

## FEP 2.04.98 Drug Testing in Pain Management and Substance Use Disorder Treatment

**Effective Date:** April 15, 2018

**Related Policies:** None

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

#### Description

Patients in pain management programs and substance use disorder treatment may misuse prescribed opioids and/or may use nonprescribed drugs. Thus, these patients are often assessed before treatment and monitored while receiving treatment. Urine drug testing (UDT) can be part of this monitoring strategy; it is most often used as part of a multifaceted intervention that includes other components, such as patient contracts.

#### FDA REGULATORY STATUS

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 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. Food and Drug Administration (FDA) has chosen not to require any regulatory review of this test.

A CLIA waiver is available for the use of certain point-of-care 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:

---

## FEP 2.04.98 Drug Testing in Pain Management and Substance Use Disorder Treatment

---

amphetamines, methamphetamine, cocaine/metabolite, opiates, marijuana/THC, phencyclidine, barbiturates, benzodiazepines, and methadone.

### POLICY STATEMENT

In outpatient pain management, presumptive (ie, immunoassay) urine drug testing may be considered **medically necessary** for:

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

In outpatient substance abuse treatment, in-office or point-of-care presumptive (ie, immunoassay) urine drug testing may be considered **medically necessary** under the following conditions:

- Baseline screening before initiating treatment or at the time treatment is initiated (ie, induction phase), 1 time per program entry, when the following conditions are met:
  - An adequate clinical assessment of patient history and risk of substance abuse is performed;
  - Clinicians have knowledge of test interpretation;
  - 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)

Definitive (ie, confirmatory) urine drug testing, in outpatient pain management or substance abuse treatment, may be considered **medically necessary** 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 (see Policy Guidelines section)

In outpatient pain management and outpatient substance abuse treatment, urine drug testing is considered **not medically necessary** when the above criteria are not met including but not limited to routine presumptive or definitive urine drug testing (eg, testing at every visit, without consideration for specific patient risk factors or without consideration for whether definitive testing is required for clinical decision making).

In outpatient pain management and substance abuse treatment, oral fluid drug testing and hair drug testing are considered **investigational**.

### 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:

---

## FEP 2.04.98 Drug Testing in Pain Management and Substance Use Disorder Treatment

---

- 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:

- 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 (eg, 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 (eg, 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

## FEP 2.04.98 Drug Testing in Pain Management and Substance Use Disorder Treatment

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 (eg, 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.

**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 (eg, oxycodone often missed by immunoassay)</li> <li>• Take a detailed history of patient’s medication use for the preceding 7 days (eg, 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 (eg, 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 (eg, 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.

### BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

### RATIONALE

#### 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

---

## FEP 2.04.98 Drug Testing in Pain Management and Substance Use Disorder Treatment

---

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 abuse 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 (ie, in the past few days), and thus has limited applicability to pain management or substance abuse treatment settings, except, perhaps, for initial intake. There are no studies comparing the diagnostic accuracy of hair testing 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 abuse treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

### SUPPLEMENTAL INFORMATION

#### Practice Guidelines and Position Statements

##### Pain Management

In 2014, Nuckols et al published a systematic review of guidelines that addressed management of opioid use for chronic pain.<sup>29</sup> Reviewers included guidelines from national organizations and specialty societies, as well as guidelines from state agencies and specific health systems. Moreover, reviewers identified 9 guidelines with recommendations on urine drug testing (UDT). Recommendations varied widely; two recommended mandatory testing for all patients, another recommended testing only patients at increased risk of medication abuse, and two stated that testing patients at low risk of abuse is not cost-effective. If UDT is used, the recommended frequency of follow-up testing was at least quarterly in 1 guideline, at least yearly in another, and randomly in two.

## FEP 2.04.98 Drug Testing in Pain Management and Substance Use Disorder Treatment

### *Centers for Disease Control and Prevention*

In 2016, the Centers for Disease Control and Prevention published guidelines on opioids for chronic pain.<sup>30</sup> The guidelines included the following recommendation on UDT: “When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.”

