



# Louisiana

## Drug Testing in Pain Management and Substance Use Disorder Treatment

**Policy #** 00387

Original Effective Date: 09/18/2013

Current Effective Date: 10/17/2018

*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) 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:
  - o An adequate clinical assessment of patient history and risk of substance use disorder is performed;
  - o Clinicians have knowledge of test interpretation;
  - o 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 use disorder treatment, in-office or point-of-care (POC) presumptive (i.e., immunoassay) UDT to be **eligible for coverage**.

#### Patient Selection Criteria

In outpatient substance use disorder treatment, in-office or POC presumptive (i.e., immunoassay) 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:
  - o An adequate clinical assessment of patient history and risk of substance use disorder is performed;
  - o Clinicians have knowledge of test interpretation;

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- o 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 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) UDT, in outpatient pain management or substance use disorder treatment to be **eligible for coverage**.

### Patient Selection Criteria

Based on review of available data, the Company may consider definitive (i.e., confirmatory) UDT, in outpatient pain management or substance use disorder 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:
  - o Unexpected positive test inadequately explained by the patient;
  - o Unexpected negative test (suspected medication diversion);
  - o 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 UDT in outpatient pain management and outpatient substance use disorder treatment is considered to be **not medically necessary\*\*** when the above criteria are not met, including but not limited to routine presumptive or definitive (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 use disorder 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 both 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.

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 to 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 USE DISORDER**

##### **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:

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- 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)

"Immunoassays 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' immunoassays 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' immunoassays 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, is 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 non-cancer pain.

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**Table PG1. Interpreting Unexpected Urine Drug Tests Results**

Unexpected Result	Possible Explanations	Possible Actions for the Physician
Test is negative for prescribed opioid	<ul style="list-style-type: none"> <li>False negative</li> <li>Noncompliance</li> <li>Diversion</li> </ul>	<ul style="list-style-type: none"> <li>Conduct confirmatory testing, specifying the drug of interest (e.g., oxycodone often missed by immunoassay)</li> <li>Take a detailed history of patient's medication use for the preceding 7 days (e.g., could learn that patient ran out several days before test)</li> <li>Ask patients if they've given the drug to others</li> <li>Monitor compliance with pill counts</li> </ul>
Test is positive for nonprescribed opioid or benzodiazepines	<ul style="list-style-type: none"> <li>False-positive</li> <li>Patient acquired opioids from other sources (double-doctoring, "street")</li> </ul>	<ul style="list-style-type: none"> <li>Repeat urine drug testing regularly</li> <li>Ask patients if they accessed opioids from other sources</li> <li>Assess for opioid misuse/addiction</li> <li>Review/revise treatment agreement</li> </ul>
UDS positive for illicit drugs (e.g., cocaine, cannabis)	<ul style="list-style-type: none"> <li>False-positive</li> <li>Patient is occasional user or addicted to the illicit drug</li> <li>Cannabis is positive for patients taking certain medications (e.g., dronabinol)</li> </ul>	<ul style="list-style-type: none"> <li>Repeat urine drug test regularly</li> <li>Assess for abuse/addiction and refer for addiction treatment as appropriate</li> </ul>

UDS: urine drug screen.

## **Background/Overview**

### **OPIOIDS**

According to a 2012 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. In 2016, the International Narcotics Control Board reported that between 1999 and 2010, the number of deaths related to the use of prescription opioid painkillers increased 5-fold among United States women and increased by a factor of 3.6 among United States men. Additionally, studies have found that a substantial proportion of chronic pain patients inaccurately report nonadherence to prescribed medications and use of illicit drugs.

### **Monitoring Strategies**

Various strategies are available to monitor pain management and substance use disorder 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.

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Aberrant behaviors include multiple lost prescriptions, obtaining prescriptions from other practitioners, and displaying evidence of acute intoxication during office visits.

### **Testing Strategies**

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.

