Health Evidence Review Commission (HERC)

Coverage Guidance:

Urine Drug Testing

Approved 8/9/2018

HERC Coverage Guidance

Urine drug testing (UDT) using presumptive testing is recommended for coverage (*weak recommendation*) when the results will affect treatment planning.

Definitive testing is recommended for coverage as a confirmatory test only when the result of the presumptive testing is inconsistent with the patient's history, presentation, or current prescribed medication plan, and the results would change management.

Definitive testing other than to confirm the results of a presumptive test as specified above is not recommended for coverage (*weak recommendation*), unless the clinician suspects use of a substance that is inadequately detected by presumptive UDT (e.g., fentanyl).

Definitive testing is recommended for coverage for no more than seven substances per day.

In patients receiving treatment for a substance use disorder, random UDT is recommended for coverage (*weak recommendation*). Up to 36 presumptive tests and 12 definitive tests are recommended per year. These limits must be applied in accordance with mental health parity law.

In patients receiving chronic opioid therapy for chronic pain, random UDT is recommended for coverage (*weak recommendation*), with frequency of testing depending on the patient's risk level (using a validated opioid risk assessment tool). Definitive testing should be conducted only for confirmatory purposes as described above and should not exceed 12 tests per year:

- Low Risk: Random presumptive testing up to two times per year
- Moderate Risk: Random presumptive testing up to four times per year
- High Risk: Random presumptive testing up to 12 times per year

In patients with unexplained alteration of mental status and when knowledge of drug use is necessary for medical management (e.g., emergency department evaluation for altered mental status), UDT (presumptive and confirmatory definitive testing, if indicated) is recommended for coverage not subject to the above limitations (weak recommendation).

Urine drug testing for the purposes of child welfare is outside the scope of this Coverage Guidance.

Note: Definitions for strength of recommendation are in Appendix A. *GRADE Table Element Description*.

Rationales for each recommendation appear below in the GRADE table.

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Rationale for development of coverage guidances and multisector intervention reports

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as plan administrators seek to improve patient experience of care, population health, and the cost-effectiveness of health care. In the era of public and private sector health system transformation, reaching these goals requires a focus on maximizing the benefits and minimizing the harms and costs of health interventions.

HERC uses the following principles in selecting topics for its reports to guide public and private payers:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

HERC bases its reports on a review of the best available research applicable to the intervention(s) in question. For coverage guidances, which focus on diagnostic and clinical interventions, evidence is evaluated using an adaptation of the GRADE methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. In some cases, HERC has reviewed evidence and identified effective interventions, but has not made formal coverage recommendations when these policies are implemented in settings other than traditional health care delivery systems because effectiveness may be dependent on the environment in which the intervention is implemented.

GRADE Table

HERC develops recommendations by using the concepts of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for performing the steps involved in developing recommendations. The table below lists the elements that determine the strength of a recommendation. HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. Assessments of confidence are from the published systematic reviews and meta-analyses, where available and judged to be reliable.

In some cases, no systematic reviews or meta-analyses encompass the most current literature. In those cases, HERC may describe the additional evidence or alter the assessments of confidence in light of all available information. Such assessments are informed by clinical epidemiologists from the Center for Evidence-based Policy. Unless otherwise noted, statements regarding resource allocation, values and preferences, and other considerations are the assessments of HERC, as informed by the evidence reviewed, public testimony, and subcommittee discussion.

Recommendations for coverage are based on the balance of benefit and harms, resource allocation, values and preferences and other considerations. See Appendix A for more details about the factors that constitute the GRADE table.

GRADE Table

Should urine drug testing be recommended in the management of patients receiving opioid prescriptions for chronic pain?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Overdose and death *(Critical outcome)*	Insufficient evidence	Point-of-care presumptive (qualitative testing) is much less expensive than definitive (quantitative) confirmatory testing. Routinely performing definitive testing adds significant cost, especially when testing for a large number of substances. A strategy of using definitive testing as confirmatory after unexpected presumptive test results could optimize resource allocation. Frequency of testing also affects overall cost.	Patients who are prescribed opioids would likely want to be treated in a way that maximizes benefit and reduces harm. Some patients would prefer not to have UDT because it could be seen as questioning their behavior, undermine the perceived validity of opioids as chronic pain treatment, and result in unplanned changes in management that a patient could feel are unwarranted. Patients would generally prefer accurate tests, so false-positive and false-negative results would not lead to an unplanned change in management. From a societal values perspective, society would	UDT can provide critical information about diversion (i.e., a negative UDT result for a patient being prescribed an opioid). This has important public safety implications, and therefore understanding the societal values and preferences related to UDT is important. UDT also provides information about concomitant use of other medications/ substances that is necessary for clinicians to know about to ensure safe and appropriate prescribing; information that patients might not provide and is otherwise difficult to verify.
Identification of diversion *(Critical outcome)*	Insufficient evidence			