### *American Society of Interventional Pain Physicians*

In 2017, the American Society of Interventional Pain Physicians issued guidelines for responsible, safe, and effective opioid prescribing for chronic non-cancer pain.<sup>31</sup> The guidelines included the following recommendations on UDT (see Table 1).

**Table 1: Recommendations on Urine Drug Testing for Chronic Non-Cancer Pain**

Recommendation	LOE	SOE
“Comprehensive assessment and documentation is recommended before initiating opioid therapy, with documentation of comprehensive history, general medical condition, psychosocial history, psychiatric status, and substance use history.”	I	Strong
“Screening for opioid abuse is recommended, as it will potentially identify opioid abusers and reduce opioid abuse.”	II-III	Moderate
“Presumptive UDT is implemented at initiation of opioid therapy, along with subsequent use as adherence monitoring, using in-office point of service testing, followed by confirmation with chromatography/mass spectrometry for accuracy in select cases, to identify patients who are not compliant or abusing prescription drugs or illicit drugs. UDT may decrease prescription drugs abuse of illicit drug use when patients are in chronic pain management therapy.”	III	Moderate

LOE: level of evidence; SOE: strength of evidence; UDT: urine drug testing.

### *American Pain Society and American Academy of Pain Medicine*

In 2009, the American Pain Society and American Academy of Pain Medicine jointly published clinical guidelines on the use of opioid therapy in chronic non-cancer pain.<sup>32</sup> The guidelines did not address UDT or other forms of monitoring adherence.

### *American College of Occupational and Environmental Medicine*

The latest guidelines from the American College of Occupational and Environmental Medicine (ACOEM) on the use of opioids for the treatment of acute, subacute, chronic, and postoperative pain, were published in 2014.<sup>33</sup> The following recommendations on UDT were made for subacute (1-3 months) and chronic pain (>3 months) (see Table 2).

**Table 2: Recommendations on Opioid Use to Treat Acute, Subacute, Chronic, and Postoperative Pain**

Recommendation	SOR	CIR
“Baseline and random urine drug screening, qualitative and quantitative, for patients prescribed opioids for the treatment of subacute or chronic pain to evaluate presence or absence of the drug, its metabolites and other substance(s) use. In certain situations, other screenings (eg, hair particularly for information regarding remote use or blood) (for acute toxicity) may be appropriate.”	C	High

Recommendations rating schema: A: strongly recommended; B: moderately recommended; C: recommended. CIR: confidence in recommendation; SOR: strength of recommendation.

Urine drug screening was not recommended for acute pain (up to 4 weeks) or for postoperative pain (up to 4 weeks).

As a companion to the guidelines, ACOEM developed a combined Opioid Consent Form and Opioid Treatment Agreement.<sup>34</sup> The form provides explanations of the potential benefits and harms to be expected from opioid treatment, and asks the patient to agree to numerous terms of opioid use, which

---

## FEP 2.04.98 Drug Testing in Pain Management and Substance Use Disorder Treatment

---

include submitting to unscheduled urine, blood, saliva, or hair drug testing at the prescriber's request and seeing an addiction specialist if requested.

Screening was recommended for all patients at baseline, and then randomly at least twice and up to 4 times a year, and at termination. Screening should also be performed if the provider suspects abuse of prescribed medication.

### ***National Opioid Use Guideline Group***

The National Opioid Use Guideline Group issued guidelines in Canada in 2010 on the safe and effective use of opioids for chronic non-cancer pain that included the following recommendation on urine drug screening<sup>5</sup>: "When using urine drug screening (UDS) to establish a baseline measure of risk or to monitor compliance, be aware of benefits and limitations, appropriate test ordering and interpretation, and have a plan to use results. (Grade C)."

