Drug Testing in Pain Management and Substance Abuse Treatment

Policy # 00387
Original Effective Date: 09/18/2013
Current Effective Date: 10/18/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Intravenous Anesthetics for the Treatment of Chronic Pain is addressed separately in medical policy 00463.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider in outpatient pain management, presumptive (i.e., immunoassay) urine drug testing (UDT) to be eligible for coverage.

Patient Selection Criteria
In outpatient pain management, presumptive (i.e., immunoassay) urine drug testing (UDT) may be eligible for coverage when the following conditions are met:

- Baseline screening before initiating treatment or at the time treatment is initiated, when the following conditions are met:
  - An adequate clinical assessment of patient history and risk of substance abuse is performed;
  - Clinicians have knowledge of test interpretation;
  - There is a plan in place regarding how to use test findings clinically.
- Subsequent monitoring of treatment at a frequency appropriate for the risk level of the individual patient (see Policy Guidelines section).

Based on review of available data, the Company may consider in outpatient substance abuse treatment, in-office or point-of-care (POC) presumptive (i.e., immunoassay) urine drug testing (UDT) to be eligible for coverage.

Patient Selection Criteria
In outpatient substance abuse treatment, in-office or point-of-care (POC) presumptive (i.e., immunoassay) urine drug testing (UDT) may be considered eligible for coverage under the following conditions:

- Baseline screening before initiating treatment or at the time treatment is initiated (i.e., induction phase), 1 time per program entry, when the following conditions are met:
  - An adequate clinical assessment of patient history and risk of substance abuse is performed;
  - Clinicians have knowledge of test interpretation;
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There is a plan in place regarding how to use test findings clinically.

- Stabilization phase – targeted weekly presumptive screening for a maximum of 4 weeks (see Policy Guidelines section);
- Maintenance phase – targeted presumptive screening once every 1 to 3 months (see Policy Guidelines section).

Note: More frequent urine drug testing (UDT) may be appropriate for some complicated patients and must be supported as medically necessary in the patient's medical records.

Based on review of available data, the Company may consider definitive (i.e., confirmatory) urine drug testing (UDT), in outpatient pain management or substance abuse treatment to be eligible for coverage.

Patient Selection Criteria
Based on review of available data, the Company may consider definitive (i.e., confirmatory) urine drug testing (UDT), in outpatient pain management or substance abuse treatment to be eligible for coverage under the following circumstances:

- When immunoassays for the relevant drug(s) are not commercially available
- In specific situations for which definitive drug levels are required for clinical decision making. These may include the following:
  - Unexpected positive test inadequately explained by the patient;
  - Unexpected negative test (suspected medication diversion);
  - Need for quantitative levels of prescribed medications to compare with established benchmarks for clinical decision making.

Note: Commercially available immunoassay testing is available for almost all drug classes of interest. Extensive custom profile panels of quantitative testing will not be covered without initial immunoassay screening on the drug classes of interest and coverage will be limited to those drug classes need for confirmation as described above.

When Services Are Considered Not Medically Necessary
The use of urine drug testing (UDT) in outpatient pain management and outpatient substance abuse treatment is considered to be not medically necessary** when the above criteria are not met, including but not limited to routine presumptive or definitive urine drug testing ([UDT] e.g., testing at every visit, without consideration for specific patient risk factors or without consideration for whether definitive testing is required for clinical decision making).

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers in outpatient pain management and substance abuse treatment, hair drug testing and oral fluid drug testing to be investigational.*
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POLICY GUIDELINES
PAIN MANAGEMENT

The risk level for an individual patient should include a global assessment of risk factors, and monitoring for the presence of aberrant behavior. Standardized risk assessment tools are available, such as the 5-item Opioid Risk Tool (ORT). Another screening instrument is the Screener and Opioid Assessment for Patients in Pain, a 24-item tool (http://painedu.org/soapp.asp?gclid=CPvLjOeFi7oCFY1FMqodzQ4ANA).

Aberrant behavior is defined by one or more of the following:
- Multiple lost prescriptions,
- Multiple requests for early refill,
- Obtained opioids from multiple providers,
- Unauthorized dose escalation, and
- Apparent intoxication during previous visits.

Opinions vary on the optimal frequency of urine drug screening to monitor patients on opioid therapy for chronic pain. Screening frequency using a risk-based approach, as recommended by the Washington State interagency guideline (Washington State Agency Medical Directors’ Group, 2015) is as follows:
- Low risk by ORT: Once a year,
- Moderate risk by ORT: Twice a year,
- High risk or opioid dose >120 mg MED/d: 3-4 times a year,
- Recent history of aberrant behavior: Each visit.

Note that the ORT is a copyrighted instrument (http://www.opioidrisk.com/node/884). The Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain does not include specific screening frequencies but states that an individual patient’s risk for opioid misuse and addiction should be considered when deciding when to order a urine drug screen (http://nationalpaincentre.mcmaster.ca/opioid).

SUBSTANCE ABUSE

Stabilization phase: Most patients are expected to be on a stable dose of opioid medication within 4 weeks of initiating treatment. In some complicated patients, the stabilization phase may last longer than 4 weeks.

Maintenance phase: For most patients, targeted presumptive screening once every 1 to 3 months is sufficient during the maintenance phase of treatment. More frequent testing may be appropriate for some complicated patients.

