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Drug Testing in Pain Management and Substance Use Disorder Treatment

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Related Policies (if applicable)
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Disclaimer

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

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 individual 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 (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 individual 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,
 - Individual'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 not medically necessary** when the above criteria are not met including but not limited to routine presumptive or definitive drug testing or standing orders (e.g., testing at every visit, without consideration for specific individual 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

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 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 1 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 individuals 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'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 individual. 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 individual'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 (e.g., individuals 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

Individuals 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.
- Individual 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. • 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. • 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. • 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' Group, 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 individual (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 • Noncompliance • Diversion	• Conduct confirmatory testing, specifying the drug of interest (e.g., oxycodone often missed by immunoassay) • Take a detailed history of individual's medication use for the preceding 7 days (e.g., could learn

		that the individual ran out several days before test) • Ask individuals if they've given the drug to others • Monitor compliance with pill counts
Test is positive for nonprescribed opioid or benzodiazepines	• False-positive • Individual acquired opioids from other sources (double-doctoring, "street")	• Repeat urine drug testing regularly • Ask individuals if they accessed opioids from other sources • Assess for opioid misuse/addiction • Review/revise treatment agreement
UDS positive for illicit drugs (e.g., cocaine, cannabis)	• False-positive • Individual is occasional user or addicted to the illicit drug • Cannabis is positive for patients taking certain medications (e.g., dronabinol)	• Repeat urine drug test regularly • Assess for abuse/addiction and refer for addiction treatment as appropriate

UDS: urine drug screen.

Description

Patients in pain management programs and substance use disorder treatment may misuse prescribed opioids and/or may use non-prescribed drugs. Thus, these patients are often assessed before treatment and monitored while they are 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.

Background

Pain Management

According to a 2012 evidence assessment by the American Society of Interventional Pain Physicians (ASIPP), approximately one-third of chronic pain patients do not use opioids as prescribed or may abuse them. (1) In 2016, the International Narcotics Control Board (INCB) reported that between 1999 and 2010, the number of deaths related to the use of prescription opioid painkillers increased 5-fold among U.S. women and increased by a factor of 3.6 among U.S. men. (2) As far as age groups, the INCB reported the rates of drug overdose deaths increased over the period from 1999 to 2017 for all age groups, however in 2017, rates were significantly higher for those 25 to 64 years of age (31.4 per 100,000) than for those age 65 and

over (6.9 per 100,000). (3) In the United States, drug overdose deaths have increased fivefold over the past 2 decades, and in 2021 alone there were over 106,00 deaths due to drug overdose. (4) Additionally, studies have found that a substantial proportion of chronic pain patients inaccurately report nonadherence to prescribed medications and the use of illicit drugs. (5)

A discussion of the controversies related to opioid therapy for the treatment of chronic non-cancer pain is beyond the scope of this policy.

Substance Use Disorder

Substance use, abuse, and addiction involving numerous prescription and illicit drugs is also a serious social and medical problem. Addiction is a primary, chronic disease of brain reward, motivation, memory, and related circuitry and is manifested by the individual pathologic pursuit of reward and/or relief by substance use and other behaviors.

Monitoring Strategies

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

Confirming whether patients follow these behavioral guidelines can be a challenge. Risk-assessment screening instruments, such as the Screener and Opioid Assessment for Patients with Pain (SOAPP), and the 5-item Opioid Risk Tool (ORT), can aid in the assessment of patients' risk for inappropriate drug use. In addition, the presence of "aberrant behaviors" can be used as a marker for patients who are at high risk for deviating from treatment protocols. Aberrant behaviors include multiple lost prescriptions, obtaining prescriptions from other practitioners, and displaying evidence of acute intoxication during office visits.

Testing Matrices

Another strategy for monitoring patients is testing of biologic specimens for the presence or absence of drugs. Currently, urine is the most commonly used biologic substance. Advantages of urine drug testing (UDT) are that it is readily available and standardized techniques for detecting drugs in urine exist. Other biologic specimens (e.g., blood, oral fluids, hair, sweat) can also be tested. 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.

Urine Drug Testing

There are 2 primary categories of UDT: presumptive testing (immunoassay) and confirmatory testing (specific drug identification).

Presumptive (Immunoassay) Testing

Immunoassay testing (also called presumptive testing or qualitative testing or screening) can be performed in a laboratory or at point-of-service. Immunoassay tests are based on the principle of competitive binding and use antibodies to detect a particular drug or drug metabolite in a urine sample. With competitive binding, a fixed amount of a labeled drug is added to the urine sample, and the drug or metabolite in the sample competes with the labeled drug for binding sites on the antibody. The amount of labeled antigen that binds with the antibody is inversely proportional to the amount of the drug or metabolite in the sample.