The guidelines also stated that there was no "compelling evidence" to guide physicians on identifying patients who should have UDS, or on how often they should be tested. The document stated that the following factors should be considered when deciding whether to order a urine drug screen:

- patient's risk for opioid misuse and addiction
- aberrant drug-related behaviors
- testing availability (note: this may be a Canadian-specific issue).

### ***Department of Veterans Affairs and Department of Defense***

In 2010, the Department of Veterans Affairs and Department of Defense issued clinical practice guidelines for managing opioid therapy for treatment of chronic pain.<sup>6</sup> The recommendations on assessing adherence to prescribed opioids includes obtaining a urine drug test (with patient consent) before initiating opioid therapy, and then randomly at follow-up to confirm appropriate use. Other strategies recommended include clinical assessment and screening aids such as random pill counts, adherence checklists, and standardized instruments such as the Screener and Opioid Assessment for Patients with Pain.

The guidelines included the following specific recommendations on UDT:

#### "RECOMMENDATIONS

1. Inform patients that drug testing is a routine procedure for all patients starting or on opioid therapy [OT], and is an important tool for monitoring the safety of their treatment.
2. With patient consent, obtain a UDT in all patients prior to initiation of OT.
3. With patient consent, monitor all patients on OT with periodic random UDTs to confirm adherence to the treatment plan. Increase the frequency of UDTs based on risk level for aberrant drug-related behaviors and following each dose increase.
4. Take into consideration a patient's refusal to take a UDT as part of the ongoing assessment of the patient's ability to adhere to the treatment plan and the level of risk for adverse outcomes.
5. When interpreting UDT results take into account other clinical information (e.g., past SUD [substance use disorder], other risk factors, aberrant drug-related behaviors, and other conditions indicating risk.)
6. Understanding of lab methods for drug testing and reporting are necessary to interpret UDT results (i.e., screen versus confirmatory test, substances tested, cut-off levels for tests). Maintain a close working relationship with the clinical laboratory to answer any questions about the UDT or for confirming the results."

## FEP 2.04.98 Drug Testing in Pain Management and Substance Use Disorder Treatment

### *Washington State Agency Medical Directors' Group*

In 2015, the Washington State Agency Medical Directors' Group updated its interagency guidelines on opioid dosing for chronic non-cancer pain.<sup>35</sup> The guidelines included recommendations on UDT. Recommendations on testing frequency differed depending on the patient risk of opioid addiction and opioid dosage, as listed below:

- Low risk: Once per year
- Moderate risk: Twice per year
- High risk or opioid dose over 120 mg MED/d: 3-4 times per year
- Aberrant behavior: Each visit.

No pain management guidelines were identified that had recommendations on oral fluid or hair testing.

### Substance Use Disorder Treatment

#### *American Society of Addiction Medicine*

The American Society of Addiction Medicine (ASAM) has published several documents on drug testing: a public policy statement (2010),<sup>36</sup> a white paper (2013), which provided background on the science and current practices of drug testing,<sup>37</sup> and guidelines (2017) on the effective use of drug testing.<sup>38</sup>

ASAM's public policy statement asserts that: "Urine drug testing is a key diagnostic and therapeutic tool that is useful for patient care and in monitoring of the ongoing status of a person who has been treated for addiction. As such, it is a part of medical care, and should not face undue restrictions."<sup>36</sup> ASAM recommended drug testing where medically appropriate in clinical diagnostic settings and clinical treatment settings. The term "drug testing" in this document was a broad term that included urine or other body fluids or tissues.

The ASAM White Paper concluded that "The most important challenge in drug testing today is not the identification of every drug that we are technologically capable of detecting, but to do medically necessary and accurate testing for those drugs that are most likely to impact clinical outcomes."<sup>37</sup> The paper acknowledged that more specific guidance on drug testing was needed, which led to the development of the 2017 guidelines, described below.

The 2017 ASAM guidance on appropriate drug testing in clinical addiction medicine advises health care providers that before choosing the type of drug test, they should first identify the questions they are seeking to answer and be aware of benefits and limitations of the various drug tests. Table 3 summarizes characteristics of urine, oral fluid, and hair drug tests that may inform the decision of what type of drug test to use.

