Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 5/1/22**
(See policy history boxes for previous effective dates)

Title: Drug Testing in Pain Management and Substance Use Disorder Treatment

Description/Background

SUBSTANCE USE DISORDER

The *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition (DSM-5), no longer uses the terms substance abuse and substance dependence, rather it refers to "substance use disorders", characterized as mild, moderate or severe to indicate the level of severity, based on the number of diagnostic criteria met by an individual. Substance use disorder is defined as the recurrent use of alcohol and/or drugs that causes clinically and functionally significant physical or mental impairment, disability, and/or failure to meet major responsibilities at work, school or home. According to the DSM-5, a diagnosis of substance use disorder is made when there is evidence of impaired control, social impairment, risky use and pharmacological criteria.[1]

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

PAIN MANAGEMENT

According to a 2012 evidence assessment by the American Society of Interventional Pain Physicians, approximately one-third of chronic pain patients do not use opioids as prescribed or may abuse them.[2] In 2016, the International Narcotics Control Board 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.[3] Additionally, studies have found that a substantial proportion of chronic pain patients inaccurately report nonadherence to prescribed medications and the use of illicit drugs.[4]

A discussion of the controversies related to opioid therapy for the treatment of chronic noncancer 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 Blue Cross Blue Shield Association Special report 'Opioids for Management of Chronic Noncancer Pain'.

Monitoring Strategies

Various strategies are available to monitor pain management and substance use disorder treatment 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 (eg, taking medication as prescribed) and not engage in (eg, 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 testing is readily available and there are standardized techniques for detecting drugs in urine. Other biologic specimens (eg, 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 two primary categories of UDT: presumptive (immunoassay, qualitative testing or screening) and definitive (specific drug identification, quantitative testing or confirmatory).

Presumptive (Immunoassay, Qualitative testing, Screening) Testing

Presumptive testing can be performed in a laboratory or at point-of-service (physician's office). 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 (ie, 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 one to four hours for laboratory-based tests.[5]

Definitive (Specific Drug Identification, Quantitative testing, Confirmatory) Testing
Definitive 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 definitive 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.[6]

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 (eg, 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.[7]

Oral Fluid Drug Testing

Oral fluid (liquid samples obtained from the oral cavity) can be used to test for drug use. Oral fluid contains secretions from several different sources, including secretions from the three 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 (eg, 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 US, 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 (eg, 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 µL). 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 (ie, within the past seven days) cannot be detected; difficulty in detecting very light drug use (eg, 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 (eg, pre-employment screening, post-drug-treatment verification of relapse).

General Testing Guidelines

Clinicians order drug tests based on the clinical scenario of the individual and the purpose for the testing. National provider organizations have discouraged establishing limits on the frequency of testing and the number of tests allowed in a benefit year, out of concern that such limits will potentially undermine physician management and be a barrier to medically necessary testing. Most guidelines suggest that testing in the initial phase of substance use disorder treatment is performed weekly. As the individual's circumstances stabilize, testing may progress to monthly and then less frequently. Based on plan data, it is extremely unlikely that an individual would require more than a combined total of 25 presumptive and definitive tests in a year.

Presumptive Test Guidelines

Prior to ordering a presumptive drug test, the following must be met:

- An adequate clinical assessment, including patient history and risk of substance use disorder, is performed;
- Clinician ordering the test has knowledge of test interpretation;
- There is a plan regarding how the test findings will be used.

In pain management, risk level assessment should include a global assessment of risk factors (using a standardized risk tool, such as the Opioid Risk Tool, etc.) and monitoring for the presence of aberrant behavior.

Definitive Test Guidelines

A definitive drug test is medically necessary and clinically justified when the results of *presumptive* testing have been evaluated and support that follow-up *definitive* testing will contribute to clinical decision making. Routine definitive drug testing that is ordered automatically, independent of an analysis of presumptive testing, is not medically necessary. A definitive drug test that is performed without consideration of a patient's specific circumstances is not medically necessary. The medical record should support the rationale for testing; and, this record may be assessed as part of a retrospective review (audit).