### **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 on-site tests, and 1 to 4 hours for laboratory-based tests.

#### *Specific Drug Identification*

Confirmatory tests are always performed in a laboratory. GC/MS and LC/MS are considered to be the criterion standard for confirmatory testing. These techniques involve using GC or LC 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.

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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 and LC/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 and LC/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 on-site testing of sample characteristics including urine temperature, creatinine concentration, and specific gravity.

The 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 detect a small amount of hydrocodone if high amounts of oxycodone were also present.

There are various approaches to incorporating UDT into pain management and substance use disorder 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 the use of presumptive vs 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 (VA)/Department of Defense guideline, patients’ refusal to consent to urine testing should be considered a 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

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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). Drug concentrations can be affected by the collection method and by the use of saliva stimulation methods. Several collection devices are commercially available in the United States, and they generally involve collection on an absorbent material, such as foam pads; pads are then placed in a container with a stabilizing buffer solution. Drug concentrations may also depend on how the oral fluid is recovered from the collection device (e.g., by centrifugation or by applying pressure). 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 ( $\approx 25 \mu\text{L}$ ). Immunoassays tend to be relatively sensitive techniques, but they have low specificity. Confirmation analysis is generally performed using mass spectrometry (MS)-based methods. In recent years, advancements have been made in MS analysis techniques, including the development of multianalyte LC-MS methods.

A practical advantage of oral fluid collection compared with urine collection 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 use disorder treatment settings, particularly when substitution or tampering with urine drug samples is suspected.

### ***Hair Testing***

Hair is composed of protein that traps chemicals in the blood at the time the hair develops in the follicle. Hair on the human head grows at approximately 0.5 inch per month. Thus, a 1.5-inch hair sample could be used to detect drug use during the previous 90 days. Potential advantages of hair as a drug testing source include: noninvasive collection; ease of collection, storage, and shipping; availability of samples for testing and retesting; and difficulty in tampering. Potential disadvantages include: recent drug use (i.e., within past 7 days) cannot be detected; difficulty in detecting very light drug use (e.g., a single episode); and drug levels can be affected by environmental exposure. 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 desired (e.g., pre-employment 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 must meet the general regulatory standards of the Clinical Laboratory

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Improvement Amendments (CLIA). Testing with GC/MS and some immunoassays are performed in laboratory settings. Laboratories that offer laboratory-developed tests 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 the 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. Moreover, there are commercially available hair testing tests such as Quest Diagnostics ELISA tests for amphetamines, opiates, cocaine, marijuana metabolites, and phencyclidine. In addition, Omega Laboratories (Mogadore, OH) 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, the 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: 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. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### **Rationale/Source**

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

This evidence review addresses UDT as a component of pain management and substance use disorder treatment. For each of these settings, the literature search focused on the accuracy of testing and on the

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clinical usefulness 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. In 2016, testing oral fluids and hair was added to this evidence review. The following is a summary of the key literature to date.

### **URINE, ORAL FLUID, AND HAIR DRUG TESTING**

#### **Clinical Context and Test Purpose**

The purpose of drug testing in patients with chronic pain treated using opioids or patients with drug addiction in substance use disorder treatment is to determine drug use. This review evaluates drug testing on urine, oral fluids, and hair.

The question addressed in this evidence review is: Does UDT, oral fluid drug testing, or hair drug testing improve the net health outcome in individuals with chronic pain being treated with opioids or individuals with drug addiction being treated for a substance use disorder?

The following PICOTS were used to select literature to inform this review.

#### ***Patients***

The populations of interest include the following: patients with chronic pain who are being treated with opioids and patients with a drug addiction who are being treated for a substance use disorder.

#### ***Interventions***

The interventions of interest are UDT, oral fluid drug testing, and hair drug testing.

#### ***Comparators***

For UDT, the comparator is no testing.

For oral fluid drug testing and hair drug testing, the comparators are UDT and no testing.