Immunoassay tests vary in the type of compounds they can detect. Some detect specific drugs and may fail to recognize similarly structured drugs within the same class. Other immunoassays identify only classes of drugs and thus results cannot be used to determine which drug a patient is taking. For example, a positive result to an opiate immunoassay can be due to morphine or hydromorphone. The degree of cross reactivity (i.e., an antibody's reactivity with a compound other than the target of the test) varies widely among immunoassays.

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

Immunoassays generally have a rapid turnaround time, to within minutes for on-site tests, and 1 to 4 hours for laboratory-based tests. (6)

Confirmatory (Specific Drug Identification)

Confirmatory tests are always performed in a laboratory. Gas chromatography/mass spectrometry (GC/MS) and liquid-chromatography/mass spectrometry (LC/MS) are considered to be the criterion standard for confirmatory testing. These techniques involve using GC or LC to separate the analytes in a specimen and for MS to identify the specific molecular structures of the drug and its metabolites. The tests are able to quantify the amount of drug or metabolite present in the urine sample. Definitive quantitative tests can be used to confirm the presence of a specific drug identified by a screening test and can identify drugs that cannot be isolated by currently available immunoassays. Results are reported as the specific levels of substances detected in the urine. GC/MS and LC/MS generally require the specification of the drug or drugs to be identified. Alternatively, "broad-spectrum screens" can be conducted. There is a several-day turnaround time for GC/MS and LC/MS testing. (7)

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

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

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

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

Full informed consent is a requirement before UDT. Patients should be informed of the specific drug testing protocol before treatment and should provide written agreement with the plan for monitoring. As stated in a joint U.S. Veterans Affairs (VA)/Department of Defense (DoD) guideline, patients' refusal to consent to urine testing should be considered a factor in the overall assessment of patients' ability to adhere to treatment. (8)

Oral Fluid Drug Testing

Oral fluid (liquid samples obtained from the oral cavity) can potentially be used to test for drug use. Oral fluid contains secretions from several different sources, including secretions from the 3 pairs of major salivary glands (parotid, sublingual, and submandibular), secretions from the minor salivary glands, oro-nasopharyngeal secretions, and cellular debris. The mixture of fluids obtained varies depending on the collection method used (e.g., spitting, suctioning, draining, or collection on some type of absorbent material). Drug concentrations can be affected by the collection method and by the use of saliva stimulation methods. Several collection devices are commercially available in the 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. Drug concentrations may also depend on how the oral fluid is recovered from the collection device (e.g., by centrifugation or by applying pressure). Drug concentrations may not reflect blood levels because of residual amounts of a drug (specifically those ingested or

smoked) remaining in the oral cavity after recent use.

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

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

Hair Drug Testing

Hair is composed of protein that traps chemicals in the blood at the time the hair develops in the follicle. Hair on the human head grows at approximately 0.5 inch per month. Thus, a 1.5-inch hair sample could be used to detect drug use during the previous 90 days. Potential advantages of hair as a drug testing source include noninvasive collection; ease of collection, storage, and shipping; availability of samples for testing and retesting; and difficulty in tampering. Potential disadvantages include: recent drug use (i.e., within past 7 days) cannot be detected; difficulty in detecting very light drug use (e.g., a single episode); and drug levels can be affected by environmental exposure. In addition, variation in hair texture as well as cosmetic hair treatments can affect drug incorporation into hair and the accuracy of drug tests on hair samples. As with other types of samples, hair can be initially tested using immunoassay techniques, with confirmation by MS-based methods. Hair testing has been used in a variety of situations where detection of drug use during the previous several months is desired (e.g., pre-employment screening, post-drug-treatment verification of relapse).

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 (e.g., 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 (CLIA). Testing with GC/MS and some immunoassays are performed in laboratory settings. Laboratories that offer laboratory-developed tests must be licensed by the CLIA for high-complexity testing.

Rationale

Guidelines with evidence reviews of published peer-reviewed scientific literature suggest that evidence of benefit on health outcomes for drug testing for both patients in chronic pain using opioids and patients with substance use disorder is limited and usually confounded with drug testing as part of a multifaceted intervention of risk mitigation or contingency management. There is also no clear evidence in the literature regarding the most effective frequency of testing. (9, 8)

Notwithstanding the lack of evidence, clinical input and guidelines indicate that drug testing is standard of care. Therefore, a rigorous study comparing drug testing to no drug testing and following patients for health outcomes is unlikely to be performed.