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 US. 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 in intended solely for use in employment and insurance testing. The FDA review does not included test systems intended for federal drug testing programs (eg, programs by the Substance Abuse and Mental Health Services Administration, the Department of Transportation and the US 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 510(k) regulatory pathways. Several collection devices are commercially available in the US, and they generally involve collection on an absorbent material, such as foam pads; pads are then placed in a container with a stabilizing buffer solution. Immunoassays of urine specimens have previously been cleared by the FDA and are used as the predicates for the oral fluid immunoassays.

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. Testing with GC/MS and some immunoassays are performed in laboratory settings. Laboratories that offer laboratory-developed tests must be licensed by CLIA for high-complexity testing.

Medical Policy Statement

Presumptive and definitive drug testing in the outpatient setting may be considered established when criteria is met.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

This policy addresses drug testing in an outpatient setting.
The policy does <u>not</u> apply to drug testing in emergency department, acute inpatient medical or behavioral health facility settings, or testing ordered by or on behalf of a provider or facility that receives per-diem reimbursement which includes clinical diagnostic laboratory testing (skilled nursing facility).

<u>Inclusions</u>:

A. PRESUMPTIVE DRUG TESTING
- For **outpatient pain management**, presumptive drug testing is considered established in:
  - Baseline screening at the initiation of treatment;
  - Subsequent monitoring of treatment at an appropriate frequency based on the risk level of the individual, including assessment of aberrant behavior.

- For **outpatient substance use disorder treatment**, presumptive drug testing is considered established in:
  - Baseline screening at the initiation of treatment;
  - Subsequent screening is based on the risk level of the individual and the substance being used .

- For an individual not participating in outpatient pain management or outpatient substance use disorder treatment:
  - When a clinical evaluation suggests use of non-prescribed medications, illegal or other substances.

B. DEFINITIVE / CONFIRMATORY DRUG TESTING
- Definitive drug testing is considered established:
  - When immunoassays for the relevant drug(s) are not commercially available;
  - In situations where definitive drug levels are required for clinical decision making (eg, unexpected positive test that is inadequately explained by the patient, unexpected negative test, quantitative levels are needed to determine clinical treatment, etc.)

Exclusions:
- Drug testing as a third-party requirement (eg, for employment, licensing, court order, etc.)
- Simultaneously testing for the same drug with two specimens from different sources (eg, blood AND urine)

Policy Guidelines

One presumptive and one definitive test code may be billed per date of service.

Billing Guidelines - Definitive Drug Testing
Bill G0480-G0483, G0659 as appropriate, for the number of drug classes tested.

Bill 80XXX and 83992 to report the appropriate drug or metabolite testing. The codes are no longer individually reimbursed for the purpose of this policy; however, we request that they are reported with the appropriate G code.

Contracted Laboratories
Providers should select contracted laboratories for the processing of drug tests. Referring a member to a non-participating laboratory may result in unnecessary services (such as processing tests not originally ordered) and greater financial liability for the member. The referring provider may be held accountable for any inappropriate behavior on the part of the non-participating laboratory.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

80305	80306	80307		
G0480	G0481	G0482	G0483	G0659

Other codes (investigational, not medically necessary, etc.):

80320-80377	83992

Proprietary tests, represented by Proprietary Laboratory Analyses (PLA) codes, are not separately payable. The laboratory should bill the appropriate representative CPT code.

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

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.[7,8]

Notwithstanding the lack of evidence, clinical input and guidelines indicate that drug testing is standard of care.

SUMMARY OF EVIDENCE

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

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

SUPPLEMENTAL INFORMATION

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

In response to requests from Blue Cross Blue Shield Association in 2014, input was received from 5 physician specialty societies and 8 academic medical centers. There was near-consensus among reviewers that, in outpatient pain management, presumptive (ie, qualitative) 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 four 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 (ie, quantitative) drug testing and particularly on whether definitive drug testing should only be performed on a drug-specific basis.

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.[9] 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 published consensus recommendations on urine drug monitoring in patients receiving opioid for chronic pain.[10] The Society recommended definitive testing at baseline for patients prescribed opioids for chronic pain unless presumptive testing is required by institutional or payer policy. The Society 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

The American Society of Interventional Pain Physicians (2017) issued guidelines for responsible, safe, and effective opioid prescribing for chronic non-cancer pain.[11] The guidelines included the following recommendations on UDT (Table 1).