GUIDANCE ON DEFINITIVE (CONFIRMATORY) TESTING

Specific situations for definitive drug testing may include, but are not limited to the following:
- Unexpected positive test inadequately explained by the patient
- Unexpected negative test (suspected medication diversion)
- Need for quantitative levels to compare with established benchmarks for clinical decision making.
There may not be commercially available tests for certain synthetic or semisynthetic opioids.

The following information on immunoassay availability and diagnostic capacity is included in the Washington State interagency guideline (Washington State Agency Medical Directors’ Group, 2015):

Natural opioids (e.g., codeine, morphine)

“Immunassays for ‘opiates’ are responsive for morphine and codeine but do not distinguish which is present. Confirmatory testing is required to reliably identify drug(s) present. Since codeine is metabolized to morphine and small quantities to hydrocodone, these drugs may be found in the urine. Also, morphine may metabolize to produce a small amount (<10%) of hydromorphone.”

Semisynthetic opioids (e.g., hydrocodone, hydromorphone, oxycodone, oxymorphone)

“‘Opiates’ immunassays may also detect semisynthetic opioids depending on their crossreactivity pattern. However, a negative result does not exclude use of semisynthetic opioids. Confirmatory testing (GC/MS [gas chromatography/mass spectrometry] or LC/MS/MS [liquid chromatography tandem mass spectrometry]) is required to verify compliance with the prescribed semisynthetic opioid(s).”

Since hydrocodone is metabolized in small amounts to hydromorphone, both may be found in the urine. Likewise, oxycodone is metabolized to oxymorphone, so these may both be present in the urine of oxycodone users. However, the reverse is not true. In other words, hydromorphone and oxymorphone use does not result in positive screens for hydrocodone and oxycodone, respectively.”

Synthetic opioids (e.g., fentanyl, meperidine, methadone, propoxyphene)

“Current ‘opiates’ immunassays do not detect synthetic opioids. Thus confirmatory testing (GC/MS or LC/MS/MS) is needed to identify these drugs. If the purpose is to document compliance with treatment, the laboratory can be instructed to remove the cutoff concentration so that the presence of lower concentrations can be identified.”

Table PG1, on interpreting unexpected results of urine drug tests, was adapted from a table developed by the Canadian National Opioid Use Guideline Group that was cited by the American Society of Interventional Pain Physicians in its guideline on prescribing opioids for chronic noncancer pain.

<table>
<thead>
<tr>
<th>Unexpected Result</th>
<th>Possible Explanations</th>
<th>Possible Actions for the Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test is negative prescribed opioid</td>
<td>False negative</td>
<td>Conduct confirmatory testing, specifying the drug of interest (e.g., oxycodone often missed by immunoassay)</td>
</tr>
<tr>
<td></td>
<td>Noncompliance</td>
<td>Take a detailed history of patient’s medication use for the preceding 7 d (e.g., could learn that patient ran out several days before test)</td>
</tr>
<tr>
<td></td>
<td>Diversion</td>
<td></td>
</tr>
</tbody>
</table>
### Background/Overview

According to an evidence assessment by the American Society of Interventional Pain Physicians, approximately one-third of chronic pain patients do not use opioids as prescribed or may abuse them. Moreover, studies have found that a substantial proportion of chronic pain patients inaccurately report nonadherence to prescribed medications and use of illicit drugs.

Various strategies are available to monitor pain management and substance abuse treatment patients, and multicomponent interventions are often used. Many settings require patients to sign a contract before they are given a prescription for opioids. The contracts generally involve obtaining patients' agreement on behaviors they will engage in during the treatment period (e.g., taking medication as prescribed) and not engage in (e.g., selling prescribed medication and/or obtaining additional prescriptions from other physicians).

Confirming whether patients follow these behavioral guidelines can be a challenge. Risk-assessment screening instruments, such as the Screener and Opioid Assessment for Patients with Pain, and the ORT, can aid in the assessment of patients' risk for inappropriate drug use. In addition, the presence of “aberrant behaviors” can be used as a marker for patients who are at high risk for deviating from treatment protocols. Aberrant behaviors include multiple lost prescriptions, obtaining prescriptions from other practitioners, and displaying evidence of acute intoxication during office visits.

Another strategy for monitoring patients is testing of biologic specimens for the presence or absence of drugs. Currently, urine is the most commonly used biologic substance. Advantages of UDT are that it is readily available and standardized techniques for detecting drugs in urine exist. Other biologic specimens (e.g., blood, oral fluids, hair, sweat) can also be tested and may gain in popularity over time as techniques for collecting and analyzing these specimens become more standardized. In addition to urine testing, this review will address testing for oral fluids and hair.

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**Expected Result**

<table>
<thead>
<tr>
<th>Possible Explanations</th>
<th>Possible Actions for the Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>False positive</td>
<td>- Ask patients if they’ve given the drug to others</td>
</tr>
<tr>
<td>Patient acquired opioids from other sources (double-doctoring, &quot;street&quot;)</td>
<td>- Monitor compliance with pill counts</td>
</tr>
<tr>
<td>- Repeat urine drug testing regularly</td>
<td>- Ask patients if they accessed opioids from other sources</td>
</tr>
<tr>
<td>- Assess for opioid misuse/addiction</td>
<td>- Review/revise treatment agreement</td>
</tr>
<tr>
<td>- Repeat urine drug test regularly</td>
<td>- Assess for abuse/addiction and refer for addiction treatment as appropriate</td>
</tr>
</tbody>
</table>

UDS: urine drug screen.
URINE DRUG TESTING

There are 2 primary categories of UDT: immunotherapy and specific drug identification.