Should urine drug testing be recommended in the management of patients receiving opioid prescriptions for chronic pain?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Identification of other substance use disorders *(Critical outcome)*	Insufficient evidence		want to ensure that patients are not being prescribed medications that increase their risk of death, overdose, or addiction, or that are contributing to street availability of controlled substances.	If UDT suggests evidence of a substance use disorder, there is a need for additional assessment and a potential opportunity for treatment.
Test performance characteristics *(Important outcome)*	Limited evidence from single-center diagnostic accuracy studies comparing point-of-care immunoassays to a reference standard (liquid chromatography or mass spectroscopy) suggests low to moderate rates of false-positive and false-negative test results depending on the substance and cutoff values (see Table 1 in the Evidence Review for further details) ●○○○ Very low certainty			

Should urine drug testing be recommended in the management of patients receiving opioid prescriptions for chronic pain?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Change in management of chronic pain or substance use disorder *(Important outcome)*	Insufficient evidence			

Balance of benefits and harms: Insufficient evidence exists to support the clinical utility of UDT or to address the relative balance of benefits to harms. Theoretically, UDT would provide a significant benefit for safe and appropriate prescribing by ensuring that the patient is using the prescribed medication appropriately and to verify that there is not concurrent use of other substances, which could increase harms. The theoretical harms of UDT include undermining the patient-physician relationship and creating a suboptimal change in management based on erroneous information. Given that opioid medications have well-known risks including overdose, death, and diversion, and lack of proven benefit, the expected benefits of UDT significantly outweigh the potential harms.
Rationale: Despite the lack of evidence, UDT can theoretically help to identify appropriate adherence to a prescribed regimen, confirm absence of illicit substances, and identify diversion. UDT is universally recommended by guidelines and other payers as a mechanism to objectively identify the appropriate use of opioids and avoidance of other concerning substances. The harms are in the false-positive and false-negative rates, which could lead to inappropriate changes in management and undermine trust in the patient-provider relationship. The data suggest that overuse of UDT occurs, resulting in significant costs, particularly when frequent definitive testing is performed for large numbers of substances. Therefore, we make a recommendation for coverage with restrictions.
Recommendation: UDT is recommended for coverage, with specified restrictions on the type and quantity of testing (see full recommendation on page 1) (*weak recommendation*).

Should urine drug testing be recommended in the management of patients with a known or suspected substance use disorder?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Overdose and death *(Critical outcome)*	Insufficient evidence	Point-of-care presumptive (qualitative) testing is much less expensive than (quantitative) confirmatory testing. Routinely performing definitive testing adds significant cost, especially when testing for a large number of substances. A strategy of using definitive testing as confirmatory after unexpected presumptive test results could	Some patients would prefer not to have UDT to verify their reported substance abstinence or use. Many patients will do whatever is necessary for treatment, including UDT, but they likely would prefer testing to be done less frequently rather than more frequently. Patients would generally prefer tests that have a low false-positive rate for illicit substances because false-positives would decrease trust in the patient-clinician relationship, and potentially erroneously decrease earned privileges (such as in an Opioid Treatment	Random UDT, rather than predictable UDT, is widely recommended by expert organizations. UDT is an essential part of law enforcement and child custody requirements for many patients to ensure ongoing abstinence or adherence to a treatment program.
Identification of diversion *(Critical outcome)*	Insufficient evidence			
Identification of other substance use disorders *(Critical outcome)*	Insufficient evidence			
Test performance characteristics *(Important outcome)*	Limited evidence from single-center diagnostic accuracy studies comparing point-of-care immunoassays to a reference standard (liquid chromatography or mass spectroscopy) suggests low to moderate rates of false-positive and false-negative test results depending on the substance and cutoff values (see Table 1 in the Evidence Review for further details) ●○○○ Very low certainty			

Should urine drug testing be recommended in the management of patients with a known or suspected substance use disorder?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Change in management of chronic pain or substance use disorder *(Important outcome)*	Insufficient evidence	optimize resource allocation. Frequency of testing also affects overall cost. There are some patients for whom very frequent definitive testing has been completed (e.g., every few days) for multiple substances (> 20) over extended periods of time.	Program). In contrast, some patients might prefer less accurate tests with high false-negative rates if they are actively using other substances that they would prefer not to disclose. From a societal perspective, there would be value that patients receiving substance use disorder treatment are confirming receipt of safe and effective treatment (without high-risk concurrent use of illicit substances) and that there is not active diversion occurring, which threatens public safety.	

Balance of benefits and harms: Insufficient evidence on the clinical utility of UDT is available. There is a compelling theoretical argument that in patients with a substance use disorder, it is critical to understand adherence to a high-risk treatment (i.e., opioid agonist therapy) and concurrent use of other substances that put the patient at high risk of death or overdose. Additionally, identifying patients who are diverting these high-risk medications into the public could be a significant societal benefit if the testing helped to decrease diversion. The harms in this population are relatively small, although tests with high false-positive or false-negative results might result in changes to the treatment plan that could negatively affect patient outcomes.

