes of determining adherence to the treatment plan and for detecting diversion and illicit drug use, this sentence presents confusion to providers as it clearly states that drug screening for compliance and diversion is not covered.
None	Add: Qualitative drug testing codes (G0431 & G0434) should only be billed once per patient encounter as indicated by the code description and should only be billed at one unit.	The intent of this LCD is to assure that Medicare beneficiaries have access to periodic qualitative drug testing for compliance monitoring of chronic pain patients for the purposes of determining adherence to the treatment plan and for detecting diversion and illicit drug use, as well as to ensure that providers are correctly submitting claims and applying the appropriate codes only once per patient encounter.
276.2; 295.00-295.30; 345.10-345.11; 345.3; 345.90-345.91; 426.10-426.13; 426.82; 427.0-427.1; 780.01; 780.09; 780.1; 780.39; 963.0; 965.00-965.09; 965.1; 965.4; 965.5; 965.61; 966.1; 967.0-967.9; 972.1; 977.9 (See " ICD-9 Codes that Support Medical Necessity" section of draft LCD)	Add: The following is a list of covered ICD-9 diagnosis codes. This list is not all-inclusive but reflects the most common covered indications. Use code V58.69 for patients on pain medication for chronic pain to monitor for the presence of illicit drugs when suspected and adherence to the plan of care.	The current draft policy does not include diagnosis codes related to compliance monitoring, opioid dependence or other drug dependence. The suggested diagnosis codes are based on other Medicare Contractor policies for Qualitative drug testing and the most commonly reported

<table>
<tr><th>Draft LCD language</th><th>Suggested Revision</th><th>Justification</th></tr>
<tr><td></td><td><table>
<tr><th>ICD-9 Code</th><th>Descriptor</th></tr>
<tr><td>V58.69</td><td>Long-term (current) use of other medications</td></tr>
<tr><td>V15.81</td><td>Noncompliance with medical treatment</td></tr>
<tr><td>V71.09</td><td>Other suspected mental condition</td></tr>
<tr><td>304.01</td><td>Opioid type dependence, continuous abuse</td></tr>
<tr><td>304.90</td><td>Unspecified drug dependence, unspecified abuse</td></tr>
<tr><td>305.90</td><td>Other, mixed, or unspecified nondependent drug abuse, unspecified pattern of use</td></tr>
</table></td><td>codes by physicians ordering tests from our laboratory.</td></tr>
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Draft LCD language	Suggested Revision	Justification
Part B Program Instructions: Coding Guidelines 1. Refer to the Correct Coding Initiative (CCI) for correct coding guidelines and specific applicable code combinations prior to billing Medicare. Provisions of this LCD do not take precedence over CCI edits. 2. Diagnosis(es) must be present on any claim submitted and coded to the highest level of specificity for that date of service. 3. To report these services, use the appropriate HCPCS or CPT code(s). 4. All coverage criteria must be met before Medicare can reimburse this service 5. When billing for this service in a non-covered situation (e.g., does not meet indications of the related LCD), use the appropriate modifier (see below). To bill the patient for services that are not covered (investigational/experimental or not reasonable and necessary) will generally require an Advance Beneficiary Notice (ABN) be obtained before the service is rendered. 6. For claims submitted to the carrier or Part B MAC: All services/procedures performed on the same day for the same beneficiary by the physician/provider should be billed on the same claim. Claims for qualitative drug screening services are payable under Medicare Part B in the following places of service: office (11), urgent care (20), independent clinic (49), federally qualified health center (freestanding) (50), rural health clinic (freestanding) (72), and independent laboratory (81). 7. Modifiers:	Add to #6: Codes G0431 & G0434 should only be billed once per patient encounter as indicated by the code description and should only be billed at one unit.	The intent of this LCD is to assure that Medicare beneficiaries have access to periodic qualitative drug testing for compliance monitoring of chronic pain patients for the purposes of determining adherence to the treatment plan and for detecting diversion and illicit drug use, as well as to ensure that providers are correctly submitting claims and applying the appropriate codes only once per patient encounter.

Draft LCD language	Suggested Revision	Justification
GA: Waiver of liability statement issued as required by payer policy, individual case. Use this modifier for patients who do not meet the covered indications and limitations of this LCD and for whom an ABN is on file. (ABN does not have to be submitted but must be made available upon request.) GZ: Waiver of liability statement is not on file. Use this modifier for patients who do not meet the covered indications and limitations of this LCD and who did not sign an ABN. GY: Item or service is statutorily excluded or does not meet the definition of any Medicare benefit.		