**Immunoassay Testing**

Immunoassay testing (also called presumptive testing or qualitative testing or screening) can be performed in a laboratory or at point-of-service. Immunoassay tests are based on the principle of competitive binding and use antibodies to detect a particular drug or drug metabolite in a urine sample. With competitive binding, a fixed amount of a labeled drug is added to the urine sample, and the drug or metabolite in the sample competes with the labeled drug for binding sites on the antibody. The amount of labeled antigen that binds with the antibody is inversely proportional to the amount of the drug or metabolite in the sample. Immunoassay tests vary in the type of compounds they can detect. Some detect specific drugs and may fail to recognize similarly structured drugs within the same class. Other immunoassays identify only classes of drugs and thus results cannot be used to determine which drug a patient is taking. For example, a positive result to an opiate immunoassay can be due to morphine or hydromorphone. The degree of crossreactivity (i.e., an antibody’s reactivity with a compound other than the target of the test) varies widely among immunoassays.

Immunoassay findings are generally reported qualitatively as either positive (drug level above a prespecified threshold) or negative (drug level below a prespecified threshold). Raising or lowering the threshold thus changes the proportion of positive tests. A negative test is interpreted as a level below the threshold and does not necessarily mean that the drug or metabolite is absent.

Immunoassays generally have a rapid turnaround time, to within minutes for onsite tests, and 1 to 4 hours for laboratory-based tests.

**Specific Drug Identification**

Confirmatory tests are always performed in a laboratory. GC/MS is considered to be the criterion standard for confirmatory testing. This technique involves using GC to separate the analytes in a specimen and for MS to identify the specific molecular structures of the drug and its metabolites. The tests are able to quantify the amount of drug or metabolite present in the urine sample. Definitive quantitative tests can be used to confirm the presence of a specific drug identified by a screening test and can identify drugs that cannot be isolated by currently available immunoassays. Results are reported as the specific levels of substances detected in the urine. GC/MS generally requires specification of the drug or drugs to be identified. Alternatively, "broad-spectrum screens" can be conducted. There is a several-day turnaround time for GC/MS testing.

An issue with both types of UDT is the possibility of sample tampering to mask the presence of illegal drugs. A variety of products and techniques are available to patients, and can be as simple as drinking a large amount of water to dilute the sample. There are also commercial dilution and cleaning products, additives, and urine substitutes. Some of these techniques can be detected by visual inspection of the sample (e.g., color) or by onsite testing of sample characteristics including urine temperature, creatinine concentration, and specific gravity.

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In addition, correct interpretation of UDT results is very important. Knowledge of drug metabolites is essential for accurate interpretation. Accurate interpretation of test results also requires knowledge of the drug manufacturing process. For example, due to manufacturing impurities, a small amount of hydrocodone may be present in urine samples from patients prescribed oxycodone. Thus, it would be acceptable to have this degree of hydrocodone if high amounts of oxycodone were also present.

There are various approaches to incorporating UDT into pain management and substance abuse treatment settings. Most commonly, patients undergo urine drug screening before beginning treatment to verify current drug use. Some clinicians believe that UDT should be routinely used to establish baseline information about substance use, but the optimal frequency and interval of testing remains uncertain. A universal approach to screening may uncover more inappropriate use and may reduce patients’ sense that testing is being performed due to a lack of trust. However, routine universal screening may place an unnecessary burden on the health care system and on the doctor-patient relationship. An alternative approach is selective testing of patients who are judged to be at increased risk for drug misuse.

Existing protocols vary for use of presumptive versus definitive tests. Some involve conducting routine confirmation of positive presumptive tests with definitive quantitative testing. Others use selective confirmation of positive presumptive tests, such as when an unexpected immunoassay result is not adequately explained by the patient. There is also a mixed approach, with routine confirmation of presumptive tests only for drugs with poor-performing immunoassays.

Full informed consent is a requirement before UDT. Patients should be informed of the specific drug testing protocol before treatment and should provide written agreement with the plan for monitoring. As stated in a joint U.S. Veterans Affairs/Department of Defense guideline, patients’ refusal to consent to urine testing should be considered as 1 factor in the overall assessment of patients’ ability to adhere to treatment.

**ORAL FLUID DRUG TESTING**

Oral fluid, liquid samples obtained from the oral cavity, can potentially be used to test for drug use. Oral fluid contains secretions from several different sources, including secretions from the 3 pairs of major salivary glands (parotid, sublingual, and submandibular), secretions from the minor salivary glands, oronasopharyngeal secretions, and cellular debris. The mixture of fluids obtained varies depending on the collection method used (e.g., spitting, suctioning, draining, or collection on some type of absorbent material). In addition, drug concentrations can be affected by the collection method, as well as by whether saliva stimulation methods were used. Several collection devices are commercially available in the United States and they generally involve collection on absorbent material (e.g., foam pad). Pads are then placed in a container with a stabilizing buffer solution. Drug concentrations may also vary depending on how the oral fluid is recovered from the collection device (e.g., by centrifugation or by applying pressure). Another issue is that drug concentrations may not reflect blood levels because of residual amounts of drug (specifically those ingested or smoked) remaining in the oral cavity after recent use.

