Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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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 individuals do not use opioids as prescribed or may abuse them.[2] 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.[3] 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 those age 65 and over (6.9 per 100,000)[4]. In the United States, drug overdose deaths increased approximately 15% from 2020 to 2021.[5] Additionally, studies have found that a substantial proportion of chronic pain

individuals inaccurately report nonadherence to prescribed medications and the use of illicit drugs.[6]

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 s' 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.[7]

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.[8]

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.[8]

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 are met.

Inclusionary and Exclusionary Guidelines

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.
  - When testing for drug or alcohol exposure during pregnancy.
  - To rule out a fetal withdrawal syndrome by testing the mother for drug use.

B. DEFINITIVE / CONFIRMATORY DRUG TESTING
- Definitive drug testing is considered established:
  - When immunoassays for the relevant drug(s) are not commercially available; **OR**
  - 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

**** When ordering 8 or more drug tests (G0481, G0482, G0483), clinical documentation will be requested for review and verification of medical necessity.***

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 individuals with substance use disorder is limited and usually confounded with drug testing as part of a multifaceted intervention of risk mitigation or contingency management There is also no clear evidence in the literature regarding the most effective frequency of testing.[9,10]

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 out 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.[11] 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.[12] 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 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 s 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.[13] 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.[14] 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, in 2022.[15] 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 (eg, 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

The Department of Veterans Affairs and Department of Defense (2022) updated clinical practice guidelines for managing opioid therapy for the treatment of chronic pain.[9] 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, "providers should factor that declination into their consideration about whether it is safe to continue opioids. Urine drug testing is required if long-term opioids are to be initiated or continued.

Washington State Agency Medical Directors' Group

In 2015, the Washington State Agency Medical Directors' Group updated its interagency guidelines on opioid dosing for chronic non-cancer pain.[15] The guidelines included recommendations on UDT. Recommendations on testing frequency differed depending on the patient risk of opioid addiction and opioid dosage, as listed below:

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

In 2020, Washington State Agency Medical Directors' Group released a guideline on long-term opioid therapy prescribing. Use of UDT was mentioned as an element of assessment of patients on long-term opioid therapy[14]. 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),[17] a white paper (2013), which provided background on the science and current practices of drug testing,[18] and guidelines (2017) on the effective use of drug testing.[10,19]

The ASAM's public policy statement asserts that: "Urine drug testing is a key diagnostic and therapeutic tool that is useful for care and in monitoring of the ongoing status of a person who has been treated for addiction. As such, it is a part of medical care, and should not face undue restrictions."[17] The ASAM recommended drug testing where medically appropriate in clinical diagnostic settings and clinical treatment settings. The term "drug testing" in this document was a broad term that included urine or other body fluids or tissues.

The ASAM White Paper concluded that "The most important challenge in drug testing today is not the identification of every drug that we are technologically capable of detecting, but to do medically necessary and accurate testing for those drugs that are most likely to impact clinical outcomes."[19] 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.[10]

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]"[20].

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 11/12/2023

Urine drug testing (UDT) provides timely, objective, and actionable information to clinicians by identifying the presence or absence of drugs of potential abuse in the body to assist the clinician in making treatment decisions.[1]

This policy details:

- The appropriate indications and allowed number of UDTs billed over time for safe medication management of prescribed substances in risk stratified pain management patients and/or in identifying and treating substance use disorders (SUDs);
- Designates documentation, by the clinician caring for the beneficiary in the beneficiary's medical record, of medical necessity for, and testing ordered on an individual patient basis;
- Provides an overview of presumptive UDT and definitive UDT testing by various methodologies.

This policy addresses UDT for Medicare patients only.

Definitions

As used in this document, the following terminology relates to the basic forms of UDT:

