

02.04.49 Drug Testing in Pain Management and Substance Use Disorder Treatment

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This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

Related Policies:

- None

Summary

Description

Individuals in pain management programs and substance use disorder treatment may misuse prescribed opioids and/or may use nonprescribed drugs. Thus, these individuals 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 participant contracts.

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, 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 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 based on an assessment of the patient's risk and substance(s) used.

Additional Information

Not applicable.

OBJECTIVE

The objective of this evidence review is to determine whether urine, oral fluid, and/or hair testing for drug use improves the net health outcome in individuals with chronic pain receiving opioid treatment or with a drug addiction who are in substance use disorder treatment.

PRIOR APPROVAL

Not applicable.

POLICY

Medically Necessary

Presumptive Drug Testing

Presumptive drug testing to verify compliance with treatment, identify undisclosed drug use or abuse or evaluate *aberrant behavior (see [Policy Guidelines](#)) may be considered **medically necessary**, beginning at the start of treatment, as part of a monitoring program using an appropriate test, matrix, and frequency of testing for the risk level of the individual and the substance being used (see [Policy Guidelines](#)) who meet one of the following:

- A. Receiving treatment for chronic pain with prescription opioid(s) or other potentially abused medication(s); **or**
- B. Undergoing treatment for, or monitoring for relapse of, opioid addiction or substance abuse disorder.

Presumptive drug testing may be considered **medically necessary**-using an appropriate test, matrix, and frequency of testing for the risk level of the individual and the substance being used-(see [Policy Guidelines](#)) for one of the following:

- A. To assess an individual when clinical evaluation suggests use of non-prescribed medication(s) or illegal substance(s); **or**
- B. On initial entrance into a pain management program or substance use disorder recovery program.

Definitive Drug Testing

Definitive drug testing to verify compliance with treatment, identify undisclosed drug use or abuse, or evaluate *aberrant behavior (see [Policy Guidelines](#)) may be considered **medically necessary** beginning at the start of treatment, as part of a monitoring program meeting both A and B below:

- A. Testing indications - *either* 1 or 2 must be present:
 - 1. Receiving treatment for chronic pain with prescription opioid or other potentially abused medications;
 - 2. Undergoing treatment for, or monitoring for relapse of, opioid addiction or substance abuse use disorder;
- B. Testing Scenarios – *either* 1 or 2 below have been met:
 - 1. Definitive testing following prior presumptive testing:
 - a. The presumptive drug testing was done for a medically necessary reason;
 - b. The presumptive drug test was positive for an illegal drug (for example, but not limited to methamphetamine or cocaine), positive for a prescription drug with abuse potential which was not prescribed, or negative for prescribed medication;
 - i. The specific definitive test(s) ordered are supported by documented rationale for each test ordered; and
 - ii. Clinical documentation reflects how the results of the test(s) will be used to guide clinical care;
 - 2. Definitive testing without prior presumptive testing:
 - a. Presumptive drug tests are not available for the drug in question (examples may include opioids and their metabolites such as fentanyl, meperidine, tramadol, and tapentadol, muscle relaxants and their metabolites such as carisoprodol, synthetic cannabinoids and their metabolites, as well as cathinones [“Bath Salts”] and their metabolites);
 - b. The specific definitive test(s) ordered are supported by documented clinical rationale for each test ordered;
 - c. Clinical documentation reflects how the results of the test(s) will be used to guide clinical care.

Not Medically Necessary

The use of drug testing in pain management and substance use disorder treatment, including but not limited to the following is considered **not medically necessary**:

- When the criteria above are not met
- Simultaneous performance of presumptive and definitive tests for the same drugs or metabolites (definitive testing should be guided by the results of presumptive testing)

- Routine testing or testing completed due to any of the following (due to non-individualized treatment):
 - Standing orders
 - Blanket orders
- Use of saliva, oral fluid, or hair samples for drug testing
- Reflex testing
- Testing for non-medical purposes to include on behalf of third parties (e.g., school, courts, employers, professional boards)

Panel Drug Testing

Any definitive drug testing panel other than G0480 (1-7 drug classes) and G0481 (8-14 drug classes) is considered **not medically necessary**. While the use of some individual tests included in these drug testing panels G0482 (15-21 drug classes), G0483 (22 or more drug classes) and G0659 (any number of drug classes) may be reasonable under specific circumstances, the use of all the tests within a panel is rarely justified in guiding clinical management of the individual.