Analysis techniques must be able to detect drugs present in low concentration and in a small volume of fluid (often <1 mL). Immunoassay techniques are available to detect drugs in oral fluid; they require a small
sample volume ($\approx 25 \mu L$). Immunoassays tend to be relatively sensitive techniques but they tend to have low specificity. Confirmation analysis is generally performed using MS-based methods. In recent years, advancements have been made in MS analysis techniques, including the development of multianalyte liquid chromatography-mass spectrometry (LC-MS) methods.

A practical advantage of oral fluid collection compared with urine is that samples can be obtained under direct supervision and without loss of privacy. It has been used in situations where urine sampling is impractical, such as testing drivers during traffic stops. Oral fluid sampling also has the potential to be useful in the pain management or substance abuse treatment settings, particularly when substitution or tampering with urine drug samples is suspected.

**HAIR TESTING**

Hair is made up of protein that traps chemicals in the blood at the time the hair was made in the hair follicle. Hair on the human head grows at the rate of approximately 0.5 inch per month. Thus, a 1.5-inch hair sample could be used to reveal drug use during the previous 90 days. Potential advantages of hair as a drug testing source include that its collection is noninvasive; it is easy to collect, store, and ship; sufficient samples are generally available for testing and retesting; and it is difficult to substitute or adulterate. Potential disadvantages are that hair analysis cannot detect recent drug use (i.e., within past 7 days), it is difficult to detect very light drug use (e.g., a single episode), and the fact that drug levels can be due to environmental exposure as well as drug use. In addition, variation in hair texture as well as cosmetic hair treatments can affect drug incorporation into hair and the accuracy of drug tests on hair samples. As with other types of samples, hair can be initially tested using immunoassay techniques, with confirmation by MS-based methods. Hair testing has been used in a variety of situations where detection of drug use during the previous several months is sought (e.g., preemployment screening, post-drug-treatment verification of relapse).

**FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests (LDTs) must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA). GC/MS tests and some immunoassays are performed in laboratory settings. Laboratories that offer LDTs must be licensed by CLIA for high-complexity testing. To date, the U.S. FDA has chosen not to require any regulatory review of this test.

A CLIA waiver is available for use of certain POC immunoassays. Tests eligible for a CLIA waiver are those considered to be simple, with low risk of error and low potential for harm. FDA is tasked with approving manufacturers’ applications for test system waivers. There are commercially available CLIA-waived urine tests for drugs such as cocaine, methadone, morphine/opiates, and oxycodone. There are also commercially available hair testing tests such as Quest Diagnostics ELISA tests for amphetamines, opiates, cocaine, marijuana metabolites, and phencyclidine. In addition, Omega Laboratories offers hair drug screening for cocaine and cocaine metabolites.
Several oral fluid drug test collection devices have been cleared for marketing by FDA through the 510(k) process. They include:

- Intercept™ Oral Fluid Drug Testing System (OraSure Technologies, Bethlehem, PA)
- Oral-Eze Saliva Collection System (Quest Diagnostics, Madison NJ)
- Quantisal® Oral Fluid Collection Device (Alere, Waltham, MA).

In addition to the oral fluid collection devices, FDA has cleared a number of assays for analysis of oral samples. For example, there are FDA-cleared assays for 9 drugs collected with the Intercept device. They are amphetamines, methamphetamine, cocaine/metabolite, opiates, marijuana/THC, phencyclidine, barbiturates, benzodiazepines, and methadone.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source
The evidence review addresses UDT as a component of pain management and substance abuse treatment. For each of these settings, the literature search focused on the accuracy of testing and on the clinical utility of testing (i.e., the impact of test results on patient management and/or on health outcomes). When published studies were not identified, relevant national and regional clinical practice guidelines were sought.

URINE DRUG TESTING
Diagnostic Accuracy for Detecting Prescribed Opioids and/or Illicit Drugs

Few studies have evaluated the accuracy of UDT outside of the research setting. One example of this type was published in 2011 by Manchikanti et al. The investigators evaluated in-office immunoassay testing and used GC/MS as the criterion standard comparison. The study was prospective and included consecutive patients recruited from a single pain management practice. Urine samples were tested for opioids and for illicit drugs. A total of 1000 patients had both the immunoassay and confirmatory tests; both tests were performed on the same urine sample. Personnel analyzing the tests were blinded to the results of the other test and to patient demographics. The study’s primary findings for the diagnostic accuracy of in-office immunoassays for detecting opioids compared with the reference standard are shown in Table 1.