#### ***Outcomes***

Outcomes of interest for all tests are test accuracy and validity, health status outcomes, and resource utilization.

A negative result for a prescribed opioid could indicate a false negative, noncompliance, or diversion. The physician may conduct confirmatory testing, obtain a detailed history of medication use to determine the cause of noncompliance, and/or discuss whether the prescribed medication was given to others.

A positive result for a nonprescribed opioid or benzodiazepine could indicate a false-positive or that the patient is obtaining medication from other sources. The physician may request regularly repeated drug testing, discuss how the patient is accessing medication, address medication addiction, and/or revise the treatment agreement.

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A positive result for illicit drug use could indicate a false-positive, a patient who is an occasional user, or a patient who is addicted to the illicit drug. The physician may request regularly repeated drug testing and/or assess the patient for drug abuse or addiction.

### **Timing**

In patients with chronic pain being treated with opioids, drug testing may occur at baseline prior to treatment initiation. Subsequent tests may be conducted at a frequency appropriate for the addiction risk level of the individual patient.

In patients with drug addiction being treated for substance use disorders, drug testing may occur at baseline screening. During the stabilization phase, drug testing should be performed weekly for 4 weeks. During the monitoring phase, drug testing may be performed every 1 to 3 months.

### **Setting**

In patients with chronic pain being treated with opioids, drug testing can be conducted in outpatient settings.

In patients with drug addiction being treated for substance use disorders, drug testing may be conducted in outpatient substance use disorder centers.

## **URINE DRUG TESTING**

### **Technically Reliable**

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

### **Clinical Validity of Detecting Prescribed Opioids and/or Illicit Drugs**

A study evaluating the accuracy of UDT outside of the research setting was published in 2011 by Manchikanti et al. The investigators compared in-office immunoassay testing with GC/MS as the criterion standard comparison. The study recruited consecutive patients 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 performed on the same urine sample. Personnel analyzing the tests were blinded to the results of the other test and to patient demographics. The diagnostic accuracy of in-office immunoassays for detecting opioids compared with the reference standard are shown in Table 1. The most common illicit drugs identified were marijuana and amphetamines. Immunoassay sensitivity and specificity for detecting marijuana were 91% and 98%, and for amphetamines 47% and 99%, respectively. There were too few data to report diagnostic accuracy of other illicit drugs reliably.

To most effectively monitor medication compliance of patients being treated for chronic pain, an algorithm has been proposed. The algorithm would first test patients using immunoassays; next, samples with positive immunoassays plus pertinent negatives (samples with negative immunoassays for a medication that was prescribed) would undergo LC-MS/MS, considered the criterion standard). A study by Snyder et al

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(2017) tested this algorithm on 530 urine samples of patients being treated for chronic pain. Urine samples were tested for amphetamines, buprenorphine, benzodiazepines, cocaine, opiates, and oxycodone. Overall sensitivity of the immunoassay tests for these 6 drugs/drug classes was 78.5%. When positive immunoassay samples and pertinent negative samples were further tested by LC/MS, the overall sensitivity was increased to 84.6%. Table 1 provides sensitivity results for immunoassays conducted on subsamples from patients prescribed specific drugs.

**Table 1. Diagnostic Accuracy of Immunoassay Compared with Gas- or Liquid-Chromatography/Mass Spectrometry**

Group	n	Sensitivity (95% CI), %	Specificity (95% CI), %
<b>Manchikanti et al (2011)</b>			
Patients prescribed opiates <sup>a</sup>	748	92.5 (90 to 94)	89.6 (82 to 95)
Patients prescribed oxycodone	134	80.0 (71 to 87)	84.2 (60 to 96)
Patients prescribed methadone	46	97.8 (88 to 99)	100 (2 to 100)
<b>Snyder et al (2017)</b>			
Patients prescribed opiates <sup>a</sup>	284	79.4	NR
Patients prescribed oxycodone/oxymorphone	207	92.5	NR
Patients prescribed benzodiazepines	82	65.4	NR

CI: confidence interval; NR: not reported.