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

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

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

Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (2016) published guidelines on opioids for chronic pain.[12] The guidelines included the following recommendation on UDT: “When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.”

Department of Veterans Affairs and Department of Defense

The Department of Veterans Affairs and Department of Defense (2017) updated clinical practice guidelines for managing opioid therapy for the treatment of chronic pain.[7] The recommendations on risk mitigation to prescribed opioids include obtaining a urine drug test (with patient consent) before initiating opioid therapy, and then randomly at a follow-up to confirm appropriate use. Other strategies recommended include clinical assessment such as random pill counts and used 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, "a provider can factor that declination into their thinking about whether it is safe to continue with opioid therapy for that patient, which is ultimately required if long-term opioid therapy is to be instituted/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.[13] The guidelines included recommendations on UDT. Recommendations on testing frequency differed depending on the patient risk of opioid addiction and opioid dosage, as listed below:

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

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

Substance Use Disorder Treatment

American Society of Addiction Medicine
The American Society of Addiction Medicine (ASAM) has published several documents on drug testing: a public policy statement (2010),[14] a white paper (2013), which provided background on the science and current practices of drug testing,[15] and guidelines (2017) on the effective use of drug testing.[8,16]

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."[14] 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."[15] The paper acknowledged that more specific guidance on drug testing was needed, which led to the development of the 2017 guidelines.

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 summarize the characteristics of urine, oral fluid and hair drug tests than may inform the decision of what type of drug test to use.[8]

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) (8)

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

Government Regulations

National:

There is no NCD on this topic.

Local:

Wisconsin Physicians Service Insurance Corporation
Local Coverage Determination: Drug Testing L34645
Original Effective Date: For services performed on or after 10/01/2015
Revision Effective Date: For services performed on or after 10/01/2021

Coverage Indications, Limitations, and/or Medical Necessity

A qualitative/presumptive drug screen is used to detect the presence of a drug in the body. A blood or urine sample may be used. However, urine is the best specimen for broad screening, as blood is relatively insensitive for many common drugs, including psychotropic agents, opioids, and stimulants. Common methods of drug analysis include chromatography, immunoassay, chemical ("spot") tests, and spectrometry.

Analysis is comparative, matching the properties or behavior of a substance with that of a valid reference compound (a laboratory must possess a valid reference agent for every substance that it identifies). Drugs or classes of drugs are commonly assayed by qualitative/presumptive testing. A test may be followed by confirmation with a second method, only if there is a positive or negative inconsistent finding from the qualitative/presumptive test in the setting of a symptomatic patient, as described below.

Examples of drugs or classes of drugs that are commonly assayed by qualitative/presumptive tests, followed by confirmation with a second method, are: alcohols, amphetamines, barbiturates/sedatives, benzodiazepines, cocaine and metabolites, methadone, antihistamines,

stimulants, opioid analgesics, salicylates, cardiovascular drugs, antipsychotics, cyclic antidepressants, and others. Focused drug screens, most commonly for illicit drug use, may be more useful clinically.

Indications:

A. Although technology has provided the ability to measure many toxins, most toxicological diagnoses and therapeutic decisions are made based on historical or clinical considerations:
    1. Laboratory turnaround time can often be longer than the critical intervention time course of an overdose.
    2. The cost and support of maintaining the instruments, staff training, and specialized labor involved in some analyses are prohibitive.
    3. For many toxins there are no established cutoff levels of toxicity, making interpretation of the results difficult.

    Although comprehensive screening is unlikely to affect emergency management, the results may assist the admitting physicians in evaluating the patient if the diagnosis remains unclear. Screening panels should be used when the results will alter patient management or disposition.

B. A qualitative/presumptive drug test may be indicated for a variety of reasons including the following:
    1. A symptomatic patient when the history is unreliable, when there has been a suspected multiple-drug ingestion, to determine the cause of delirium or coma, or for the identification of specific drugs that may indicate when antagonists may be used.
    2. For monitoring patient compliance during active treatment for substance abuse or dependence.
    3. To monitor for compliance/adherence to the treatment plan or illicit drug use in patients under treatment or seeking treatment for a chronic pain condition. The clinical utility of drug tests in the emergency setting may be limited because patient management decisions are unaffected, since most therapy for drug poisonings is symptom directed and supportive.