Table 1: Diagnostic Accuracy Findings in Manchikanti et al (2011)

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients prescribed morphine, hydrocodone, codeine, hydromorphone</td>
<td>748</td>
<td>92.5% (90% to 94%)</td>
<td>89.6% (82% to 95%)</td>
</tr>
<tr>
<td>Patients prescribed oxycodone</td>
<td>134</td>
<td>80.0% (71% to 87%)</td>
<td>84.2% (60% to 96%)</td>
</tr>
<tr>
<td>Patients prescribed methadone</td>
<td>46</td>
<td>97.8% (88% to 99%)</td>
<td>100% (2% to 100%)</td>
</tr>
</tbody>
</table>

CI: confidence interval.
The most commonly identified illicit drugs were marijuana and amphetamines. The sensitivity and specificity of the immunoassay for detecting marijuana were 90.9% and 98.0%, respectively. Similar statistics for amphetamines were 47.0% and 99.1%, respectively. There were too few data to reliably report diagnostic accuracy of other illicit drugs.

A 2016 retrospective analysis by Johnson-Davis et al evaluated the diagnostic accuracy of an in-house urine drug screen panel at a national reference laboratory. Samples were from routine clinical testing in consecutive patients. The panel tested for 9 drug classes using immunoassay testing. Specimens that screened positive underwent confirmatory testing with GC/MS or liquid chromatography with tandem-mass spectrometry (LC/MS/MS). A shared confirmatory panel was used for samples testing positive to opiates or oxycodone. A total of 8825 samples were tested. Of them, 2642 (30%) tested positive for opiates and 1215 (14%) tested positive for oxycodone. Confirmatory testing identified 898 (34%) false-positive tests for opiates and 23 (2%) false-positives tests for oxycodone. Authors did not include information on what drugs, if any, were prescribed to patients.

**Section Summary: Diagnostic Accuracy for Detecting Prescribed Opioids and/or Illicit Drugs**

Few studies have evaluated the accuracy of UDT outside of the research setting, either for pain management or substance abuse treatment patients. One study found that diagnostic accuracy varied by drug type (e.g., was higher for patients prescribed methadone than for those prescribed oxycodone). Another study of a urine drug panel found a relatively high false-positive rate.

**Clinical Utility for Chronic Pain Patients Treated With Opioids**

The preferred study design is a randomized controlled trial (RCT) comparing treatment decisions and/or health outcomes in patients managed with and without use of UDT. When multifaceted interventions are used, it may be difficult to isolate the impact of drug testing from that of other components of the intervention. In that case, the preferred study design would include 1 arm with the full intervention and another arm with the same intervention but without UDT. In the absence of RCTs, the next most preferred study design is a non-RCT that adjusts findings for potential confounding factors.

**Managing Patients With UDT vs Without UDT**

A systematic review of the available literature on UDT in the chronic pain management setting, alone or as part of a treatment agreement, was published in 2010 by Starrels et al. Studies were eligible for inclusion in the review if they enrolled patients with chronic noncancer pain who were treated in an outpatient setting and measured opioid misuse outcomes after intervention implementation. Eleven studies met eligibility criteria; none was a RCT. Eight studies addressed UDT, 7 of the 8 interventions also involved treatment agreements. Studies used different protocols for UDT (e.g., some used random screening, others screened on a regular basis). Three studies stated that drug screening was done at a minimum frequency (i.e., at enrollment and/or annually), with additional testing if deemed necessary by the physician. Five studies described the type of testing used; 4 of them included confirmatory GC/MS testing. Reviewers reported that 4 of 11 studies included a control or comparison group. On closer inspection, 2 of the 4 studies labeled as controlled used historic comparison groups and 1 was a prospective single-arm study. Starrels et al did not
pool findings of the 4 studies. In the individual studies, opioid misuse was reduced by 7% before to 23% after intervention initiation compared with preintervention or historic controls.

Only 1 study included in the systematic review used a concurrent comparison group. The study, by Goldberg et al, retrospectively reviewed data from a medical center database on 91 patients with a documented pain management contract. By signing the contract, the patient agreed to 8 provisions, 1 of which was "lab tests may be used to check opioid use." Among the other 7 provisions was an agreement not to use illegal drugs and not to share or sell any medication, and an agreement that the patient would receive opioid medication only from a single primary care or pain clinic physician. The comparison group consisted of 224 similar patients without pain management contracts. Consumption of opioids was significantly higher in the intervention group than in the comparison group. For example, the intervention group consumed an average of 91 units of opioids quarterly and the comparison group consumed an average of 81 units (p<0.05; an opioid unit was defined as equivalent to 1 systematic administration of 10-mg morphine sulfate). Some of the data presented in the study were contradictory. For example, a table showed a significantly greater number of emergency department visits among patients in the pain contract group than in the comparison group, but the text stated that there were not more emergency department visits among patients in the pain contract group.

In the uncontrolled studies included in the systematic review, the proportion of patients with opioid misuse after intervention initiation ranged from 3% to 43%. Eight studies that included UDT as a component of the intervention. The protocol and frequency of UDT varied in these studies. In 3 studies, there was a minimum baseline frequency, at the time of enrollment, annually, or both, with additional testing performed according to the judgment of the treating clinician. One study performed testing at baseline and on a monthly basis. In the remaining 4 studies, the frequency was not specified explicitly, but was described as “regular" or “random.” In 2014, Dupouy et al published a systematic review of literature on the impact of UDT on patient management. All study designs and clinical settings were eligible for inclusion. Other article inclusion criteria were that the urine drug screens were conducted using the enzyme immunoassay technique and, for controlled studies, the comparison arm was patient management in the absence of urine testing. In addition, some type of medical management outcome had to be reported (e.g., reassessment of treatment, referral for specialist visits, hospitalization). Eight studies met reviewers’ inclusion criteria. Five were rated as poor quality and 3 as fair quality. The studies consisted of 1 RCT, 2 quasi-randomized studies, 1 observational cohort study, and 4 cross-sectional studies. The RCT was a study of routine drug screening in a psychiatric emergency center, a setting not addressed in this evidence review. Most of the other studies were also conducted in settings that fall outside of the scope of this evidence review. However, only 2 studies evaluated relevant populations: one was an uncontrolled evaluation of UDT of opioid-addicted patients and the other was a quasi-randomized study conducted in U.S. pain centers. The latter study, by Manchikanti et al, was included in the Starrels et al 2010 meta-analysis, previously described. Authors of the 2014 systematic review (Dupouy et al) did not pool study findings.