Should urine drug testing be recommended in the management of patients with a known or suspected substance use disorder?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Rationale: There is insufficient evidence to demonstrate the relative benefits and harms of UDT in individuals with a substance use disorder. Despite the lack of evidence, UDT can theoretically help to identify appropriate adherence to a prescribed regimen, confirm absence of illicit substances, and help to identify diversion. UDT is universally recommended by guidelines as a mechanism to monitor adherence to the treatment plan and determine whether changes in the treatment plan are needed. Harms could involve false-positives (or false-negatives), which might lead to unwarranted changes in the management plan. Frequent drug testing might also feel like a burden or invasion of privacy for patients. There are data suggesting overuse of UDT, which entails significant costs, particularly when frequent definitive testing is performed. Therefore, we make a recommendation for coverage with restrictions. The expected benefits of performing UDT on individuals with a substance use disorder outweigh the expected harms, although patient values of accurate and less frequent testing and moderate expense temper the recommendation, resulting in a weak recommendation in favor of coverage with restrictions.				
Recommendation: UDT is recommended for coverage in patients with a substance use disorder, with specified restrictions on the type and quantity of testing (see full recommendation on page 1) (*weak recommendation*).				

Note: GRADE table elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.

Background

Urine drug testing (UDT) is a noninvasive procedure used to screen for drug use among patients being treated for a substance use disorder (SUD) and patients prescribed opioids for chronic pain, to test for the use of prescribed medications and other substances. UDT can fulfill multiple purposes during substance use treatment as:

- Part of the initial assessment of a patient being evaluated for a diagnosis of a SUD
- A screen to prevent potential adverse effects of pharmacotherapy (e.g., opioid screen prior to starting naltrexone)
- A component of the treatment plan for a SUD
- A way to monitor the patient's use of illicit substances or adherence to pharmacotherapy treatment for a SUD
- A way to assess the efficacy of the treatment plan (i.e., level of care) (Substance Abuse and Mental Health Services Administration [SAMHSA], 2012)

Although UDT had been used in SUD treatment for decades, UDT has increased in recent years because of increases in prescriptions for opioid medications, the number of patients with opioid use disorders (OUDs), and overdose deaths (American Society of Addiction Medicine [ASAM], 2013). Opioid Treatment Programs (which can administer methadone or buprenorphine) are federally mandated to provide adequate testing or analysis for drugs of abuse for patients in OUD maintenance treatment, including a minimum of eight random drug abuse tests each year. Patients receiving long-term detoxification treatment (opioid agonist medication in decreasing doses for more than 30 days) in an Opioid Treatment Program must receive an initial drug abuse test and then monthly random tests (Code of Federal Regulations, 2015).

In recent years, there have been concerns about the overuse of drug tests. For example, the U.S. Department of Justice announced a settlement with Millennium Health in 2015 to resolve alleged violations of the False Claims Act for billing Medicare, Medicaid, and other federal health care programs for medically unnecessary urine drug tests (U.S. Department of Justice, 2015). Millennium Health allegedly gave physicians free UDT cups in exchange for referring drug testing to their labs, which violated the federal Physician Self-Referral Law (Stark law) and Anti-Kickback Statute (Office of Inspector General, U.S. Department of Health & Human Services, n.d.). Millennium Health encouraged physicians to order "custom profiles," which caused physicians to order a large number of tests for each patient without an individualized assessment of that patient's needs. Millennium Health agreed to pay more than $200 million for excessive and unnecessary urine drug tests from 2008 to 2015 (U.S. Department of Justice, 2015).

Indications

There are generally two types of patients that are given periodic UDT. First, patients being treated for a SUD can be given UDT to screen for use of substances that the patient might be abusing. Second, patients with chronic pain who are being treated with opioids can be given UDT to ensure that the patient is taking the prescribed medications (and not diverting the opioids and distributing to others) and that the patient is not using other drugs of abuse.

Technology Description

Presumptive (sometimes called qualitative) drug tests are generally performed by immunoassay, and definitive (sometimes called quantitative) drug tests are performed by gas chromatography-mass spectrometry (GC-MS) or liquid chromatography-tandem mass spectrometry (LC-MS/MS). Definitive testing is more accurate and more expensive than presumptive testing. Definitive testing is often used as a confirmation test when results of the presumptive test are unexpected. More recently, definitive testing has been used without an initial presumptive test to provide information about an array of medications, including those that cannot be reliably detected by presumptive tests (ASAM, 2013).

Presumptive immunoassay tests can be analyzed at the point of care or sent to a laboratory. In immunoassay tests, competitive binding and antibodies to the drug of interest are used to detect the presence of a drug at a specific level. A fixed amount of labeled drug is added to a urine sample, and the drug present in the urine competes with the labeled drug to bind to the antibodies. The test measures the amount of labeled drug that binds to the antibody, which is inversely proportional to the concentration of drug in the urine. Immunoassay tests for different drugs vary in their accuracy and cross-reactivity (i.e., ability of the antibody to bind with drugs other than the drug of interest). Presumptive drug tests are reported as "positive" or "negative," based on a specified level of drug detected. Immunoassay tests analyzed at the point of care can be interpreted within minutes, and those sent to a laboratory for analysis are typically analyzed within one to four hours (SAMHSA, 2012).