1. **Presumptive/Qualitative Drug Testing** (hereafter called "presumptive" UDT) - Covered when medically necessary to immediately determine the presence or absence of drugs or drug classes in a urine sample; results expressed as negative or positive or as a numerical result; includes competitive immunoassays (IA) and thin layer chromatography.[2]
2. **Definitive/Quantitative/Confirmation** (hereafter called "definitive" UDT) - Covered when clinically indicated and medically reasonable and necessary based on this LCD to identify specific medications, illicit substances, and metabolites; reports the results of analytes absent or present typically in concentrations such as ng/mL; definitive methods include but are not limited to GC-MS and LC-MS/MS testing methods only.[2]
3. **Specimen Validity Testing** - Urine specimen testing to ensure that it is consistent with normal human urine and has not been adulterated or substituted, may include, but is not limited to pH, specific gravity, oxidants, and creatinine. This however is quality assurance, not a Medicare benefit, and thus not separately payable by Medicare.
4. **Immunoassay (IA)** - Ordered by clinicians primarily to identify the presence or absence of drug classes and some specific drugs; biochemical tests that measure the presence above a cutoff level of a substance (drug) with the use of an antibody; read by photometric technology.[2]
5. **Point of Care Testing (POCT)** - Covered when medically necessary by clinicians caring for the beneficiary for immediate test results for the immediate management of the beneficiary; available when the beneficiary and physician are in the same location; IA test method that primarily identifies drug classes and a few specific drugs; platform consists of cups, dipsticks, cassettes, or strips; read by the human eye, or read by instrument assisted direct optical observation.[3]
6. **Standing Orders** - Test request for a specific patient representing repetitive testing to monitor a condition or disease for a limited number of sequential visits; individualized orders for certain patients for pre-determined tests based on historical use, risk, and community trend patient profiles; clinician can alter the standing order. Note: A profile is developed based on specific characteristics of a specific patient, while a panel is a general non-specific group of tests that may have unnecessary tests for the specific patient being treated.
7. **Blanket Orders** - Test request that is not for a specific patient; rather, it is an identical order for all patients in a clinician's practice without individualized decision making at every visit.
8. **Reflex Testing** - Laboratory testing that is performed "reflexively" after initial test results to identify further diagnostic information essential to patient care. This testing is not necessarily based on a specific physician's order.

Drug Testing Methods

The Clinical Laboratory Improvement Amendments (CLIA) regulates laboratory testing and requires clinical labs to be certified by their State as well as the Center for Medicare & Medicaid Services (CMS) before they can accept human samples for diagnostic testing.[3] Multiple types of CLIA certificates may be obtained based on the complexity of testing a lab conducts. CLIA levels of complexity (CLIA-waived, moderate complexity, and high complexity) are addressed only as they correspond to the Healthcare Common Procedure Coding System (HCPCS) code description in the related billing and coding article.

A. **Presumptive Testing Methods**

1. **Presumptive UDT:**

A presumptive UDT that consists of various platforms including cards, dipsticks, cassettes, and cups based on qualitative competitive immunoassay methodology with one or more analytes in the test. A presumptive IA test detects the presence of the amount of drug/substance present in urine above a predetermined “cut-off” value and may be read by direct optical observation or by instrument assisted direct optical observation.

A positive test result is reported when the concentration of drug is above the cutoff; a negative is reported when the concentration of drug is below the cut-off. Positive test results are presumptive but not necessarily definitive due to sensitivity and cross-reactivity limitations.[4] Negative test results do not necessarily indicate the absence of a drug or substance in the urine specimen.[3] The accuracy of the results of a presumptive UDT will depend on the testing environment, type of test, the drug being tested for, and training of the individual conducting the test. This type of test should only be used when results are needed immediately.

2. **Presumptive UDT by Instrumented Chemistry Analyzers:**

Chemistry analyzers with IA UDT technology can be used in an office or clinical laboratory setting. This test provides less immediate test results. At no time is IA technology by chemistry analyzer analysis considered confirmatory (definitive) testing.

A presumptive positive IA test detects the presence of a drug/substance in urine at or above the “cut-off” value. If the concentration of the drug is below the cut-off, the result will be negative. Presumptive positive tests are not always true positives due to sensitivity, specificity, and cross-reactivity limitations. Negative test results do not necessarily indicate the absence of a drug or substance in the urine specimen.[3]

Food and Drug Administration (FDA) approved/cleared test platforms are available in the marketplace as well as laboratory developed tests (LDTs) such as modified FDA approved/ cleared and non-FDA approved/cleared platforms and/or reagents. LDTs generally have been modified to test at a lower cutoff in order to detect substances that would have been missed at a higher cutoff. For example, an FDA labeled cutoff may be 300 ng/mL and the LDT cutoff for the same drug may be 100 ng/mL.[3]

Presumptive UDT can be carried out at any validated cut-off concentration. Lowering of the cut-off concentration provides more stringent cutoffs for illicit drugs. LDTs may include non-FDA cleared tests not available in CLIA-waived or moderate complexity tests (e.g., tramadol,

tapentadol, carisoprodol, fentanyl, zolpidem). Lowering the cutoff increases the possibility of detecting a drug when the test has been modified from the recipe of the manufacturer.