In 2016, Krishnamurthy et al published a retrospective cohort study comparing no-show and dropout rates in chronic pain patients who did and did not receive UDT. Before each clinic visit, patients received a letter stating that their provider might monitor adherence to treatment, including UDT. UDTs were not preformed...
randomly; investigators used propensity score matching to adjust for potential selection bias and confounding. The sample included 723 patients with a total of 4448 clinic visits (all patients had at least 2 visits). Results were that UDT in the first visit was significantly associated with a higher rate of no-shows at the second visit (odds ratio, 2.73; 95% confidence interval, 1.66 to 4.47; \( p<0.001 \)). The no-show rate was 10.2% in patients without UDT and 23.8% in patients with UDT. Moreover, the no-show rate was higher in patients testing positive for illicit drugs (34.6%) than in those testing negative for illicit drugs (21.7%). In addition, the rate of dropout from treatment increased significantly with each additional UDT (95% CI of the hazard ratio, 1.54 to 2.61).

**Managing Patients With Routine UDT vs Selective UDT**

No studies were identified.

**Managing Patients With Routine Confirmation of Positive Presumptive Tests vs Selective Confirmation of Positive Presumptive Tests**

No studies were identified.

**Section Summary: Clinical Utility for Chronic Pain Patients Treated With Opioids**

No RCTs were identified. There are several nonrandomized studies with comparison groups. In one of them, consumption of opioids was significantly higher in the intervention group (which signed a pain management contract, including the possibility of drug testing) than in the comparison group. In another study, the no-show rate was higher in patients who had UDT in a previous visit. The evidence is insufficient to demonstrate whether UDT in the pain management setting improves patient outcomes.

**Clinical Utility for Substance Abuse Treatment**

**Managing Patients With UDT vs Without UDT**

One RCT was identified that suggested UDT increases treatment compliance when receiving take-home methadone compared with no UDT. In 2001, Chutuape et al published findings of a study that included patients in a methadone treatment program who had submitted fewer than 80% positive opiate and/or cocaine-positive urine samples during a 5-week baseline period. These patients then participated in a methadone take-home program and were randomized to 1 of 3 groups: (1) continued permission to take-home methadone was contingent on 1 negative urine sample, randomly selected each week; (2) continued permission to take-home methadone was contingent on 1 negative urine sample, randomly selected each month; or (3) permission to take-home methadone was not based on results of urine testing (control group). After participating in the intervention, the rate of sustained (≥8 weeks) opiate and cocaine abstinence was significantly higher in the groups receiving UDT. The percentage of patients with sustained (≥8 ore weeks) opiate and cocaine abstinence was 56.6%, 38.9%, and 10.5% in the weekly, monthly, and control groups, respectively (\( p<0.002 \)).

In 2016, McDonell published an RCT evaluating a drug treatment intervention in primary care and that included analysis of whether UDT can detect underreporting of drug use. The trial included 829 patients with self-reported nonprescribed drug use or illegal drug use in the past 90 days. UDT were performed at baseline and at 3, 6, 9, and 12 months. Investigators found that 331 (40%) participants denied drug use but
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had a positive drug screen during at least 1 of the 5 assessments. Patients who denied opioid use but whose UDT was positive were more likely to be older, female, and have a higher Addition Severity Index (ASI) drug composite score. This trial was not designed to compare treatment success rates in patients managed with and without UDT.

Managing Patients With Routine UDT vs Selective UDT
No studies were identified.

Managing Patients With Routine Confirmation of Positive Presumptive Tests vs Selective Confirmation of Positive Presumptive Tests
No studies were identified.

Section Summary: Clinical Utility for Substance Abuse Treatment
No studies were identified that evaluated the accuracy of UDT compared with a valid reference standard in individuals undergoing substance abuse treatment. One RCT on UDT of patients in substance abuse treatment focused on the specific situation of testing to determine eligibility for take-home methadone. Another RCT found UDT identified drug use in a substantial number of patients who denied illicit usage; the impact on treatment success was not addressed.