POLICY GUIDELINES

NOTE: Iowa House File 2668 (Iowa Code section 514C.36) requires that certain health plans issued or renewed on or after January 1, 2025 “provide coverage for biomarker testing for the purposes of diagnosing, treating, appropriately managing, or monitoring a disease or condition in a covered person when the biomarker testing has demonstrated clinical utility.” Iowa House File 2668 defines clinical utility as “sufficient medical and scientific evidence indicating that the use of a biomarker test will provide meaningful information that affects treatment decisions and guides improvement of net health outcomes, including an improved quality of life or longer survival.” Wellmark has reviewed this Medical Policy in light of Iowa House File 2668.

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

Documentation Requirements

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

“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.”

Frequency Limits Related to Drug Testing

Frequency will be limited to 24 tests based on a rolling calendar year for each presumptive (80305 80306, 80307) and definitive testing (G0480 and G0481). (Total of 48 per a rolling calendar year).

Note: *If presumptive codes 80305-80307 are billed more frequently than three times every seven days, they will be denied. If CPT 80320-80377 are billed, they will be denied.*

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, which is 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.

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.

Selecting an Appropriate Matrix

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 be appropriate when urine cannot be collected (e.g., individuals on dialysis or with a shy bladder). Justification of matrix other than urine should be included in the medical record. See [Policy](#) criteria above regarding matrices considered not medically necessary.

There may not be commercially available tests for certain synthetic or semisynthetic opioids. Table PG1 below 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 patient's medication use for the preceding 7 days (e.g., could learn that patient ran out several days before test) - Ask patients if they've given the drug to others - Monitor compliance with pill counts

Test is positive for nonprescribed opioid or benzodiazepines	• False-positive • Patient acquired opioids from other sources (double doctoring, "street")	• Repeat urine drug testing regularly • Ask patients 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 • Patient 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

USD: urine drug screen.

Definitions

Blanket order: A test request that is not for a specific individual, but it is an identical order for all individuals in a clinician's practice. Such orders do not take the clinical situation of each individual into consideration at the time of request, or during each visit.

Definitive testing: A type of testing that is more specific than presumptive testing and allows for the detection of specific drugs or metabolites.

Drug class: Drugs, medications, or illicit substances (including metabolites of each member of the class) that share similar essential aspects of their chemical structure and at least one similar mechanism of action (i.e., bind to the same biological target). For example, opioids interact with one or more opioid receptor. Drugs associated with substance use disorders, including alcohol and inhalants, are thought to directly activate the brain reward system as a common mode of action.

Drug diversion: Prescription drugs provided to an individual other than the one to whom the drugs were prescribed.

Drug testing panel: A type of test that involves tests for more than one type of drug and may test for a pre-defined set of drug classes or metabolites of specific drugs or drug classes.

Member-specific profile: This term refers to the specific characteristics of an individual being treated for chronic pain or an individual undergoing treatment for opioid addiction and substance use disorder, which may be used to help guide treatment. These characteristics may include current and past alcohol and drug use patterns and clinical findings such as slurred speech, hallucinations or pin-point pupils that tend to be specific to a drug or drug class. Use of member-specific profiles assist in guiding the selection of the specific tests for drugs and their metabolites.

Planned testing: Testing being conducted at a time previously scheduled and known to the individual being tested.

Presumptive testing: A type of testing that is intended to identify the use or non-use of a drug or general class of drugs.

Random testing: Testing being conducted at a time not previously scheduled and not known to the individual being tested.