3. **Limitations of Presumptive UDT:**

Presumptive UDT testing is limited due to:

- Primarily screens for drug classes rather than specific drugs, and therefore, the practitioner may not be able to determine if a different drug within the same class is causing the positive result;
- Produces erroneous results due to cross-reactivity with other compounds or does not detect all drugs within a drug class;[5]
- Given that not all prescription medications or synthetic/analog drugs are detectable and/or have assays available, it is unclear as to whether other drugs are present when some tests are reported as positive;
- Cut-off may be too high to detect presence of a drug.[5]

These limitations may mean that presumptive testing is insufficient for certain clinical needs. An IA involves an antibody that reacts best with the stimulating drug and reacts to a lesser extent (cross-reactive) or not at all with other drugs in the drug class. While presumptive tests vary in their ability to detect illicit drugs such as tetrahydrocannabinol (THC), cocaine, 3,4-methylenedioxy-N-methylamphetamine (MDMA; “ecstasy”), and phencyclidine (PCP), they may not be optimal tests for many prescription drugs, such as: opiates, barbiturates, benzodiazepines, and opioids.

For example, opiate reagents are formulated from morphine. Consequently, the cross-reactivity for other opioids and opiates varies based on the manufacturer and lot number. The semisynthetic opioids, hydromorphone and hydrocodone, may contribute to a positive presumptive result, while the semisynthetic opioids, oxycodone and oxymorphone, will not typically be detected even at a 300 ng/mL cutoff. Synthetic opioids, such as fentanyl, meperidine, and methadone, will not be detected by current opiate IA testing. Consequently, a positive opiate result by IA normally necessitates more specific identification of the substance(s) that account for the positive result, and a negative result does not rule out the presence of opiates or opioids.[6]

Presumptive UDT reagents for benzodiazepine are typically formulated for oxazepam, a metabolite of diazepam (Valium®) and chlordiazepoxide (Librium®), the main benzodiazepines prescribed 20 years ago. However, many of the more than 10 benzodiazepines that are currently available do not cross-react with IA benzodiazepine reagents. In particular, clonazepam and lorazepam give false negative results with presumptive IA tests and may necessitate more specific identification to account for the negative result. Similarly, a positive screening test result may require definitive UDT to identify the specific drug(s).

Synthetic/analog or “designer” drugs manufactured to elude law enforcement require definitive testing for detection. Most commercially available IA reagents fail to detect designer drugs such as psychedelic phenethylamines even at very high concentrations.
In summary, presumptive IA UDT is often unable to identify specific drugs within many drug classes, particularly within the amphetamine, barbiturate, benzodiazepine, tricyclic antidepressants, and opiate/opioid drug classes. Drugs such as buprenorphine, amphetamines, benzodiazepines, and cocaine/heroin may yield false negative IA results due to low cross-reactivity or non-reactivity, and drugs such as fentanyl, carisoprodol, tramadol, tapentadol, and synthetic designer drugs cannot be detected by presumptive IA. Therefore, it

may be medically necessary for clinicians to utilize definitive UDT when the presumptive tests for these drugs are negative.[1,5]

B. **Definitive UDT:**

Gas Chromatography coupled with Mass Spectrometry (GC-MS) and Liquid Chromatography coupled with Mass Spectrometry (LC-MS/MS) are complex technologies that use the separation capabilities of gaseous or liquid chromatography with the analytical capabilities of mass spectrometry. These methodologies require the competency of on-site highly trained experts in this technology and interpretation of results. While these tests require different sample preparation and analytical runs, they identify specific drugs, metabolites, and most illicit substances and report the results as absent or present typically in concentrations of ng/mL.[2]

Quantification should not be used to determine adherence with a specific dosage or time of dose of a pain medication or illicit drug for clinical purposes. Rather, the use of quantitative drug data may be important for many reasons such as in a differential patient assessment.[1] For example, when several opioids are present in the urine of a patient prescribed a single opioid, quantification may help the clinician decide whether the presence of the other opioids is consistent with metabolism of the prescribed opioid, opioid contamination during manufacturing, or if more than 1 drug within a class is being used.