ORAL FLUID DRUG TESTING
Diagnostic Accuracy for Detecting Prescribed Opioids and/or Illicit Drugs
Several studies were identified that compared oral fluid testing and UDT using paired samples collected concurrently. In 2011, Vindenes et al in Norway published a study comparing drug detection in oral fluid and urine samples in the drug treatment setting. A total of 164 pairs of urine and oral fluid samples, obtained at the same time, were collected from 45 opioid-dependent patients participating in a drug treatment program. Oral fluid samples were collected using the Intercept device and analyzed using a LC/MS/MS method developed in Norway. Urine samples were screened using immunoassays and confirmed using LC/MS/MS. All patients were being treated with buprenorphine or methadone, so it was expected that 1 of these drugs would be detected in each sample. Other than these 2 drugs, those most commonly detected were 7-aminoflunitrazepam (metabolite of flunitrazepam), amphetamine, and tetrahydrocannabinol. The sensitivity and specificity of the oral fluid samples compared with urine results were calculated. Key findings are shown in Table 2.

Table 2: Sensitivity and Specificity of Oral Fluid Samples in Vindenes et al (2011), Using Urinalysis as the Reference Standard

<table>
<thead>
<tr>
<th>Drug</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methadone</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>75%</td>
<td>Not applicable (analytic problems)</td>
</tr>
<tr>
<td>7-aminoflunitrazepam</td>
<td>76%</td>
<td>97%</td>
</tr>
<tr>
<td>Amphetamine</td>
<td>100%</td>
<td>95%</td>
</tr>
<tr>
<td>Tetrahydrocannabinol</td>
<td>82%</td>
<td>98%</td>
</tr>
<tr>
<td>6-MAM (heroin)</td>
<td>95%</td>
<td>80%</td>
</tr>
</tbody>
</table>

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A 2012 study by Heltsley et al included 133 patients undergoing pain management treatment who consented to provide oral fluid and urine samples. Oral samples were collected with the Quantisal device and specimens were analyzed by LC/MS/MS. Urine specimens were screened by immunoassay procedures and non-negative samples were confirmed by MS. Samples were tested for 34 drugs or drug metabolites, although in some instances different analyses were performed on urine and oral fluid specimens. A total of 1544 paired tests were performed. Of these, 329 (21.3%) were positive and 984 (63.7%) were negative in both matrices, for an overall agreement of 85%. Eighty-three (5.4%) findings were positive in oral fluid only and 148 (9.6%) were positive in urine only. Authors conducted several analyses of the sensitivity and specificity of oral fluid samples using urinalysis as the reference standard (see Table 3).

Table 3: Sensitivity and Specificity of Oral Fluid Samples in Heltsley et al (2012), Using Urinalysis as the Reference Standard

<table>
<thead>
<tr>
<th>Drug</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All drugs</td>
<td>69.0% (64.6% to 73.1%)</td>
<td>92.2% (90.4% to 93.7%)</td>
</tr>
<tr>
<td>Four drug categories&lt;sup&gt;a&lt;/sup&gt;</td>
<td>76.1% (60.9% to 86.9%)</td>
<td>95.9% (92.0% to 98.0%)</td>
</tr>
<tr>
<td>Six drug categories&lt;sup&gt;b&lt;/sup&gt;</td>
<td>82.3% (75.0% to 87.9%)</td>
<td>92.2% (88.7% to 94.7%)</td>
</tr>
</tbody>
</table>

CI: confidence interval.
<sup>a</sup> Categories include amphetamines, cannabis, cocaine, and opiates.
<sup>b</sup> Includes the above categories plus hydrocodone and oxycodone.

In 2014, Conermann et al compared findings of oral fluid and urinalysis in 153 paired samples from patients attending a pain management clinic. This study focused on confirmation that a treatment drug was being taken and did not report the sensitivity and specificity of oral fluid samples compared with urine samples. Oral fluid samples were collected with the Quantisal device. All specimens were screened with immunoassays and presumptive positive findings were confirmed using LC/MS. A total of 136 (89%) of the 153 paired samples tested positive for 1 or more treatment drugs (i.e., opioids, benzodiazepines) in 1 or both matrices. After excluding 4 paired samples due to missing data, 101 (76.5%) of 132 positive specimen pairs had exact drug class matches. In another 21 paired samples, there was at least 1 (15.9%) drug class match. Thus, there was an overall agreement between samples of 92.4%. Two analyses were positive in oral fluid only and 8 were positive in urine only.

**Clinical Utility**

No studies were identified that compared patient management decisions or health outcomes in patients managed using oral fluid drug testing versus UDT or no drug testing.

**Section Summary: Oral Fluid Testing**

The limited number of studies on the diagnostic accuracy of oral fluid testing compared with urine testing had variable findings. No studies were identified on the impact of oral fluid testing on health outcomes compared with UDT or no drug testing.
HAIR TESTING

Diagnostic Accuracy for Detecting Prescribed Opioids and/or Illicit Drugs

No studies were identified that compared the accuracy of hair and urine testing using paired samples collected concurrently in the pain management setting or drug abuse treatment setting. One study using paired samples of urine and hair was identified. It was published by Musshoff et al in 2006 and was conducted in Germany. Patients underwent drug testing as part of the intake process for psychiatric treatment. Urine and hair samples (both head hair and pubic hair) from known drug users were analyzed. Fifty-one patients were included; all provided urine samples, 47 provided head hair samples (1-3 segments), and 36 provided pubic hair samples. Drug analysis was done using GC-MS methods. The hair test was considered positive if any segment had a positive finding. Urine samples were analyzed using standard immunoassays; positive findings were not confirmed. Prevalence rates of drugs identified in hair and urine samples, as well as self-report of drug use, are shown in Table 4.

