BlueCross BlueShield Federal Employee Program.

# FEP Medical Policy Manual

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

**Effective Policy Date: April 1, 2021**

**Original Policy Date: October 2016**

**Related Policies:**

5.70.32 Suboxone Drug Class
5.70.41 Methadone

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

### Description

### 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. Drug testing 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.

## OBJECTIVE

The objective of this evidence review is to provide guidance on the appropriate use of drug testing for patients who are in chronic pain treated with opioids or who are in substance use disorder treatment.

# POLICY STATEMENT

In outpatient pain management, presumptive (i.e. immunoassay) 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 use disorder is performed;
    - Clinicians have knowledge of test interpretation;
    - There is a plan in place regarding how to use test findings clinically;
    - Drug testing is ordered by a clinician during an office visit.
- Subsequent monitoring of treatment at a frequency appropriate for the risk level of the individual patient (see Policy Guidelines section)

In outpatient substance use disorder treatment, laboratory, in-office or point-of-care presumptive (i.e. immunoassay) drug testing may be considered **medically necessary** under the following conditions:

- Baseline screening before initiating treatment or at the time treatment is initiated (i.e. induction phase), 1 time per program entry, when the following conditions are met:
    - An adequate clinical assessment of patient history and risk of substance use disorder is performed;
    - Clinicians have knowledge of test interpretation;
    - There is a plan in place regarding how to use test findings clinically;
    - Drug testing is ordered by a clinician during an office visit.
- Stabilization and Maintenance phase -
    - Using an appropriate test, matrix and frequency of testing for the risk level of the individual and the substance being used (see Policy Guidelines section)
    - Documentation in the medical record explains the following (see Policy Guidelines section):
        - Rationale for the specific test(s) ordered,
        - Patient's history of substance use,
        - How drug testing results will guide medical decision-making

Definitive (i.e. confirmatory) drug testing, in outpatient pain management or substance use disorder 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 use disorder treatment, drug testing is considered **investigational** when the above criteria are not met including but not limited to routine presumptive or definitive drug testing or standing orders (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) and validity testing when used as a separate evaluation (see Policy Guidelines).

Drug testing in the following settings may be considered **medically necessary**:

- Emergency rooms
- Ambulatory surgery
- Inpatient Services
- An abrupt change in mental status (to rule out substance intoxication or delirium)
- Drug or alcohol exposure during pregnancy
- To rule out a fetal withdrawal syndrome by testing the mother for drug use.

# POLICY GUIDELINES

Notes:

This policy does not apply to testing required by third parties such as but not limited to: testing for a medico-legal purpose such as child custody; testing for pre-employment or random testing for employment; or testing for athletics.

Validity testing includes pH, specific gravity, nitrates, chromates, and creatinine which are performed on the same specimen that is being drug tested. Validity testing is an internal process to affirm that the reported results are accurate and valid.

## Pain Management

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

Aberrant behavior is defined by one or more of the following:

- multiple lost prescriptions,
- multiple requests for early refill,
- obtained opioids from multiple providers,
- unauthorized dose escalation, and
- apparent intoxication during previous visits.

Opinions vary on the optimal frequency of urine drug screening to monitor patients on opioid therapy for chronic pain. Screening frequency using a risk-based approach, as recommended by the Washington State interagency guideline (Washington State Agency Medical Directors' Group, 2015) is as follows:

- Low risk by ORT: Once a year
- Moderate risk by ORT: Twice a year

- High risk or opioid dose >120 morphine milligram equivalents/day: 3 to 4 times a year
- Recent history of aberrant behavior: Each visit

Note that the ORT is a copyrighted instrument. 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

## Substance Use Disorder

The 2017 consensus statement from the American Society of Addiction Medicine provides guidance on appropriate use of drug testing in substance use disorder.

Medical records should support the need for testing for the specific substance(s) of interest by documentation regarding the diagnosis, history and physical examination and/or behavior of the patient. Medical records should also justify the test that is being used and describe how results of testing will guide medical decision-making.

## Presumptive Testing

### Selecting an Appropriate Test

A medical and psychosocial assessment should guide the process of choosing a drug test that is individualized based on the patient's needs, appropriate for the substance(s) targeted and the particular window of time of suspected use.

If a panel that includes testing for several substances is being ordered, justification for the use of a panel instead of individual testing is needed.

### Selecting an Appropriate Matrix

Urine, blood, exhaled breath, oral fluid, sweat, and hair are matrices used in drug testing. Urine is the preferred matrix but all matrices have advantages and disadvantages with respect to sensitivity and specificity over different time windows, time to obtain results, different susceptibility to sample tampering and ease of collection.

Matrices other than urine may also be appropriate when urine cannot be collected (eg, patients on dialysis or with shy bladder) or when a sample collection technique is too invasive. Justification of matrix other than urine should be included in the medical record.