Quantification may also provide information in the setting of illicit drug use. Serial creatinine-corrected quantitative values may assist in the differential assessment of ongoing drug use or cessation of drug use with continued drug excretion.[1]

1. GC-MS
   GC-MS can only be performed on molecules that are volatile. If the test drug is not volatile in its own right, it must be modified or derivatized to a volatile form. To derivatize, the test drug must be extracted from the urine, eluted from the extraction device, concentrated, and then reacted with a chemical reagent to make a volatile product. Each drug class may require a different derivatizing agent. For patients on multiple classes of medications, laboratories using GC procedures must make different volatile derivatives in order to perform comprehensive testing. Since a GC column may not be able to separate more than one class of compounds, multiple chromatographic runs on different column types may be required to monitor multiple drug classes[1]. Newer GC-MS instruments often use tandem systems. GC-MS methodology allows for the testing of multiple substances but differs in ease of run.
2. LC-MS/MS
   LC-MS/MS is roughly 100 times more sensitive and selective, involves fewer human steps, provides quicker turn-around time, uses less specimen volume, and can test for a larger number of substances simultaneously when compared to GC-MS.[1] After sample preparation, it is injected into the LC-MS/MS. The sample has to undergo hydrolysis to break the glucuronide bond that frees the drug and drug metabolites. Hydrolysis is followed by multiple additional steps including protein precipitation, centrifugation, and purification. Deuterium-labeled isotopic internal standards are added to quantify the drugs and drug metabolites.

The sample is injected when the mobile phase is flowing through the chromatographic column. Each drug and drug metabolite interacts with the mobile phase and stationary phase differently and moves at different speeds depending on their chemical properties. In other words, each analyte elutes at different times. Specific drugs and metabolites are identified by their retention

time and quantified against isotopic internal standards for each drug and metabolite. Each drug peak has a minimum of 2 mass transmissions to be compared to drug standards (calibrators) to ensure identification.

CLIA-Certified Laboratories-Informational only

CLIA specifies quality standards for proficiency testing, facility administration, general laboratory systems, pre-analytic, analytic, and post-analytic systems, onsite supervision requirements, personnel qualifications and responsibilities, quality control, and quality assessment.[3]

High complexity laboratories must ensure that testing is carried out by onsite qualified, trained personnel using validated reliable methods compliant with regulatory procedures (42 CFR Part 493). Both GC-MS and LC-MS/MS require a quality program to monitor the quality and audit the competency of the staff. LC-MS/MS instrument maintenance must be performed daily as well as the validation of instrument performance prior to patient specimens. Final review and approval of GC-MS and LC-MS/MS results must be performed by a qualified clinical laboratory scientist as defined in 42 CFR Part 493.1489 (Testing Personnel Qualifications). A GC-MS or LC-MS/MS laboratory must have a qualified laboratory director, qualified physician, or qualified clinical laboratory scientist, as provided in 42 CFR 493.1443 (Laboratory Director Qualifications).

Purpose of UDT:

Presumptive UDT may be ordered by the clinician caring for a beneficiary when it is necessary to rapidly obtain and/or integrate results into clinical assessment and treatment decisions.

Definitive UDT is considered reasonable and necessary when the clinical information supplied supports the definitive testing as in:

- Identify a specific substance or metabolite that is inadequately detected by a presumptive UDT screen;
- Definitively identify specific drugs in a large family of drugs;
- Identify a specific substance or metabolite that is not detected by presumptive UDT such as fentanyl, meperidine, synthetic cannabinoids, and other synthetic/analog drugs;
- Identify drugs when a definitive concentration of a drug is needed to guide management (e.g., discontinuation of THC use according to a treatment plan);
- Identify a negative, or confirm a positive, presumptive UDT result that is inconsistent with a patient's self-report, presentation, medical history, or current prescribed pain medication plan;
- Rule out an error as the cause of a presumptive UDT result;
- Identify non-prescribed medication or illicit use for ongoing safe prescribing of controlled substances; and
- Use in a differential assessment of medication efficacy, side effects, or drug-drug interactions.

Definitive UDT may be reasonable and necessary based on patient specific indications, including historical use, medication response, and clinical assessment, when accurate results are necessary to make clinical decisions.[1] **To establish that a test is reasonable and necessary, the clinician's rationale for the definitive UDT and the tests ordered must be documented in the patient's medical record.**

Drug Testing Panels

A. Presumptive UDT Panels
   Presumptive UDT typically involves testing for multiple analytes based on the specific beneficiary's clinical history and risk assessment and must be documented in the medical record. May be ordered as a panel and billed a "Per Patient encounter" regardless of the number of analytes tested.
B. Definitive UDT Panels
   Physician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient **based upon historical use, clinical findings, and community trends**. However, the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice. **Definitive UDT orders should be individualized based on clinical history and risk assessment and must be documented in the medical record.**

Specimen Type

Urine or oral fluid is the preferred biologic specimen for testing because of the ease of collection, storage, and cost-effectiveness.[1] UDT cannot detect the dosage of drug ingested/used, the time of use, or the means of delivery (intravenous vs. oral vs. inhaled). Detection time of a substance in urine is typically 1-3 days depending on the drug, rate of metabolism, and rate of excretion. Lipid-soluble drugs, such as marijuana, may remain in body fat and be detected upwards of a week or more.