<sup>a</sup> Includes morphine, hydrocodone, codeine, or hydromorphone.

A 2016 retrospective analysis by Johnson-Davis et al evaluated the diagnostic accuracy of an in-house urine drug screen (UDS) 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 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.

A retrospective analysis by Bertholf et al (2016) evaluated the diagnostic accuracy of UDS in an outpatient setting by sending unexpected positive specimens to a reference laboratory for confirmatory testing. A total of 786 urine specimens with positive screening results were submitted for confirmation. Of the 387 amphetamine-positive specimens, 36 were confirmed by the reference laboratory as having amphetamine and/or methamphetamine, for a positive predictive value (PPV) of 9.3%. Of the 114 opiate-positive specimens, 99 were confirmed for a PPV of 86.8%. The PPV for methadone was 44.1% (45/102 positive specimens). The PPV for oxycodone and/or oxymorphone was 67.6% (38/74 positive specimens) and for both cannabinoid and cocaine was 100% (19/19 positive cannabinoid specimens and 27/27 positive cocaine specimens).

### **Section Summary: Clinical Validity of 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 use disorder treatment patients. Two studies conducted in pain management

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clinical settings reported that diagnostic accuracy varied by drug type. Among patients prescribed opiates, sensitivity of the UDT ranged from 79% to 93%, and among patients prescribed oxycodone, sensitivity ranged from 80% to 93%. A retrospective analysis of a urine drug panel found false-positive rates of 34% for opiates and 2% for oxycodone. A retrospective analysis focusing on unexpected positive samples reported a wide range of PPVs for UDS, from 100% for cocaine and cannabis to 87% for opioids.

### **Clinical Utility of 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 the 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 an 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***

#### *Systematic Reviews*

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 non-cancer pain who were treated in an outpatient setting and measured opioid misuse outcomes after intervention implementation. Eleven studies met eligibility criteria; none was an RCT. Quality of the studies was assessed as poor to fair. Eight studies included UDT, with seven of the eight interventions also involving treatment agreements. The protocol and frequency of UDT varied in these studies. In three studies, UDTs were performed at baseline and annually, 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 four studies, the frequency was not specified explicitly, but was described as “regular” or “random.” Five studies described the type of testing used; four of them included confirmatory GC/MS testing.

Reviewers reported that four of the studies included a control or comparison group. However, two of those studies used historical comparison groups and one was a prospective single-arm study. Due to the heterogeneity of interventions, Starrels et al did not pool findings of the 4 studies, with individual studies reporting opioid misuse reductions from 7% to 23% after intervention compared with preintervention rates or historical controls. In the 7 uncontrolled studies in the systematic review, the proportion of patients with opioid misuse after treatment agreements, drug testing, or both ranged from 3% to 43%.

Only a single study included in the systematic review used a concurrent comparison group. Goldberg et al (2005) retrospectively reviewed data from a university-affiliated VA medical center database on 91 patients with a documented pain management contract. By signing the contract, the patient agreed to 8 provisions, one 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

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comparison group consisted of 224 patients who received opioid prescriptions without pain management contracts during the same time period, matched by age, sex, and race. Consumption of opioids was higher in the intervention group (average of 91 opioid units quarterly) than in the comparison group (average of 81 opioid units quarterly), though this difference was not statistically significant. An opioid unit was defined as 1 systematic administration of morphine sulfate 10 mg. Patients in the intervention group visited their primary care providers significantly more than the control group. Visits to the emergency department did not differ statistically between the groups.

In 2014, Dupouy et al published a systematic review of the literature on the impact of UDT on patient management. All study designs and clinical settings were eligible for inclusion. For a study to be included, the UDS had to be conducted using the enzyme immunoassay technique. 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 three 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. Other studies were either drug screening in an emergency department or parents requesting screening of their children. Only 2 studies evaluated relevant populations for this review: 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 (2006), was included in the 2010 systematic review, previously described. Authors of the 2014 systematic review (Dupouy et al) did not pool study findings.