Definitive tests are performed in a laboratory and typically take several days to analyze. Gas or liquid chromatography is used to separate the urine analytes, and then mass spectrometry is used to identify the drugs and metabolites by their molecular structure. Results are reported as drug concentrations detected in the urine. Single-drug definitive tests are available, and definitive drug test panels can assess for multiple drugs (ASAM, 2013). According to SAMHSA (2012), common drug test panels include the following:

- Amphetamine, methamphetamine
- Barbiturates (amobarbital, butabarbital, butalbital, pentobarbital, phenobarbital, secobarbital)
- Benzodiazepines (alprazolam, chlordiazepoxide, clonazepam, clorazepate, diazepam, flurazepam, lorazepam, oxazepam, temazepam)
- Illicit drugs (cocaine, methylenedioxyamphetamine [MDA], methylenedioxymethamphetamine [MDMA], methylenedioxyethylamphetamine [MDEA], marijuana)
- Opiates/opioids (codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, meperedine, methadone, morphine, oxycodone, oxymorphone, propoxyphene)

Evidence Review

The search for evidence found four systematic reviews and two diagnostic accuracy studies pertaining to the use of UDT for patients with chronic pain or SUD. An updated search of the literature did not find any randomized controlled trials published since 2014, the date of the most recent systematic reviews.

The first systematic review (Chou et al., 2009) was a good-quality systematic review of studies examining the use of UDT for patients receiving treatment for chronic pain. No studies reported on the effects of UDT on patient outcomes. The authors did identify two studies of the effects of UDT on concomitant use of illicit or other controlled substances in patients with chronic pain. In one of the studies (Manchikanti, Manchukonda, Pampati, et al., 2006), a historically controlled cohort study, UDT

was associated with decreased use of marijuana, but no difference in the use of other illicit drugs. The second study (Manchikanti, Manchukonda, Damron, et al., 2006), also a historically controlled cohort study, found that UDT, when used as part of a multicomponent approach that also included treatment contracts, pill counts, and frequent monitoring and education, was associated with a reduction in controlled substance abuse from 18% to 9%. These studies were limited by the use of historical controls and the use of multiple interventions.

The second systematic review (Starrels et al., 2010) was a good-quality review that summarized the effects of treatment contracts and routine UDT in patients with chronic non-cancer pain. The authors identified seven cohort studies that examined the use of treatment contracts and UDT; six of the studies were rated as fair quality and one was rated as poor quality. The studies were performed in outpatient settings including pain clinics and primary care clinics. Notably, four of the studies relied on confirmatory tests (mass spectroscopy or chromatography) rather than immunoassays. Approximately 15% of the patients included in these studies had a history of substance abuse. In one retrospective study (Wiedemer et al., 2007) conducted in a Veterans Affairs primary care setting, the use of treatment contracts and UDT was associated with a reduction in opioid misuse (51% to 28%). Two historically controlled cohort studies (Manchikanti, Manchukonda, Damron, et al., 2006; Manchikanti, Manchukonda, Pampati, et al., 2006) conducted in pain clinics found reductions in the use of opioids prescribed by another source (18% to 9%) and the use of illicit substances (23% to 16%) with the introduction of treatment agreements and UDT. Both of these studies were also included in the review by Chou et al. (2009) mentioned above. None of the studies included in this systematic review examined outcomes of opioid use or dependence, overdose, death, or diversion.

The third systematic review (Chou, Deyo et al., 2014) was a good-quality systematic review for the Agency for Healthcare Research and Quality (AHRQ) that examined evidence for long-term use of opiates for chronic pain and included a key question on risk mitigation approaches including UDT. The AHRQ review identified no studies that addressed clinical outcomes related to UDT.

Two diagnostic accuracy studies compared the performance of point-of-care immunoassay tests to confirmatory tests. Those results are summarized in Table 1. However, these results should be interpreted with caution because they represent the experience of a single center using one type of point-of-care immunoassay and with different cutoffs defining positivity for the index and the reference tests. Additionally, Millennium Health sponsored both studies, provided the urine drug tests, and conducted the reference testing.

Table 1. Diagnostic Accuracy of Immunoassay Testing Compared to LC-MS/MS

<table>
<tr><th>Citation and Study Details</th><th>Findings</th><th>Cutoff values (Immunoassay vs. LC-MS/MS, ng/mL)</th><th>Comments</th></tr>
<tr>
<td>Manchikanti et al. (2011b)

Setting:
U.S. tertiary referral center and intervention pain management practice

Comparators: immunoassay and LC-MS/MS
N = 1,000</td>
<td>Compared to LC-MS/MS, immunoassay had the following:

<table>
<tr><th>False- Negative Reports</th><th>n</th><th>%</th></tr>
<tr><td>Morphine</td><td>52</td><td>8%</td></tr>
<tr><td>Oxycodone</td><td>34</td><td>25%</td></tr>
<tr><td>Methadone</td><td>2</td><td>4%</td></tr>
<tr><td>Marijuana</td><td>3</td><td>9%</td></tr>
<tr><td>Cocaine</td><td>6</td><td>75%</td></tr>
<tr><td>Methamphetamines</td><td>3</td><td>60%</td></tr>
<tr><td>Amphetamines</td><td>9</td><td>53%</td></tr>
</table>

<table>
<tr><th>False-Positive Reports</th><th>n</th><th>%</th></tr>
<tr><td>Morphine</td><td>23</td><td>7%</td></tr>
<tr><td>Oxycodone</td><td>66</td><td>8%</td></tr>
<tr><td>Methadone</td><td>11</td><td>1%</td></tr>
<tr><td>Marijuana</td><td>19</td><td>2%</td></tr>
<tr><td>Cocaine</td><td>0</td><td>0%</td></tr>
<tr><td>Methamphetamines</td><td>12</td><td>1%</td></tr>
<tr><td>Amphetamines</td><td>9</td><td>1%</td></tr>
</table>
</td>
<td>Morphine: 300 vs. 50
Oxycodone: 100 vs. 50
Methadone: 300 vs. 100
Marijuana: 50 vs. 15
Cocaine: 300 vs. 50
Methamphetamines: NA vs. 50
Amphetamines: 1000 vs. 100</td>
<td>The authors concluded that confirmatory testing will be needed 20% to 32% of the time, but that overall point-of-care testing is efficient in this population.