**Table 3: Summary of Drug Testing Characteristics**

Characteristics	Urine	Oral Fluid	Hair
General detection period	Hours to days	Minutes to hours	Weeks to months
Point-of-care testing	Yes	Yes	No
Primarily detects	Drug metabolite	Parent drug compound	Parent drug compound
Best use in treatment setting	Intermediate-term detection in ongoing treatment	Short-term detection in ongoing treatment	Long-term monitoring, 3-month history
Ease of collection	Requires restroom	Easily collected	Easily collected
Resistance to tampering	Low	High, with some uncertainty	High when chemically untreated
Retesting same sample	Possible	Difficult	Easy

Adapted from Jarvis et al (2017).<sup>38</sup>

## FEP 2.04.98 Drug Testing in Pain Management and Substance Use Disorder Treatment

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

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

### REFERENCES

1. Manchikanti L, Abdi S, Atluri S, et al. American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: Part I--evidence assessment. *Pain Physician*. Jul 2012;15(3 Suppl):S1-65. PMID 22786448
2. International Narcotics Control Board (INCB). Report of the International Narcotics Control Board for 2016. 2016; [https://www.incb.org/documents/Publications/AnnualReports/AR2016/English/AR2016\\_E\\_ebook.pdf](https://www.incb.org/documents/Publications/AnnualReports/AR2016/English/AR2016_E_ebook.pdf). Accessed October 30, 2017.
3. Fishbain DA, Cutler RB, Rosomoff HL, et al. Validity of self-reported drug use in chronic pain patients. *Clin J Pain*. Sep 1999;15(3):184-191. PMID 10524471
4. Manchikanti L, Atluri S, Trescot AM, et al. Monitoring opioid adherence in chronic pain patients: tools, techniques, and utility. *Pain Physician*. Mar 2008;11(2 Suppl):S155-180. PMID 18443638
5. National Opioid Use Guideline Group (NOUGG). Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain. Part B: Recommendations for practice. Version 5.6. 2010; [http://nationalpaincentre.mcmaster.ca/documents/opioid\\_guideline\\_part\\_b\\_v5\\_6.pdf](http://nationalpaincentre.mcmaster.ca/documents/opioid_guideline_part_b_v5_6.pdf). Accessed October 23, 2017.
6. Veteran's Affairs (VA) and Department of Defense (DoD) Management of Opioid Therapy for Chronic Pain Working Group. Clinical practice guideline: management of opioid therapy for chronic pain. 2010; [http://www.va.gov/painmanagement/docs/cpg\\_opioidtherapy\\_fulltext.pdf](http://www.va.gov/painmanagement/docs/cpg_opioidtherapy_fulltext.pdf). Accessed October 23, 2017.
7. Manchikanti L, Malla Y, Wargo BW, et al. Comparative evaluation of the accuracy of immunoassay with liquid chromatography tandem mass spectrometry (LC/MS/MS) of urine drug testing (UDT) opioids and illicit drugs in chronic pain patients. *Pain Physician*. Mar-Apr 2011;14(2):175-187. PMID 21412372
8. Snyder ML, Fantz CR, Melanson S. Immunoassay-based drug tests are inadequately sensitive for medication compliance monitoring in patients treated for chronic pain. *Pain Physician*. Feb 2017;20(2S):SE1-SE9. PMID 28226337
9. Johnson-Davis KL, Sadler AJ, Genzen JR. A retrospective analysis of urine drugs of abuse immunoassay true positive rates at a national reference laboratory. *J Anal Toxicol*. Mar 2016;40(2):97-107. PMID 26668238
10. Bertholf RL, Sharma R, Reisfield GM. Predictive value of positive drug screening results in an urban outpatient population. *J Anal Toxicol*. Nov 2016;40(9):726-731. PMID 27550994
11. Starrels JL, Becker WC, Alford DP, et al. Systematic review: treatment agreements and urine drug testing to reduce opioid misuse in patients with chronic pain. *Ann Intern Med*. Jun 1 2010;152(11):712-720. PMID 20513829
12. Goldberg KC, Simel DL, Oddone EZ. Effect of an opioid management system on opioid prescribing and unscheduled visits in a large primary care clinic. *J Clin Outcomes Manage*. 2005;12:621-628. PMID
13. Manchikanti L, Manchukonda R, Damron KS, et al. Does adherence monitoring reduce controlled substance abuse in chronic pain patients? *Pain Physician*. Jan 2006;9(1):57-60. PMID 16700282
14. Manchikanti L, Manchukonda R, Pampati V, et al. Does random urine drug testing reduce illicit drug use in chronic pain patients receiving opioids? *Pain Physician*. Apr 2006;9(2):123-129. PMID 16703972
15. Wiedemer NL, Harden PS, Arndt IO, et al. The opioid renewal clinic: a primary care, managed approach to opioid therapy in chronic pain patients at risk for substance abuse. *Pain Med*. Oct-Nov 2007;8(7):573-584. PMID 17883742
16. Dupouy J, Memier V, Catala H, et al. Does urine drug abuse screening help for managing patients? A systematic review. *Drug Alcohol Depend*. Mar 1 2014;136:11-20. PMID 24417964
17. Krishnamurthy P, Ranganathan G, Williams C, et al. Impact of urine drug screening on no shows and dropouts among chronic pain patients: a propensity-matched cohort study. *Pain Physician*. Feb 2016;19(2):89-100. PMID 26815253
18. Brennan PL, Del Re AC, Henderson PT, et al. Healthcare system-wide implementation of opioid-safety guideline recommendations: the case of urine drug screening and opioid-patient suicide- and overdose-related events in the Veterans Health Administration. *Transl Behav Med*. Dec 2016;6(4):605-612. PMID 27384953