Reflex Testing: A laboratory test that is performed "reflexively" after an initial or presumptive test result suggests the need for further diagnostic information. This type of testing is not based on a specific clinical

situation and provider's order but is built into the testing process. Testing performed as a step necessary to complete the request of physician responsible for a members care and provided by an order is not considered reflex testing.

Standing order: A test request for a specific individual representing: 1) repetitive testing to monitor a condition or disease, or 2) individualized orders for repetitive automatic testing for certain individuals for pre-determined tests based on historical use, risk, and community trend patient profiles. Definitive drug testing standing orders are not consistent with ordering laboratory testing based upon clinical findings, nor are they sensitive to the individual's history of drug use and community patterns of drug use.

Testing panel: A type of laboratory procedure where multiple tests are automatically run on a single sample to detect the presence of a variety of substances or class of substances.

Coding

See the [Codes](#) table for details.

BACKGROUND

Pain Management

According to a 2012 evidence assessment by the American Society of Interventional Pain Physicians, approximately one-third of patients with chronic pain do not use opioids as prescribed or may abuse them. 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. 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). In the United States, drug overdose deaths have increased fivefold over the past 2 decades, and in 2021 alone there were over 106,000 deaths due to drug overdose. Additionally, studies have found that a substantial proportion of patients with chronic pain inaccurately report nonadherence to prescribed medications and the use of illicit drugs.

A discussion of the controversies related to opioid therapy for the treatment of chronic non-cancer pain is beyond the scope of this review. For a review of evidence-based guidelines from national and international medical societies that examine the place of opioid-based interventions within the management of selected chronic noncancer pain indications, see the BCBSA Special Report 'Opioids for Management of Chronic Noncancer Pain'.

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, and multicomponent interventions are often used. Many settings require patients to sign a contract before they

are given a prescription for opioids. The contracts generally involve obtaining patients' agreement on behaviors they will engage in during the treatment period (e.g., taking medication as prescribed) and not engage in (e.g., selling prescribed medication and/or obtaining additional prescriptions from other physicians).

Confirming whether patients follow these behavioral guidelines can be a challenge. Risk-assessment screening instruments, such as the Screener and Opioid Assessment for Patients with Pain, and the Opioid Risk Tool, 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 of 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.

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.

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

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

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

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

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

Oral Fluid Drug Testing

Oral fluid (liquid samples obtained from the oral cavity) can potentially be used to test for drug use. Oral fluid contains secretions from several different sources, including secretions from the 3 pairs of major salivary glands (parotid, sublingual, and submandibular), secretions from the minor salivary glands, oropharyngeal 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.,¹ 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 (≥ 25 μ 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 pain management or substance use disorder treatment settings, particularly when substitution or tampering with urine drug samples is suspected.

Hair Testing

Hair is composed of protein that traps chemicals in the blood at the time the hair develops in the follicle. Hair on the human head grows at approximately 0.5 inches 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 the 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

This evidence review was created in November 2014 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through November 2025.

Guidelines with evidence reviews of published peer-reviewed scientific literature suggest that the 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.

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 evidence review will not be performed, and relevant national and regional clinical practice guidelines were sought to inform the review. The guidelines are reviewed in the [Supplementary Information](#) section of the review.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input

received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input

In response to requests, input was received from 5 physician specialty societies and 8 academic medical centers 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. In addition, clinical input was mixed on confirmatory definitive (i.e., quantitative) drug testing and particularly on whether definitive drug testing should only be performed on a drug-specific basis.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Pain Management

Nuckols et al (2014) published a systematic review of guidelines that addressed the management of opioid use for chronic pain.

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 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 opioids for chronic pain. 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. These were updated in 2023. The guidelines included the following recommendations on UDT (see Table 1).

Table 1. Recommendations on Urine Drug Monitoring for Chronic Non-Cancer Pain

Recommendation	LOE	SOE
"Comprehensive evaluation of pain history, medical history, psychosocial history, functional assessment, and appropriate consultations are recommended prior to initiation of opioid therapy."	Strong	Strong
"UDM should be implemented at the initiation of opioid therapy and conducted periodically for monitoring therapeutic compliance as per available guidance referential to mode and frequency of testing."	Moderate	Strong

LOE: level of evidence; SOE: strength of evidence; UDM: urine drug monitoring.