### *Observational Studies*

In 2016, Krishnamurthy et al conducted a retrospective cohort study in a university-based pain clinic comparing no-show with 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. 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 showed that UDT at 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% confidence interval [CI] of the hazard ratio, 1.54 to 2.61).

To address the increase in suicide and overdose events occurring with the increase in prescription opioid use, the VA and the Department of Defense formulated clinical practice guidelines for the safe use of opioid treatment for chronic pain. In the guideline, baseline and random UDS were recommended (see the Supplemental Information section). Brennan et al (2016) evaluated the effect of implementing these guidelines on suicide- and overdose-related events. Facility-level data and patient-level data were used in the analysis. From 141 VA healthcare facilities, the facility percentage of opioid-prescribed patients who

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obtained one or more UDS was calculated. The following data on 484,241 patients from the VA National Patient Care Data files was collected: age, sex, race (white or non-white), marital status, medical comorbidities, mental health comorbidities, UDS, and suicide or drug-related events. The statistical model estimated the effect of UDS practices from 2010 to 2013 on opioid-prescribed patients' suicide/overdose risk in 2013. Patients' average age was 60 years, and 7% were women, 19% non-white, and 50% unmarried. Twenty-nine percent had medical comorbidities, and 55% had mental health comorbidities. From 2010 to 2013, the percent of opioid-prescribed patients who received UDS increased from 29% to 42% in VA health care facilities. Patient-level analyses showed that younger, non-white, and unmarried patients had significantly higher risk of suicide or overdose events. Facility-level analyses showed that conducting more UDS in a facility was significantly related to a reduction in suicide and overdose events. Model estimates suggested that for every 1% increase in UDS, there was a 1% reduction in patient-level risk of suicide or overdose event.

Stammet et al (2016) evaluated treatment changes occurring after a pharmacist-run UDT e-consult service was implemented in a southeast VA health care system. During the 2-year pilot study period, 143 e-consults interpreting 190 UDT results were assessed. Based on VA prescription records, the UDS results were classified as: expected (18%), unexpected (28%), and not necessarily inappropriate (54%). In more than 50% of the unexpected results group, the e-consult service recommended immediate action to be taken and, in 35% of those situations, providers documented action within a 30 day period. Other recommendations by the pharmacist included: orders for immediate UDT or more frequent UDT, changes in drug prescriptions, and referrals to pain management services or substance use disorder treatment programs. Follow-up to the recommendations was not available.

### ***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 of Chronic Pain Patients Treated With Opioids***

A single RCT in the systematic reviews was identified, though the setting was a psychiatric emergency facility and not relevant to this review. There are several nonrandomized studies with comparison groups and several observational studies. However, both the interventions and the outcomes differed among studies. The interventions often involved patient contract agreements in which UDTs were a component, and 1 intervention was an e-consult service that included UDT recommendations. UDTs were usually conducted randomly and at the discretion of the health care provider. Outcomes across the studies included: primary care visits, emergency room visits, suicide and overdose risk, and opioid misuse. Due to the heterogeneity across interventions and outcomes, pooling of results studies was not possible.

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### Clinical Utility of Substance Use Disorder 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 conducted a study of 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 in which patients were tested every Monday, Wednesday, and Friday. These patients then participated in a methadone take-home program and were randomized into 1 of 3 groups: (1) continued permission to take-home methadone was contingent on 1 negative urine sample, randomly selected each week (n=16); (2) continued permission to take-home methadone was contingent on 1 negative urine sample, randomly selected each month (n=18); or (3) permission to take-home methadone was not based on results of urine testing, but on results of a random drawing in which half of the control group were given the take-home methadone (control group) (n=19). Ten subjects withdrew from the trial, six from the weekly-tested group, three from the monthly-tested group, and one from the never-tested group. After participating in the intervention, the rate of sustained ( $\geq 8$  weeks) opiate and cocaine abstinence was significantly higher in the groups receiving UDT. The percentages of patients with sustained ( $\geq 8$  weeks) opiate and cocaine abstinence were 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 that included an 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 was performed at baseline and at 3, 6, 9, and 12 months. Investigators found that 331 (40%) participants denied drug use but 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 Addiction Severity Index 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 of Substance Use Disorder Treatment***