(The authors assumed that if someone is prescribed an opioid they are actually taking it. Thus, they regard the 11% of people who had negative immunoassay and negative LC-MS for opioids in spite of a prescription as having two false-negative results rather than evidence that the person wasn't taking the medication.)</td>
</tr>
<tr>
<td>Manchikanti et al. (2011b)

Setting:
U.S. tertiary referral center and intervention pain management practice</td>
<td>Compared to LC-MS/MS, immunoassay had the following for benzodiazepines [n (%)]

Patients prescribed benzodiazepines
False-negative reports:
99 (24.5%)
False-positive reports:
10 (10.5%)

Patients NOT prescribed benzodiazepines</td>
<td>300 ng/mL vs. not reported</td>
<td></td>
</tr>
</table>

Citation and Study Details	Findings	Cutoff values (Immunoassay vs. LC-MS/MS, ng/mL)	Comments
Comparators: immunoassay and LC-MS/MS N = 1,000	False-negative reports: 16 (36.4%) False-positive reports: 1 (0.2%)		

The fourth systematic review (Dupuoy et al., 2014) was a good-quality systematic review of the effects of UDT in patients with a known or suspected SUD in inpatient or outpatient settings. These studies mainly relied on point-of-care or laboratory immunoassay testing with or without confirmatory testing. Of the eight included studies, six were conducted in inpatient settings. With the exception of one fair-quality randomized controlled trial, all the studies were judged to be poor quality. In the single included RCT, patients in a psychiatric emergency setting were randomly assigned to receive a mandatory UDT or routine care directed by the psychiatrist's clinical judgement (which could include UDT). There was no difference between the two groups with respect to disposition or duration of hospitalization in the intention-to-treat analysis. In an as-treated analysis, patients who were in the routine care arm and who did not receive a UDT were more likely to be admitted to an inpatient unit at a county hospital compared to those who received a UDT. In a cross-sectional study of primary care providers who manage patients with OUD in France, many reported that UDT influenced their decisions about referral to counseling, consultation, and whether to prescribe medication-assisted treatment. The authors concluded that there was insufficient evidence to assess the usefulness of UDT for managing patients with a known or suspected SUD.

Evidence Summary

Limited observational evidence suggests that UDT, particularly when combined with other interventions, could be associated with reductions in opioid misuse and concomitant use of marijuana, but not with other illicit substances in patients with chronic non-cancer pain. There is insufficient evidence to assess the effects of UDT on clinical outcomes including opioid dependence or abuse, overdose, death, or diversion. There was insufficient evidence to draw conclusions about the effects of UDT in patients with a known or suspected SUD.

Policy Landscape

Payer Coverage Policies

Medicaid

Washington

As outlined in the *Physician-Related Services/Health Care Professional Services Billing Guide*, the Washington Medicaid program covers drug testing for SUD when both of the following apply:

- The screen is medically necessary and ordered by a physician as part of a medical evaluation
- The drug or alcohol screen is required to assess suitability for medical tests or treatment being provided by the physician

The Washington Medicaid billing guide states that, "Periodic reviews of ordering patterns will be performed to look for and contact practices that appear to be outliers compared to their peers" (Washington State Health Care Authority, 2017, p. 146).

For patients receiving medication-assisted treatment (MAT) for a SUD, the Washington Medicaid program considers presumptive (in office) testing with a point-of-care immunoassay test medically necessary to:

- Confirm the use of prescribed substances
- Identify the presence of illicit or non-prescribed substances
- Start a patient on MAT for a SUD

Confirmatory testing with GC-MS or LC-MS/MS is considered medically necessary when there is a discrepancy between a presumptive drug test and the patient report. In addition, confirmatory testing should only be ordered and performed on a patient- and drug-specific basis with clinical documentation of a follow-up plan based on the test results. The Washington Medicaid program covers a maximum of 24 presumptive drug tests each year. The allowed Current Procedural Terminology (CPT) codes for presumptive UDT are 80305, 80306, and 80307, and only one of the three codes can be billed per client per day. A maximum of 12 definitive tests, used as follow-up to presumptive tests, are allowed each year. The allowed Healthcare Common Procedure Coding System (HCPCS) codes for definitive UDT are G0480 and G0481, and only one of the two codes can be billed per client per day. If additional tests are needed, providers can submit a limitation extension request to the agency.

Washington Medicaid does not pay for routine drug screening panels or monitoring for program compliance in residential or outpatient drug or alcohol treatment programs. When monitoring a patient for drug or alcohol use, providers are instructed to refer the client to a program approved by the Division of Behavioral Health and Rehabilitation for evaluation and treatment, where the patient may receive drug or alcohol screening as determined by their treating provider.