### Selecting an Appropriate Frequency of Testing

Plans may wish to set a threshold for the number of tests that are approved without review with subsequent tests requiring medical review. Patients who have unusually high numbers of tests ordered need medical review to confirm that the tests meet medical necessity.

Appropriate frequency of testing depends on many factors:

- Tests" detection capabilities and windows of detection
- Patient factors such as severity and chronicity of addiction
- Substance(s) used
- Phase of treatment
    - During the stabilization phase, drug testing may be scheduled more frequently
    - During the maintenance phase, drug testing may be scheduled less frequently

## Presumptive Test Availability

There may not be commercially available tests for certain synthetic or semisynthetic opioids. Table PG1 describes limitations on availability of presumptive tests.

### Table PG1, Limitations in Availability of Presumptive Immunoassays

| Drug Type | Potential limitations in availability of or sensitivity of presumptive immunoassays for certain drugs in urine |
|---|---|
| Benzodiazepines | • Clonazepam and lorazepam are detected with varying sensitivity by different assays.<br>• Therapeutic doses of benzodiazepines are generally not detected |
| Semisynthetic Opioids | • Oxycodone and oxymorphone (a metabolite of oxycodone) are detected in a few but not most standard opiate immunoassays depending on the antibodies used by the manufacturer.<br>• Hydrocodone and hydromorphone (a metabolite of hydrocodone) are also detected in most standard opiate immunoassays. |
| Synthetic opiates | • Meperidine, methadone, buprenorphine, and fentanyl will not be detected in a standard opiate immunoassay and require their own definitive test for detection. |
| Natural opioids | • Morphine and codeine (which is metabolized to morphine) are detected by standard immunoassays for opiates but presumptive testing does not distinguish specific drug present.<br>• Heroin is unable to be specifically detected by presumptive tests due to rapid metabolism to 6-MAM and subsequently to morphine. |

Sources: Based on information included in ASAM 2017 guideline and Washington State interagency guideline (Washington State Agency Medical Directors" Grou p, 2015)

# Guidance on Definitive (Confirmatory) Testing

Specific situations for definitive drug testing may include, but are not limited to the following:

- Need to detect a specific substance not adequately identified by presumptive methods (see Presumptive Test Availability, above)
- Unexpected positive test inadequately explained by the patient (e.g., a positive result on a presumptive test is inconsistent with the history and physical exam)
- Unexpected negative test (suspected medication diversion)
- Need for quantitative levels to compare with established benchmarks for clinical decision making such as treatment transition or changes in medication therapies.

Table PG2, 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 PG2. Interpreting Unexpected Urine Drug Tests Results**

| Unexpected Result | Possible Explanations | Possible Actions for the Physician |
|---|---|---|
| Test is negative for prescribed opioid | • False-negative<br>• Noncompliance<br>• Diversion | • Conduct confirmatory testing, specifying the drug of interest (eg, oxycodone often missed by immunoassay)<br>• 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)<br>• Ask patients if they've given the drug to others<br>• Monitor compliance with pill counts |
| Test is positive for nonprescribed opioid or benzodiazepines | • False-positive<br>• Patient acquired opioids from other sources (double-doctoring, "street") | • Repeat urine drug testing regularly<br>• Ask patients if they accessed opioids from other sources<br>• Assess for opioid misuse/addiction<br>• Review/revise treatment agreement |
| UDS positive for illicit drugs (eg, cocaine, cannabis) | • False-positive<br>• Patient is occasional user or addicted to the illicit drug<br>• Cannabis is positive for patients taking certain medications (eg, dronabinol) | • Repeat urine drug test regularly<br>• Assess for abuse/addiction and refer for addiction treatment as appropriate |

UDS: urine drug screen.

## BENEFIT APPLICATION

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

## FDA REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates drugs of abuse tests that are sold to consumers or health care professionals in the U.S. The FDA reviews many of these tests before they are sold for use. In its review, the FDA evaluates the design and performance of tests and sample collection systems to help ensure that they produce accurate results. The FDA does not review drugs of abuse tests

intended for employment and insurance testing provided they include a statement in their labeling that the device is intended solely for use in employment and insurance testing. The FDA review does not include test systems intended for federal drug testing programs (eg, programs run by the Substance Abuse and Mental Health Services Administration, the Department of Transportation, and the U.S. military.)

The FDA has cleared assays for urine testing of drugs of abuse as well as oral fluid specimen collection devices and assays for analysis of oral fluid for drugs of abuse through the 510(k) regulatory pathways. Several collection devices are commercially available in the U.S., and they generally involve collection on an absorbent material, such as foam pads; pads are then placed in a container with a stabilizing buffer solution. Immunoassays of urine specimens have previously been cleared by the FDA and are used as the predicates for the oral fluid immunoassays.