One small RCT on UDT of patients in substance use disorder treatment focused on the specific situation of testing to determine eligibility for take-home methadone. The percentage of patients with 8 or more weeks of opiate or cocaine abstinence was significantly larger in the groups receiving UDT compared with the group not receiving UDT, though there was a large dropout rate in the groups receiving UDTs. 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 in this trial. A currently ongoing RCT sponsored by the French

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Ministry of Health is evaluating the effectiveness of performing on-site UDS on patients receiving drug addiction treatment in a general practitioner's office. Patients were randomized to a control group (usual care) or to an intervention group in which the practitioners receive UDS supplies and a training session on the use and interpretation of UDS. The primary outcome is retention of opioid management treatment at 6 months. Secondary outcomes are patient adherence to buprenorphine, psychoactive substance use, patient acceptance of UDS, and practitioner acceptance of UDS. Data collection is expected to continue through July 2018.

### ORAL FLUID DRUG TESTING

#### Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist.

#### Clinically Valid

In 2011 Heltsley et al collected oral fluid samples from 231 pain clinics across 20 states, analyzed the samples for 40 drugs or metabolites, and ran confirmatory tests with LC-MS/MS. A total of 6441 samples were collected and 5401 tested positive for at least 1 drug category: 38% for 1 drug, 33% for 2 drugs, and 29% for 3 or more drugs. The highest drug prevalence rates detected through immunoassay testing were: opiates (52%), oxycodone (41%), and benzodiazepines (16%). Confirmatory analyses showed the true positive rates for the oral fluid tests of these 3 highest detected drugs to be 76%, 88%, and 99%, respectively.

Several studies have compared oral fluid testing with UDT using paired samples collected concurrently. For example, in 2011, Vindenes et al in Norway published a study comparing drug detection in oral fluid with 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 an LC-MS/MS method developed in Norway. Urine samples were screened using immunoassays and confirmed using LC-MS/MS. All patients were treated with buprenorphine or methadone, so it was expected that one of these drugs would be detected in each sample. Other than these 2 drugs, drugs 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.

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

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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 2).

**Table 2. Sensitivity and Specificity of Oral Fluid Samples Using Urinalysis as the Reference Standard**

Drug	Sensitivity (95% CI), %	Specificity (95% CI), %
Vindenes et al (2011)		
Methadone	100	100
Buprenorphine	75	Not applicable (analytic problems)
7-aminoflunitrazepam	76	97
Amphetamine	100	95
Tetrahydrocannabinol	82	98
6-MAM (heroin)	95	80
Heltsley et al (2012)		
All drugs	69.0 (64.6 to 73.1)	92.2 (90.4 to 93.7)
Four drug categories <sup>a</sup>	76.1 (60.9 to 86.9)	95.9 (92.0 to 98.0)
Six drug categories <sup>b</sup>	82.3 (75.0 to 87.9)	92.2 (88.7 to 94.7)

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 one or more treatment drugs (i.e., opioids, benzodiazepines) in one 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 eight were positive in urine only.

Kunkel et al (2015) conducted a retrospective analysis of 4560 unobserved urine collection samples and 2368 observed oral fluid collection samples of patients undergoing opioid addiction treatment. The samples were tested for 13 different illicit and prescription drugs. Oral fluid testing detected higher rates of most of the drugs compared with urine testing. For example, oral fluid tests detected 6.5% morphine, 5.2% oxycodone, 3.8% codeine, and 3% cocaine use, while urine tests detected 2.3% morphine, 0.6% oxycodone, 0.7% codeine, and 1.4% cocaine use. Interpretation of these results is limited because the urine and oral fluid samples were not paired.