Drug testing for patients who are on chronic opioid therapy for the treatment of chronic non-cancer pain must follow the Agency Medical Directors' Group *Interagency Guideline on Prescribing Opioids for Pain* (Washington State Agency Medical Directors' Group, 2015). These guidelines recommend UDT annually for those at low risk of abuse or diversion, twice yearly for those at moderate risk, and three to four times yearly for those at high risk. Testing is also recommended as needed for aberrant behavior identified during an office visit. Because of cross-reactivity and the differences in sensitivity and specificity among immunoassay tests, a confirmatory (definitive) test is required unless the result was expected or the patient has disclosed drug use.

North Carolina

North Carolina Medicaid's drug testing policy covers presumptive testing up to 24 times and definitive testing up to 24 times per fiscal year. Only one presumptive and one definitive test will be reimbursed per beneficiary, per day, regardless of the number of providers performing this service.

Testing frequency for a SUD is based upon consecutive days of beneficiary abstinence from illicit substances:

- Zero to 30 days: Once per calendar week
- 31-90 days: Twice per calendar month
- Greater than 90 days: Once per 30 calendar days

Testing frequency for patients treated for chronic pain is based on risk assessment:

- Low-Risk Beneficiaries: Up to two times every 365 consecutive days
- Moderate-Risk Beneficiaries: Up to four times every 365 consecutive days
- High Risk: Up to three times every 90 consecutive days

New York

In New York Medicaid's drug testing policy, CPT codes 80305, 80306, or 80307 must be used for presumptive drug screening. Only substances that return a positive result on a presumptive test or are inconclusive or inconsistent with clinical presentation are reimbursable for definitive testing, using CPT codes 80320–80377. Definitive testing without a prior presumptive test is only reimbursable when no presumptive screening method is available, using HCPCS code G0480. This direct to definitive testing is reimbursable once per date of service, up to a maximum of six times within 365 days.

Provision of drug tests must be based on the patient's medical history or current clinical presentation, and medical records must support the need for each test and be kept on file for a minimum of six years for audit purposes.

Alabama

Alabama Medicaid's policy on presumptive drug limits presumptive drug testing to one specimen every seven days per recipient, using CPT codes 80100, 80101, 80102, and 80104. The ordering/referring provider must retain documentation supporting medical necessity in the medical record.

A 2015 update to the Alabama Medicaid drug testing policy delineates coverage for HCPCS codes G0434 and G6058:

- HCPCS code G0434 will cover one drug screen, regardless of the number of drugs or classes, procedure(s)/methodology(ies), any source(s), per appropriately billed date of service.
- HCPCS code G6058 will cover one drug test (confirmatory and/or definitive, qualitative and quantitative), regardless of the number of drugs or drug classes, procedure(s)/methodology(ies), source(s), including sample validation.

Medicare

No National Coverage Determination was identified for drug testing, and 10 Medicare Local Coverage Determinations (LCDs) were identified. Three (L34501, L34645, L35920) of these 10 LCDs are less comprehensive than the others, although generally consistent with the more comprehensive LCDs.

The seven more comprehensive LCDs (L35006, L36037, L36029, L36393, L36668, L36707, L35724) categorize patients needing UDT into three groups:

- Group A – Symptomatic patients, multiple drug ingestion, or patients with unreliable history
- Group B – Diagnosis and treatment for substance abuse or dependence
- Group C – Treatment for patients on chronic opioid therapy

Group A patients can present in a variety of medical settings, and patients with symptoms such as coma, altered mental status or seizures can be given presumptive UDT as part of evaluation and management. The presumptive drug test findings, any definitive drug tests ordered, and reasons for the testing must be documented in the patient's medical record.

For diagnosis of a SUD in Group B, the clinician may screen for a broad range of commonly abused drugs using presumptive UDT for patients with no known indicators of risk for a SUD. For patients with known indicators of risk for a SUD, the clinician may screen for a broad range of commonly abused drugs using definitive UDT.

For patients with a diagnosed SUD, the clinician should perform random UDT in order to properly monitor the patient. The expected frequency of UDT is one to three tests per week for patients with less than 90 consecutive days of abstinence and one to three tests per month for patients with more than 90 consecutive days of abstinence.

Six of the seven comprehensive LCDs also have limits on the frequency of definitive UDT:

- For patients with zero to 30 consecutive days of abstinence, definitive UDT is expected at a frequency not to exceed one testing profile in one week
- For patients with 31 to 90 consecutive days of abstinence, definitive UDT is expected at a frequency of 1-3 testing profiles in one month
- For patients with >90 days of consecutive abstinence, definitive UDT is expected at a frequency of 1-3 testing profiles in three months

For Group C patients on chronic opioid therapy, medical necessity for drug testing must be based on patient-specific elements and documented in the patient's medical record, including:

- Patient history, physical examination, and previous laboratory findings
- Current treatment plan
- Prescribed medications
- Risk assessment plan

Six of the seven comprehensive LCDs have frequency limitations on UDT for patients on chronic opioid therapy:

- Low Risk: Random testing 1-2 times every 12 months
- Moderate Risk: Random testing 1-2 times every six months
- High Risk: Random testing 1-3 times every three months

Across all three groups of patients (A, B, C), definitive testing to confirm a positive presumptive UDT result is reasonable and necessary when the result is inconsistent with the expected result, a patient's self-report, presentation, medical history, or current prescribed medication plan. Definitive testing to confirm a negative presumptive UDT result is reasonable and necessary when:

- The result is inconsistent with a patient's self-report, presentation, medical history, or current prescribed medication plan
- The clinician suspects use of a substance that is inadequately detected or not detected by a presumptive UDT
- To rule out an error as the cause of a negative presumptive UDT result

Definitive UDT without a prior presumptive UDT is reasonable and necessary, when individualized for a particular patient.