Ethanol is not discussed in this LCD:

Note: Ethanol is a known drug of abuse but is routinely tested in blood, not urine. In addition, the DEA Resource Guide[7] states that alcohol is exempt from control by the Controlled Substances Act (CSA).

Covered Indications for UDT

Group A – Symptomatic patients, Multiple drug ingestion, and/or Patients with unreliable history

A patient who presents in a variety of medical settings with signs or symptoms of substance use toxicity will be treated presumptively to stabilize the patient while awaiting presumptive, then definitive testing to determine the cause(s) of the presentation. The need for definitive UDT is based upon presumptive test findings, responses to medical interventions, and treatment plan.[1] A presumptive UDT should be performed as part of the evaluation and management of a patient who presents in an emergency room or urgent care setting with any 1 of the following:

- Coma;
- Altered mental status in the absence of a clinically defined toxic syndrome or toxidrome;
- Severe or unexplained cardiovascular instability (cardiotoxicity);
- Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome;
- Seizures with an undetermined history;
- To provide antagonist to specific drug.

The presumptive findings, definitive drug tests ordered, and reasons for the testing must be documented in the patient's medical record.

Group B - Diagnosis and treatment for substance abuse or dependence

A patient in active treatment for a SUD or monitoring across different phases of recovery may undergo medical management for a variety of medical conditions. A physician who is writing prescriptions for medications to treat either the SUD or other conditions may need to know if the patient is taking substances which can interact with prescribed medications or taking prescribed medications as expected.[1] The risk of drug-drug interactions is inherent to the patient and may be compounded by prescribed medications. UDT is a medically necessary and useful component of chemical dependency diagnosis and treatment. The UDT result influences treatment and level of care decisions.[3] Ordered tests and testing methods (presumptive and/or definitive) must match the stage of screening, treatment, or recovery; the documented history; and Diagnostic and Statistical Manual of Mental Disorders (DSM V) diagnosis. For patients with no known indicators of risk for SUD, the clinician may screen for a broad range of commonly abused drugs using presumptive UDT. For patients with known indicators of risk for SUD, the clinician may screen for a broad range of commonly abused drugs using definitive UDT. For patients with a diagnosed SUD, the clinician should perform random UDT at random intervals to properly monitor the patient3. Testing profiles must be determined by the clinician based on the following medical necessity guidance criteria:

- Patient history, physical examination, and previous laboratory findings;
- Stage of treatment or recovery;
- Suspected abused substance;
- Substances that may present high risk for additive or synergistic interactions with prescribed medication (e.g., benzodiazepines, alcohol).

The patient's medical record **must include an appropriate number of UDTs billed over time based on the stage of screening, treatment, or recovery;**[8] **and the rationale for the drugs/drug classes ordered; the results must be documented in the medical record and used to direct care.**[3]

1. **Maximum Number of Allowed Presumptive UDTs for SUD**

The number of UDTs billed over time must meet medical necessity and be documented in the patient's medical record.[8]

a. For patients with **0 to 30 consecutive days of abstinence**, presumptive UDT is not to exceed 3 presumptive UDTs in a rolling 7 days. More than 3 presumptive UDTs in a rolling 7 days is not reasonable and necessary and is not covered by Medicare.
b. For patients with **31 to 90 consecutive days of abstinence**, presumptive UDT is not to exceed 3 presumptive UDTs in a rolling 7 days. More than 3 presumptive UDTs in a rolling 7 days is not reasonable and necessary and is not covered by Medicare.
c. For patients with > **90 consecutive days of abstinence**, presumptive UDT is not to exceed 3 presumptive UDTs in a rolling 30 days. More than 3 presumptive UDTs in a rolling 30 days is not reasonable and necessary and is not covered by Medicare.