Thus, a traditional review of the evidence will not be performed, and relevant national and regional clinical practice guidelines were sought to inform the medical policy.

Clinical Input from Specialty Societies

2014 Input

Input was received from 5 physician specialty societies while this policy was under review in 2014. There was near-consensus among reviewers that, in outpatient pain management, presumptive (i.e. qualitative) urine drug testing may be considered medically necessary for patients who meet the stated criteria and that the frequency of repeat drug testing should depend on the risk level of the individual. There was also near-consensus among reviewers that, in substance abuse treatment, baseline presumptive drug testing may be considered medically necessary for patients who meet the stated criteria and that targeted weekly qualitative screening for a maximum of 4 weeks may be considered medically necessary during the stabilization phase. There was mixed input on the frequency of presumptive drug testing that may be considered medically necessary during the maintenance phase of substance abuse treatment.

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. (10)

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. (11) 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 (ASIPP)

In 2017, the ASIPP issued guidelines for responsible, safe, and effective opioid prescribing for chronic non-cancer pain. (12) 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	III	Moderate

or illicit drugs. UDT may decrease prescription drugs abuse of illicit drug use when patients are in chronic pain management therapy."		
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LOE: level of evidence; SOE: strength of evidence; UDT: urine drug testing.

Centers for Disease Control and Prevention (CDC)

In 2016, The CDC published guidelines on opioids for chronic pain. (13) In 2022, these guidelines were updated and expanded to include management of pain of a shorter duration, and to clarify that they are not applicable to sickle cell disease- or cancer-related pain or patients receiving palliative or end-of-life care. (14) The updated guidelines recommend the following regarding drug testing: "When prescribing opioids for subacute or chronic pain, clinicians should consider the benefits and risks of toxicology testing to assess for prescribed medications as well as other prescribed and nonprescribed controlled substances." The authors note that such testing should not be used punitively, including as a basis for dismissing patients from care, and that clinicians should consider the benefits and risks of toxicology testing prior to initiation and at least annually during opioid therapy. The guideline authors further note that restricting definitive confirmatory testing to situations and substances for which results are expected to affect management (e.g., results will influence decisions with major clinical or non-clinical implications, there is a need to detect specific agents or agents that cannot be identified in standard immunoassays, or to confirm unexpected screening test results) can reduce costs.

Department of Veterans Affairs and Department of Defense

In 2022, the Department of Veterans Affairs and Department of Defense updated clinical practice guidelines for managing opioid therapy for the treatment of chronic pain. (8) The recommendations on risk mitigation to prescribed opioids include obtaining a UDT (with patient consent) before initiating opioid therapy, and then randomly at a follow-up to confirm appropriate use. Other strategies recommended include clinical assessment such as random pill counts and use of prescription drug monitoring programs.

The guidelines included the following specific recommendations on UDT as part of risk mitigation:

"We recommend implementing risk mitigation strategies upon initiation of long-term opioid therapy, starting with an informed consent conversation covering the risks and benefits of opioid therapy as well as alternative therapies. The strategies and their frequency should be commensurate with risk factors and include:

- Ongoing, random urine drug testing (including appropriate confirmatory testing)
- Checking state prescription drug monitoring programs
- Monitoring for overdose potential and suicidality
- Providing overdose education
- Prescribing of naloxone rescue and accompanying education"

The guideline states that gaining consent is required prior to a UDT; if a patient declines consent, "providers should factor that declination into their consideration about whether it is safe to continue opioids. Urine drug testing is required if long-term opioids are to be initiated or

continued."

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. (15) 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.

In 2020, Washington State Agency Medical Directors' Group released a guideline on long-term opioid therapy prescribing. Use of UDT was mentioned as an element of assessment of patients on long-term opioid therapy. (16) No pain management guidelines were identified that had recommendations on oral fluid or hair testing.

Substance Use Disorder Treatment

American Society of Addiction Medicine (ASAM)

The ASAM has published several documents on drug testing: a public policy statement (2010), (17) a white paper (2013) which provided background on the science and current practices of drug testing, (18) and guidelines (2017) on the effective use of drug testing. (9)

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." (17) 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." (18) The paper acknowledged that more specific guidance on drug testing was needed, which led to the development of the 2017 guidelines, 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. (9)

The ASAM also published a focused update in 2020 focusing on the treatment of opioid use disorder. The guideline states that "urine drug testing is a reasonably practical and reliable

method to test for adherence to medication and illicit drug use. However, other reliable biological tests for the presence of drugs may be used. The frequency of drug testing should be determined by a number of factors, including the stability of the patient, the type of treatment, and the treatment setting. Drug testing is required a minimum of eight times per year for patients in OTP [opioid treatment programs]." (19)