Private Payers

Center researchers searched private payer policies for UDT for Aetna, Cigna, Moda, and Regence. No national policy was found for Aetna, but an update for Aetna's Western Region in 2016 stated that the frequency limit for drug testing per year is eight times each for definitive and presumptive testing.

Cigna's drug testing policy covers UDT when these criteria are met:

- The diagnosis, history and physical examination and/or behavior of the individual being tested support the need for the specific drug testing being requested
- The results of testing will affect treatment planning
- Testing is performed in a physician-supervised treatment setting

Cigna covers presumptive drug testing not to exceed one unit per date of service up to 32 units per year, and definitive drug testing not to exceed 16 dates of service per year for a maximum of eight units per date of service up to 128 units per year. A unit may include testing for a specific individual drug and/or its metabolites, or its structural isomers. Definitive drug testing is allowed only if the presumptive test results are inconsistent with the individual's condition, history, and examination, or if a presumptive drug test is not available for the drug for which there is a suspicion of abuse or misuse.

Moda's policy on *Therapeutic Drug Monitoring (Urine drug testing)* covers presumptive urine drug screening up to 12 units per plan year for patients:

- Where there is a suspicion of drug misuse or abuse
- With a diagnosis where drug toxicity may be a contributing factor
- Who are pregnant and there is possible exposure of the fetus to drug abuse
- Who are being treated for chronic non-cancer pain with opioid therapy, to establish a baseline and random monitoring for adherence or diversion of prescribed medications
- Who are in treatment for chemical dependency—more frequent UDT might be required to monitor compliance with the treatment program

Definitive drug testing to confirm a positive presumptive screening is covered up to 12 units per plan year.

Regence's policy on UDT for substance abuse and chronic pain limits presumptive tests to one per day and 15 times each year unless there is suspected abuse, misuse, or diversion, and documentation indicates how test results will affect management. These same restrictions apply to definitive UDT. Drug testing is not covered in conjunction with participation in a substance abuse facility because UDT is included in the facility reimbursement.

Recommendations from Others

Guidelines: Substance Use Disorder

Four guidelines were identified related to the use of UDT for patients with a SUD:

- *VA/DoD Clinical Practice Guideline for the Management Of Substance Use Disorders* (U.S. Department of Veterans Affairs & Department of Defense, 2015)
- SAMHSA's *Clinical Drug Testing in Primary Care* (SAMHSA, 2012)
- ASAM's *Appropriate Use of Drug Testing in Clinical Addiction Medicine* (ASAM, 2017)

- *Methadone Safety: A Clinical Practice Guideline from the American Pain Society and College on Problems of Drug Dependence, in Collaboration with the Heart Rhythm Society* (Chou, Cruciani et al. 2014)

These guidelines recommend drug testing at baseline and then periodic monitoring during drug treatment. The guidelines often do not mention a specific interval for ongoing drug testing, explaining that evidence is not available on the most appropriate frequency of testing and that testing frequency should be based on individual patient characteristics. The most detailed recommendations are in ASAM's guidelines, which recommend that drug testing be done at least weekly during the initial phase of treatment and at least monthly when a patient is stable in treatment.

Guidelines: Chronic Pain

Four guidelines were identified that are related to the use of UDT for patients undergoing treatment for chronic pain:

- *CDC Guideline for Prescribing Opioids for Chronic Pain* (Dowel et al., 2016)
- *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain* (U.S. Department of Veterans Affairs & Department of Defense, 2017)
- SAMHSA's *Clinical Drug Testing in Primary Care* (SAMHSA, 2012)
- *American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain* (Manchikanti et al., 2012)

These guidelines recommend UDT before starting opioid therapy and then ongoing monitoring to assess for prescribed medications and other controlled prescription drugs and illicit drugs. The CDC guidelines recommend UDT at least annually. The ASIPP guidelines recommend that patients at low risk for aberrant behaviors should have UDT every one to two years, patients at medium risk should have UDT every six to 12 months, and patients at high risk should have UDT every three to six months. The guidelines from SAMHSA and VA/DoD are less specific, stating the UDT frequency should be based on individual patient characteristics.

Quality Measures

One quality measure was identified when searching the National Quality Measures Clearinghouse for measures related to drug testing. The Institute for Clinical Systems Improvement developed the measure: *percentage of patients diagnosed with chronic pain who are prescribed an opioid who have an opioid agreement form and urine toxicology screen documented in the medical record*.