### Clinically Useful

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

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### 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

#### Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist.

#### Clinically Valid

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 use disorder treatment setting. One study using paired samples of urine and hair from patients in a psychiatric facility was identified (Musshoff et al, 2006). 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 3.

**Table 3. Prevalence Rates of Drug Use (N=47)**

Source	Opiates	Cocaine	Methadone	Cannabinoids	Amphetamines
Musshoff et al (2006)					
Self-report, n (%)	42 (89)	18 (38)	15 (32)	26 (55)	1 (2)
Urine test, n (%)	33 (70)	13 (28)	14 (30)	21 (45)	0 (0)
Hair test, n (%)	38 (81)	26 (55)	23 (49)	15 (32)	1 (2)

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.

#### Clinically Useful

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

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### **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 vs UDT for most drugs; however, the implications of study findings for patients in pain management or substance use disorder treatment is unclear. No studies were identified on the diagnostic accuracy of hair testing vs UDT in patients with chronic pain or substance use disorder. In addition, no studies were identified on the clinical utility of hair testing in pain management or substance use disorder treatment.

### **SUMMARY OF EVIDENCE**

For individuals who have chronic pain treated with opioids who receive UDT, the evidence includes nonrandomized comparative studies and systematic reviews. Relevant outcomes are test accuracy and validity, health status measures, and resource utilization. The evidence on the diagnostic accuracy of urine immunoassay tests, as confirmed by gas- or liquid-chromatography/mass spectrometry, shows sensitivities ranging from about 80% to 93% for both opiates and oxycodone. No RCTs evaluating clinical utility were identified. Several nonrandomized comparative studies have been conducted, though interventions and outcomes have varied across the studies. Most interventions included patient contracts along with UDT, and therefore, the effect of UDT alone could not be determined. Most studies did not provide details on the frequency of UDTs and whether the testing was random or scheduled. As a result, these studies 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 use disorder 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 use disorder treatment. One small RCT focused specifically on UDT 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 use disorder 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 the diagnostic accuracy of oral fluid testing compared with UDT have varied 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 use disorder treatment who receive hair drug testing, the evidence includes a 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

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limited applicability to pain management or substance use disorder treatment settings, except, perhaps, for initial intake. There are no studies comparing the diagnostic accuracy of hair testing with UDT in either setting. One 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 use disorder treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

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### **Policy History**

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Current Effective Date: 10/17/2018

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.

04/01/2018 Coding update

10/04/2018 Medical Policy Committee review

10/17/2018 Medical Policy Implementation Committee approval. Title changed from "Drug Testing in Pain Management and Substance Abuse Treatment" to "Drug Testing in Pain Management and Substance Use Disorder Treatment". The term "abuse" replaced with "substance use" to align text with title change. Coverage eligibility unchanged.

Next Scheduled Review Date: 10/2019

### **Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT)<sup>®</sup>†, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	80188, 80299, 80300, 80301, 80302, 80305, 80303, 80304, 80306, 80307, 80320, 80321, 80322, 80324, 80325, 80326, 80329, 80330, 80331, 80332, 80333, 80345, 80346, 80347, 80348, 80349, 80350, 80351, 80352, 80353, 80354, 80355, 80356, 80357, 80358, 80359, 80360, 80361, 80362, 80363, 80364, 80365, 80366, 80367, 80368, 80369, 80370, 80371, 80372, 80373, 80374, 80375, 80376, 80377, 83992 Code deleted eff 10/1/2018: 0020U
HCPCS	G0480, G0481, G0482, G0483
ICD-10 Diagnosis	All related diagnoses

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- 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:
  - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

\*\*Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- 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.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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