Table 4: Prevalence Rates of Drug Use in Musshoff et al (2006) (n=47)

<table>
<thead>
<tr>
<th>Source</th>
<th>Opiates</th>
<th>Cocaine</th>
<th>Methadone</th>
<th>Cannabinoids</th>
<th>Amphetamines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-report, n (%)</td>
<td>42 (89%)</td>
<td>18 (38%)</td>
<td>15 (32%)</td>
<td>26 (55%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Urine test, n (%)</td>
<td>33 (70%)</td>
<td>13 (28%)</td>
<td>14 (30%)</td>
<td>21 (45%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Hair test, n (%)</td>
<td>38 (81%)</td>
<td>26 (55%)</td>
<td>23 (49%)</td>
<td>15 (32%)</td>
<td>1 (2%)</td>
</tr>
</tbody>
</table>

Hair tests revealed a higher prevalence of drug use than UDT for most drugs, with the exception of cannabinoids. The prevalence of amphetamines was too low to make meaningful comparisons. Cannabinoids are known to be excreted slowly in urine and to have a low incorporation rate into hair. It is important to note that the hair analysis was used to detect drug use anytime during the past several months and the urine analysis to detect drug use in the past several days.

Clinical Utility

No studies were identified that compared patient management decisions or health outcomes in patients managed using testing of hair versus UDT or no drug testing.

Section Summary: Hair Testing

Hair testing cannot detect recent drug use (i.e., in the past few days). One study looked at this longer time frame in patients starting psychiatric treatment. It found a higher prevalence of drug use with hair testing versus UDT testing for most drugs; however, the implications of study findings for patients in pain management or substance abuse treatment is unclear. No studies were identified on the diagnostic accuracy of hair testing versus urine testing in patients with chronic pain or substance abuse. In addition, no studies were identified on the clinical utility of hair testing in pain management or substance abuse treatment.

SUMMARY OF EVIDENCE

For individuals who have chronic pain treated with opioids who receive UDT, the evidence includes nonrandomized comparative studies and a systematic review. Relevant outcomes are test accuracy and validity, health status measures, and resource utilization. There is insufficient evidence on diagnostic
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accuracy. No RCTs evaluating clinical utility were identified. Several nonrandomized comparative studies have provided inconclusive evidence on whether UDT in the pain management setting improves patient outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have a drug addiction who are in substance abuse treatment who receive UDT, the evidence includes 2 RCTs. Relevant outcomes are test accuracy and validity, health status measures, and resource utilization. No studies were identified that evaluated the accuracy of UDT compared with a valid reference standard in individuals undergoing substance abuse treatment. One RCT focused specifically on testing to determine eligibility for take-home methadone. The second RCT found that UDT identified drug use in a substantial number of patients who denied illicit usage; the impact on treatment success was not addressed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have chronic pain treated with opioids or with a drug addiction in substance abuse treatment who receive oral fluid drug testing, the evidence includes diagnostic accuracy studies using UDT as the reference standard. Relevant outcomes are test accuracy and validity, health status measures, and resource utilization. The limited number of studies on diagnostic accuracy of oral fluid testing compared with UDT had variable findings. No studies were identified assessing the impact of oral fluid testing on health outcomes compared with UDT or no drug testing. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have chronic pain treated with opioids or with a drug addiction in substance abuse treatment who receive hair drug testing, the evidence includes 1 diagnostic accuracy study in the psychiatric treatment setting. Relevant outcomes are test accuracy and validity, health status measures, and resource utilization. Hair testing cannot detect recent drug use (i.e., in the past few days) and thus has limited applicability to pain management or substance abuse treatment settings, except, perhaps, for initial intake. There are no studies comparing the diagnostic accuracy of hair testing compared to UDT in either setting. However, 1 relatively small study tested the hair and urine of known drug users recruited from a psychiatric clinic. The study looked for drug use over the past several months rather than the shorter timeframe generally needed in pain management or drug treatment settings. No studies were identified on the clinical utility of hair testing in pain management or substance abuse treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

References

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Policy History
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09/05/2013 Medical Policy Committee review
09/18/2013 Medical Policy Implementation Committee approval. New policy.
10/02/2014 Medical Policy Committee review
10/15/2014 Medical Policy Implementation Committee approval. Changed a phrase in the Policy Guidelines to read that, "quantitative mass spectrometry testing that is subsequently performed is only covered for confirmation of unexpected screening results, or for positive results for a prescribed drug." Changed a phrase in the Policy Guidelines to read that, "extensive custom profile panels of quantitative testing will not be covered without initial immunoassay screening on the drug classes of interest and coverage will be limited to those drug classes need for confirmation as described above."
01/01/2015 Coding Update
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/08/2015 Medical Policy Committee review
10/21/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2016 Coding update
10/06/2016 Medical Policy Committee review
10/19/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2016 Medical Policy Committee review
10/19/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes and CPT coding update.
10/05/2017 Medical Policy Committee review
10/18/2017 Medical Policy Implementation Committee approval. Title changed from "Urinary Drug Testing" to "Drug Testing in Pain Management and Substance Abuse Treatment". Replaced our entire policy with Blue Cross Blue Shield Association's policy to incorporate more updated guidelines for frequency and terminology.

Next Scheduled Review Date: 10/2018

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A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

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2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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