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. Testing with GC/MS and some immunoassays are performed in laboratory settings. Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments for high-complexity testing.

# RATIONALE

## Summary of Evidence

For individuals who have chronic pain treated with opioids who receive drug testing, there is limited peer-reviewed scientific literature to guide drug testing strategies; however, guidelines indicate that drug testing is standard of care. Guidelines from Centers for Disease Control and Prevention, American Society of Interventional Pain Physicians, American Pain Society and American Academy of Pain Medicine, American College of Occupational and Environmental Medicine, Department of Veterans Affairs and Department of Defense have recommended drug testing and consider the frequency of testing to be at the discretion of the health care provider, based on an assessment of the patient's risk for misuse or addiction.

For individuals who have a drug addiction who are in substance use disorder treatment who receive drug testing, there is limited peer-reviewed scientific literature to guide drug testing strategies; however, guidelines indicate that drug testing is standard of care. Guidelines from the American Society of Addiction Medicine have recommended drug testing and consider the frequency of testing to be at the discretion of the health care provider, based on an assessment of the patient's risk and substance(s) used.

# SUPPLEMENTAL INFORMATION

## Practice Guidelines and Position Statements

### Pain Management

Nuckols et al (2014) published a systematic review of guidelines that addressed the management of opioid use for chronic pain.[8,] 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; 2 recommended mandatory testing for all patients, another recommended testing only patients at increased risk of a medication use disorder, and 2 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 2.

## American Academy of Pain Medicine

In 2018, the American Academy of Pain Medicine (AAPM) published consensus recommendations on urine drug monitoring in patients receiving opioid for chronic pain.[9,] The AAPM recommended definitive testing at baseline for patients prescribed opioids for chronic pain unless presumptive testing is required by institutional or payer policy. The AAPM also recommended that the choice of substances to be analyzed should be based on considerations that are specific to each patient and related to illicit drug availability. Baseline risk assessment for aberrant medication-taking behavior, misuse, and opioid use disorder should be conducted using patient history, validated risk assessment tools, prescription drug monitoring program data, previous urine drug monitoring results, and evaluation of behaviors indicative of risk. The recommended frequency of urine drug monitoring was based on risk assessment: At least annually for patients at low risk, 2 or more times per year for those at moderate risk, and 3 or more times per year for those at high risk.

## 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.[10,] 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.

## Centers for Disease Control and Prevention

In 2016, the Centers for Disease Control and Prevention published guidelines on opioids for chronic pain.[11,] 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."

## 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 the treatment of chronic pain.[6,] The recommendations on assessing adherence to prescribed opioids include obtaining a urine drug test (with patient consent) before initiating opioid therapy, and then randomly at a 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."

### 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.[12,] 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),[13,] a white paper (2013), which provided background on the science and current practices of drug testing[14,], and guidelines (2017) on the effective use of drug testing.[7,15,]

The 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."[13,] The 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."[14,] The paper acknowledged that more specific guidance on drug testing was needed, which led to the development of

the 2017guidelines, described below.

The ASAM (2017) 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 the benefits and limitations of the various drug tests. Table 2 summarizes the characteristics of urine, oral fluid, and hair drug tests that may inform the decision of what type of drug test to use.[7,]

**Table 2. 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).[7,]**

## U.S. Preventive Services Task Force Recommendations

Not applicable.

## Medicare National Coverage

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

## REFERENCES

## REFERENCES

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## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

| Date | Action | Description |
|---|---|---|
| October 2016 | New policy | |
| February 2017 | Administrative update | Policy updated with literature review through October 25, 2016; references 7, 14, 16, and 22 added. In policy statements and policy guidelines, “qualitative” changed to “presumptive” and “quantitative” changed to “definitive”. |

| Date | Action | Description |
|---|---|---|
| March 2018 | Replace policy | Policy updated with literature review through October 16, 2017; references 8, 10, 18-19, 22-23, 31, 33, and 8 added. Policy statements unchanged except “not medically necessary” changed to “investigational in oral fluid drug testing and hair drug testing due to 510(k )and CLIA approval status of tests. Title changes to “Drug Testing in Pain Management and Substance Use Disorder Treatment”. |
| March 2021 | Replace policy | Policy updated with literature review through July 23, 2019. Policy converted to review informed by guidelines format. Clarifications made to policy statements regarding documentation required in medical record; Policy Guidelines expanded to provide guidance regarding factors that determine appropriate testing modalities, intervals and matrices. |
| March 2021 | Replace policy | Policy updated with literature review through October 12, 2020; references added. Terminology in policy statement corrected from "not medically necessary" to "investigational" when criteria are not met. Policy statements otherwise unchanged. |