Centers for Disease Control and Prevention

In 2016, the Centers for Disease Control and Prevention published guidelines on opioids for chronic pain. 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. 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. 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 Director's Group

In 2015, the Washington State Agency Medical Directors' Group updated its interagency guidelines on opioid dosing for chronic non-cancer pain. 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 morphine-equivalent dose (MED)/d: 3 to 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. 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), a white paper (2013), which provided background on the science and current practices of drug testing, and guidelines (2017) on the effective use of drug testing.

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." 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." 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.

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]."

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)

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		

	80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures (e.g., immunoassay); capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges) includes sample validation when performed, per date of service
	80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures (e.g., immunoassay); read by instrument assisted direct optical observation (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service
	80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures, by instrument chemistry analyzers (e.g., utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (e.g., GC, HPLC), and mass spectrometry either with or without chromatography, (e.g., DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service
	0007U	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, includes specimen verification including DNA authentication in comparison to buccal DNA, per date of service. For the ToxProtect Test from Genotox Lab
	0011U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites. For the Cordant CORE test by Cordant Health Solutions
	0051U	Prescription drug monitoring, evaluation of drugs present by liquid chromatography tandem mass spectrometry (LC-MS/MS), urine or blood, 31 drug panel, reported as quantitative results, detected or not detected, per date of service. For the UCompliDX test by Elite Medical Labs
	0054U	Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service. For the AssuranceRX Micro Serum test by Firsttox Lab
	0082U	Drug test(s), definitive, 90 or more drugs or substances, definitive chromatography with mass spectrometry, and presumptive, any number of drug classes, by instrument chemistry analyzer (utilizing immunoassay), urine, report of presence or absence of each drug, drug metabolite or substance with description and severity of significant interactions per date of service. For the NextGen Precision test by Precision Diagnostics
	0093U	Prescription drug monitoring, evaluation of 65 common drugs by LC-MS/MS, urine, each drug reported detected or not detected. For the ComplyRX test by Claro Labs
	0116U	Prescription drug monitoring, enzyme immunoassay of 35 or more drugs confirmed with LC-MS/MS, oral fluid, algorithm results reported as a patient compliance measurement with risk of drug-to-drug interactions for prescribed medications

	0227U	Drug assay, presumptive, 30 or more drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, includes sample validation. Comprehensive Screen, Aspent Health
	0328U	Drug assay, definitive, 120 or more drugs and metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), includes specimen validity and algorithmic analysis describing drug or metabolite and presence or absence of risks for a significant patient-adverse event, per date of service (CareView 360, Newstar Medical Laboratories LLC.)
HCPCS		
	G0480	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 1-7 drug class(es), including metabolite(s) if performed
	G0481	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 8-14 drug class(es), including metabolite(s) if performed
	G0482	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 15-21 drug class(es), including metabolite(s) if performed

	G0483	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 22 or more drug class(es), including metabolite(s) if performed
	G0659	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes
	P2031	Hair analysis (excluding arsenic)
Type of Service	Laboratory	
Place of Service	Outpatient	

POLICY HISTORY

Date	Action	Action
December 2025	Annual Review	Policy Renewed
December 2024	Annual Review	Policy Renewed
April 2024	Interim Review	Policy Revised
December 2023	Annual Review	Policy Revised
August 2023	Interim Review	Policy Revised
October 2022	Annual Review	Policy Renewed
October 2021	Annual Review	Policy Revised

October 2020	Annual Review	Policy Revised
November 2019	Annual Review	Policy Revised
October 2018	Annual Review	Policy Revised
October 2017	Annual Review	Policy Renewed
October 2016	Annual Review	Policy Revised
October 2015	Annual Review	Policy Renewed
November 2014		New Medical Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
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