## FEP 2.04.98 Drug Testing in Pain Management and Substance Use Disorder Treatment

19. Stammel MM, Spradley SS. Evaluation of treatment changes following electronic consultation to a pharmacist-run urine drug testing service in a veterans healthcare system. *J Opioid Manag.* Nov/Dec 2016;12(6):389-395. PMID 28059431
20. Chutuape MA, Silverman K, Stitzer ML. Effects of urine testing frequency on outcome in a methadone take-home contingency program. *Drug Alcohol Depend.* Mar 1 2001;62(1):69-76. PMID 11173169
21. McDonnell MG, Graves MC, West, II, et al. Utility of point-of-care urine drug tests in the treatment of primary care patients with drug use disorders. *J Addict Med.* May-Jun 2016;10(3):196-201. PMID 27159345
22. Esub-Mg Study Group. Study protocol of the ESUB-MG cluster randomized trial: a pragmatic trial assessing the implementation of urine drug screening in general practice for buprenorphine maintained patients. *BMC Fam Pract.* Mar 01 2016;17:24. PMID 26931763
23. Heltsley R, DePriest A, Black DL, et al. Oral fluid drug testing of chronic pain patients. I. Positive prevalence rates of licit and illicit drugs. *J Anal Toxicol.* Oct 2011;35(8):529-540. PMID 22004671
24. Vindenes V, Yttredal B, Oiestad EL, et al. Oral fluid is a viable alternative for monitoring drug abuse: detection of drugs in oral fluid by liquid chromatography-tandem mass spectrometry and comparison to the results from urine samples from patients treated with methadone or buprenorphine. *J Anal Toxicol.* Jan 2011;35(1):32-39. PMID 21219701
25. Heltsley R, Depriest A, Black DL, et al. Oral fluid drug testing of chronic pain patients. II. Comparison of paired oral fluid and urine specimens. *J Anal Toxicol.* Mar 2012;36(2):75-80. PMID 22337775
26. Conermann T, Gosalia AR, Kabazie AJ, et al. Utility of oral fluid in compliance monitoring of opioid medications. *Pain Physician.* Jan-Feb 2014;17(1):63-70. PMID 24452646
27. Kunkel F, Fey E, Borg D, et al. Assessment of the use of oral fluid as a matrix for drug monitoring in patients undergoing treatment for opioid addiction. *J Opioid Manag.* Sep-Oct 2015;11(5):435-442. PMID 26535971
28. Musshoff F, Driever F, Lachenmeier K, et al. Results of hair analyses for drugs of abuse and comparison with self-reports and urine tests. *Forensic Sci Int.* Jan 27 2006;156(2-3):118-123. PMID 16410161
29. Nuckols TK, Anderson L, Popescu I, et al. Opioid prescribing: a systematic review and critical appraisal of guidelines for chronic pain. *Ann Intern Med.* Jan 7 2014;160(1):38-47. PMID 24217469
30. Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain--United States, 2016. *JAMA.* Apr 19 2016;315(15):1624-1645. PMID 26977696