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Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

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Appendix A. GRADE Table Element Descriptions

Element	Description
Balance of benefits and harms	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded.
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Other considerations	Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

Strong recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors., but further research or additional information could lead to a different conclusion.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, and values and preferences, but further research or additional information could lead to a different conclusion.

Confidence in estimate rating across studies for the intervention/outcome

Assessment of confidence in estimate includes factors such as risk of bias, precision, directness, consistency and publication bias.

High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

Moderate: The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical

sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

Low: The subcommittee's confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

Very low: The subcommittee has very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

Appendix B. GRADE Evidence Profile

Quality Assessment (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Overdose and death							
0							Insufficient
Identification of diversion							
0							Insufficient
Identification of other substance use disorders							
0							Insufficient
Test performance characteristics							
2	Diagnostic accuracy studies	Moderate	N/A	Not serious	N/A	Sparse single-center data	Very low ●○○○
Change in management of chronic pain or substance use disorder							
0							Insufficient

Appendix C. Methods

Scope Statement

Populations

Patients receiving opioids for chronic pain and patients with a substance use disorder

Population scoping notes: None

Interventions

Urine drug testing (screening and confirmatory testing, presumptive and definitive, individual drug assays and panels of tests)

Intervention exclusions: None

Comparators

Standardized risk assessment tools, no testing, other interventions

Outcomes

Critical: Overdose and death, identification of diversion, identification of other substance use disorders

Important: Test performance characteristics, change in management of chronic pain or substance use disorder

Considered but not selected for the GRADE table: None

Key Questions

KQ1: What is the comparative effectiveness of presumptive versus definitive and screening versus diagnostic urine drug testing?

KQ2: What is the comparative effectiveness of different testing strategies?

KQ3: How does the comparative effectiveness vary by:

a. Underlying patient risk
b. Presence of comorbid conditions
c. Presence of multiple controlled substances
d. Types of drugs tested (e.g., illicit such as cocaine, methamphetamines, cannabinoids; licit such as alcohol, or prescription such as benzodiazepines)
e. Frequency of testing
f. Observed versus unobserved testing
g. Dose of prescribed opioid medication

Contextual Questions

CQ1: What is the cost-effectiveness of the different screening/diagnostic test strategies?

CQ2: What is the effectiveness of urine drug testing in patients receiving acute treatment (e.g., in an urgent care or emergency department setting) in patients who also meet the population criteria?

Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, and technology assessments that meet the criteria for the scope described above. Searches of core sources were limited to citations published after 2012.

The following core sources were searched:

Agency for Healthcare Research and Quality (AHRQ)
Blue Cross/Blue Shield Center for Clinical Effectiveness
Canadian Agency for Drugs and Technologies in Health (CADTH)
Cochrane Library (Wiley Online Library)
Institute for Clinical and Economic Review (ICER)
Medicaid Evidence-based Decisions Project (MED)
National Institute for Health and Care Excellence (NICE)
Tufts Cost-Effectiveness Analysis Registry
Veterans Administration Evidence-based Synthesis Program (ESP)
Washington State Health Technology Assessment Program

A MEDLINE® search was also conducted to identify systematic reviews, meta-analyses, and technology assessments, using search terms for urine drug tests and substance abuse disorders. The search was limited to publications in English published since 2012. In addition, a MEDLINE® search was conducted for randomized controlled trials published after the search dates of the most recent systematic reviews (2014). In addition, a MEDLINE® search was conducted for randomized controlled trials published after the search dates of the selected systematic reviews.

Searches for clinical practice guidelines were limited to those published since 2009. A search for relevant clinical practice guidelines was also conducted using MEDLINE® and the following sources:

Australian Government National Health and Medical Research Council (NHMRC)
Canadian Agency for Drugs and Technologies in Health (CADTH)
Centers for Disease Control and Prevention (CDC), Community Preventive Services
National Guidelines Clearinghouse
National Institute for Health and Care Excellence (NICE)
Scottish Intercollegiate Guidelines Network (SIGN)
United States Preventive Services Task Force (USPSTF)
Veterans Administration/Department of Defense (VA/DoD) Clinical Practice Guidelines

Inclusion/Exclusion Criteria

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, randomized controlled trials, or clinical practice guidelines.

Appendix D. Applicable Codes

CODES	DESCRIPTION
CPT Codes	
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; read by instrument assisted direct optical observation (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; by instrument chemistry analyzers (e.g., utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (e.g., GC, HPLC), and mass spectrometry either with or without chromatography, (e.g., DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service
80320-80377	Definitive drug tests of individual substances (many payers do not cover these tests, preferring to use the G0480-G0483)
HCPCS Level II Codes	
G0477	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service
G0478	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) read by instrument-assisted direct optical observation (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service
G0479	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers utilizing immunoassay, enzyme assay, tof, maldi, ldtd, desi, dart, ghpc, gc mass spectrometry), includes sample validation when performed, per date of service
G0480	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 1-7 drug class(es), including metabolite(s) if performed
G0481	…8-14 drug class(es)…
G0482	…15-21 drug class(es)…
G0483	…22 or more drug class(es)…

CODES	DESCRIPTION
G0659	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes

Note: Inclusion on this list does not guarantee coverage.