C. Medicare will consider performance of a qualitative/presumptive drug test reasonable and necessary when a patient presents with suspected drug overdose and one or more of the following conditions:
    1. Unexplained coma
    2. Unexplained altered mental status in the absence of a clinically defined toxic syndrome or toxidrome
    3. Severe or unexplained cardiovascular instability (cardiotoxicity)
    4. Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome
    5. Testing on neonates suspected of prenatal drug exposure
    6. Seizures with an undetermined history

D. Medicare will consider performance of a qualitative/presumptive drug test reasonable and necessary when a patient presents with one or more of the following conditions:

1. For monitoring patient compliance during active treatment for substance abuse or dependence.
2. A drug screen is considered medically reasonable and necessary in patients on chronic opioid therapy:
   - In whom illicit drug use, non-compliance or a significant pre-test probability of non-adherence to the prescribed drug regimen is suspected and documented in the medical record; and/or
   - In those who are at high risk for medication abuse due to psychiatric issues, who have engaged in aberrant drug-related behaviors, or who have a history of substance abuse.
3. Medicare will consider performance of a drug test reasonable and necessary in patients with chronic pain to:
   - determine the presence of other substances prior to initiating pharmacologic treatment
   - detect the presence of illicit drugs
   - monitor adherence to the plan of care

Drugs, or drug classes for which testing is performed, should reflect only those likely to be present, based on the patient's medical history, current clinical presentation, and illicit drugs that are in common use. Drugs for which specimens are being tested must be indicated by the referring provider in a written order.

A drug test may be reasonable and necessary for patients with known substance abuse or dependence, only when the clinical presentation has changed unexpectedly and one of the above indications is met.

A drug test may be reasonable and necessary for patients with symptoms of schizophrenia suspected to be secondary to drug or substance intoxication.

Definitive drug testing is indicated when:
1. The results of the screen are presumptively positive.
2. Results of the screen are negative and this negative finding is inconsistent with the patient's medical history.
3. This test may also be used, when the coverage criteria of the policy are met AND there is no presumptive test available, locally and/or commercially, as may be the case for certain synthetic or semi-synthetic opioids.

A positive screen often results in an inadequate result upon which to make a proper determination. A more specific method, such as gas or liquid chromatography coupled with mass spectrometry, may be needed in order to obtain a confirmed analytical result. In particular, screens are frequently inadequate for interpretation of opiate and benzodiazepine results and therefore; quantitative testing may be needed in these instances. Confirmation testing is usually not required for drugs like methadone, wherein false positive results are rare. However, factors such as cross-reactivity with other similar compounds or interfering substances in the specimen may affect test results. Confirmatory testing eliminates the risk of false positives. Also, eliminated by confirmation, is the risk of a “pill scraper” slipping through. Patients diverting their drug, attempt to cheat the test by scraping a bit of drug from a pill into their urine sample. It would screen positive, but there would be no metabolite upon

confirmation. Frequent use of this code will be monitored for appropriateness.

Limitations:
It is considered not reasonable or necessary to test for the same drug with both a blood and a urine specimen simultaneously.

Drug screening for medico-legal purposes (e.g., court-ordered drug screening) or for employment purposes (e.g., as a pre-requisite for employment or as a requirement for continuation of employment) are not covered.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

NA

References

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 12/29/21, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/19	5/1/19		Joint policy established
3/1/20	12/17/19		Routine maintenance, removal of “urine” from “drug tests”, removal of E/I statement. Policy updated based on BCBSA updates. Title changed to: Drug Testing in Pain Management and Substance Use Disorder Treatment.
3/1/21	12/15/20		Routine maintenance. Ref 10 added
5/1/21	2/16/21		Routine maintenance.
5/1/22	2/15/22		Routine maintenance

Next Review Date: 1st Qtr, 2023

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: DRUG TESTING IN PAIN MANAGEMENT AND SUBSTANCE USE DISORDER TREATMENT

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, medical policy criteria apply.
BCNA (Medicare Advantage)	See Government Regulations Section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.