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). (9)

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 the Centers for Disease Control and Prevention, American Society of Interventional Pain Physicians, 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.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	80156, 80188, 80299, 80305, 80306, 80307, 80320, 80321, 80322, 80323, 80324, 80325, 80326, 80327, 80328, 80329, 80330, 80331, 80332, 80333, 80334, 80335, 80336, 80337, 80338, 80339, 80340, 80341, 80342, 80343, 80344, 80345, 80346, 80347, 80348, 80349, 80350, 80351, 80352, 80353, 80354, 80355, 80356, 80357, 80358, 80359, 80360, 80361, 80362, 80363, 80364, 80365, 80366, 80367, 80368, 80369, 80370, 80371, 80372, 80373, 80374, 80375, 80376, 80377, 82077, 82542, 82570, 83992, 84311, 84999, 0007U, 0011U, 0051U, 0054U, 0079U, 0082U, 0093U, 0116U, 0117U, 0227U
HCPCS Codes	G0480, G0481, G0482, G0483, G0659

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <<https://www.cms.hhs.gov>>.

Policy History/Revision

Date	Description of Change
01/01/2026	Document updated. The following changes were made to Coverage: 1) Removed NOTES 1-7; 2) Removed section on documentation requirements; and 3) Modified both the conditional criteria language as well as the not medically necessary statements. References 3, 4 and 14 added; some updated and others removed. Title changed from Drug Testing (e.g. Pain Management and Substance Use Disorder Monitoring) and Screening.
06/15/2024	Reviewed. No changes.
09/15/2023	Document updated with literature review. Coverage unchanged. References 13 and 23 added; others updated.
11/01/2022	Document updated with literature review. The following changes were made to Coverage: Added "NOTE 6: Validity testing with abnormal results invalidates the sample and should not be submitted for testing reimbursement" and "NOTE 7: "Insufficient sample for testing" means no testing should be submitted for reimbursement". References updated.
04/01/2021	Document updated with literature review. Coverage unchanged. Reference 15 added.
08/01/2020	Document updated with literature review. The following changes were made to Coverage: 1) Added the following to Documentation requirements: 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 medically necessary when urine cannot be collected (e.g., patients on dialysis or with shy bladder) or when a sample collection technique is too invasive. Documentation with justification of matrix other than urine must be included in the medical record. 2) Replaced Urine Drug Testing (UDT) with drug testing in the coverage section to include other drug tests (blood, oral fluids, hair, sweat); 3) To the medically necessary for Qualitative (presumptive) drug testing for substance use disorder treatment coverage statement the following was added: laboratory, in-office or point-of-care and for 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. Documentation in the medical record explains the following: a. Rationale for the specific test(s) ordered, b. Patient's history of substance use, c. How drug testing results will guide medical decision-making. 4) The investigational coverage statement for pain management and substance use disorder treatment, hair drug testing and oral fluid drug testing was removed; and 5) 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 was added. References 11, 12, and 16 were added and some references removed.
04/15/2018	Document updated with literature review. Coverage unchanged; however, “substance abuse treatment” was replaced with “substance use disorder treatment” throughout entire policy. “Urine” and “Abuse” removed from title and exchanged “Including” for “In” in the title; title changed to: Drug Testing In Pain Management and Substance Use Disorder Monitoring. References added: 2, 8-10, 17-19, 21-23, 27, 30, 33; and reference list updated.
04/15/2017	Reviewed. No changes.
12/15/2016	Document update with literature review. The following coverage statement was added: In outpatient pain management and substance abuse treatment, hair drug testing and oral fluid drug testing are considered experimental, investigational and/or unproven. The following was added to the routine screening coverage statement that is considered not medically necessary: “without documented individual patient assessment.” The following NOTES were added: NOTE 1: In general, qualitative urine drug testing should not require more than 15 tests within a 12-month period. Additional testing would require clinical justification of medical necessity; NOTE 2: In general, quantitative urine drug testing should not require more than 12 tests within a 12-month period. Additional testing would require clinical justification of medical necessity; NOTE 4: Simultaneous blood and urine drug screening or testing is not appropriate and should not be done routinely; and NOTE 5: Risk stratification is discussed in the Description section of this medical policy.
11/01/2015	Document updated with literature review. Coverage unchanged.
12/15/2014	New medical document. Urine drug testing, qualitative or quantitative, is considered medically necessary when specific criteria are met, for outpatient pain management or for outpatient substance abuse monitoring. Urine drug testing, qualitative or quantitative, is considered not medically necessary when specific criteria are not met, for outpatient pain management or for outpatient substance abuse monitoring.