31. Manchikanti L, Kaye AM, Knezevic NN, et al. Responsible, safe, and effective prescription of opioids for chronic non-cancer pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines. *Pain Physician.* Feb 2017;20(2S):S3-S92. PMID 28226332
32. Chou R, Fanciullo GJ, Fine PG, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain.* Feb 2009;10(2):113-130. PMID 19187889
33. Hegmann KT, Weiss MS, Bowden K, et al. ACOEM practice guidelines: opioids for treatment of acute, subacute, chronic, and postoperative pain. *J Occup Environ Med.* Dec 2014;56(12):e143-159. PMID 25415660
34. American College of Occupational and Environmental Medicine (ACOEM). Opioid Treatment Agreement. 2014; [http://www.mdguidelines.com/documents/stateguidelines/apg3\\_opioid\\_06\\_treatment\\_agreement.pdf](http://www.mdguidelines.com/documents/stateguidelines/apg3_opioid_06_treatment_agreement.pdf). Accessed October 30, 2017.
35. Washington State Agency Medical Directors' Group. Interagency guideline on prescribing opioid dosing for pain. 2015; 3rd:<http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf>. Accessed October 23, 2017.
36. American Society of Addiction Medicine (ASAM). Public Policy Statement On Drug Testing as a Component of Addiction Treatment and Monitoring Programs and in other Clinical Settings. 2010; <http://www.asam.org/docs/public-policy-statements/1drug-testing---clinical-10-10.pdf?sfvrsn=0>. Accessed October 23, 2017.
37. American Society of Addiction Medicine (ASAM). Drug Testing: A White Paper of the American Society of Addiction Medicine (ASAM). 2013; <https://www.asam.org/docs/default-source/public-policy-statements/drug-testing-a-white-paper-by-asam.pdf>. Accessed October 23, 2017.
38. Jarvis M, Williams J, Hurford M, et al. Appropriate use of drug testing in clinical addiction medicine. *J Addict Med.* May/June 2017;11(3):163-173. PMID 28557958

### POLICY HISTORY

Date	Action	Description
October 2016	New Policy	
February 2017	Administrative	Policy updated with literature review through October 25, 2016;

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

## FEP 2.04.98 Drug Testing in Pain Management and Substance Use Disorder Treatment

	Update	references 7, 14, 16, and 22 added. In policy statements and policy guidelines, “qualitative” changed to “presumptive” and “quantitative” changed to “definitive”.
March 2018	Update Policy	Policy updated with literature review through October 16, 2017; references 8, 10, 18-19, 22-23, 31, 33, and 38 added. Policy statements unchanged except “not medically necessary” changed to “investigational in oral fluid drug testing and hair drug testing due to 510k and CLIA approval status of tests. Title changes to “Drug Testing in Pain Management and Substance Use Disorder Treatment”.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.