2. **Maximum Number of Allowed Definitive UDTs for SUD**

Depending on the patient's specific substance use history, definitive UDT to accurately determine the specific drugs in the patient's system may be necessary. Definitive testing may be ordered when accurate and reliable results are necessary to integrate treatment decisions and clinical assessment. The number of UDTs billed over time and the rationale for definitive UDT must be documented in the patient's medical record.

a. For patients with **0 to 30 consecutive days of abstinence**, definitive UDT is not to exceed 1 definitive UDT in a rolling 7 days. More than 1 definitive UDT in a rolling 7 days is not reasonable and necessary and is not covered by Medicare.
b. For patients with **31 to 90 consecutive days of abstinence**, definitive UDT is not to exceed 3 definitive UDTs in a rolling 30 days. More than 3 definitive UDTs in a rolling 30 days is not reasonable and necessary and is not covered by Medicare.
c. For patients with > **90 days of consecutive abstinence**, definitive UDT is not to exceed 3 definitive UDTs in a rolling 90 days. More than 3 definitive UDTs in a rolling 90 days is not reasonable and necessary and is not covered by Medicare.

Group C - Treatment for patients on chronic opioid/opiate therapy (COT).

A physician who is writing prescriptions for medications to treat chronic pain can manage a patient better if the physician knows whether the patient is consuming another medication or substance, which could suggest the possibility of SUD or lead to drug-drug interactions. Additionally, UDT may help the physician monitor for medication adherence, diversion, efficacy, side effects, and patient safety in general.[9] A broad cross section of the general population will develop either cancer pain syndrome or non-cancer pain which will require prolonged or chronic opioid therapy for management with normal risk of addiction inherent to the substance(s) exposed.[10]

1. **COT UDT Testing Objectives:**

a. Identifies absence of prescribed medication and potential for abuse, misuse, and diversion;
b. Identifies undisclosed substances, unsanctioned prescription medication, or illicit substances;
c. Identifies substances that contribute to adverse events or drug-drug interactions;
d. Provides objectivity to the treatment plan;[9]
e. Reinforces therapeutic compliance with the patient;
f. Provides additional documentation demonstrating compliance with patient evaluation and monitoring;[11]

g. Provides diagnostic information to help assess individual patient response to medications (e.g., metabolism, side effects, drug-drug interaction, etc.) over time for ongoing management of prescribed medications.

2. **Medical Necessity Guidance:**

Criteria to establish medical necessity for UDT must be based on patient-specific elements identified during the clinical assessment, and documented by the clinician in the patient's medical record and minimally include the following elements:[12]

a. Patient history, physical examination, and previous laboratory findings;
b. Current treatment plan;
c. Prescribed medication(s);
d. Risk assessment plan.

National pain organizations, physician societies, and the Federation of State Medical Boards[13] recommend a practical management approach to definitive UDT for COT. The number of UDTs billed over time beyond the baseline presumptive UDT must be based on individual patient needs substantiated by documentation in the patient's medical record. Recommendations for the ordering of presumptive and definitive UDT for patients on COT are as follows:

3. **COT Baseline Testing:**

Depending on the patient's specific circumstances, initial presumptive and/or definitive COT patient testing may include amphetamine/ methamphetamine, barbiturates, benzodiazepines, cocaine, methadone, oxycodone, tricyclic antidepressants, tetrahydrocannabinol, opioids, opiates, heroin, and synthetic/analog or "designer" drugs.

4. **COT Monitoring Testing:**

a. Ongoing testing may be medically reasonable and necessary based on the patient history, clinical assessment, including medication side effects or inefficacy, suspicious behaviors, self-escalation of dose, doctor-shopping, indications/symptoms of illegal drug use, evidence of diversion, or other clinician documented change in affect or behavioral pattern.[14] As part of the clinical evaluation of the patient, the provider should inquire about prescription compliance and potential issues of abuse or diversion such as lost prescriptions, early refill requests, or requests for escalating dose of medication.[14] The number of UDTs billed over time must be based on the individual's risk potential.[1] Appropriate number of UDTs billed over time based on risk is listed in the table below.[14]
b. The clinician should perform random UDT at random intervals to properly monitor a patient.[15] UDT testing does not have to be associated with an office visit.
c. Patients with specific symptoms of medication aberrant behavior or misuse may be tested in accordance with this document's guidance for monitoring patient adherence and compliance during active treatment (<90 days) for substance use or dependence.

UDT Frequency Based on Risk Assessment and Stratification*:

Testing must be based on clinician's documented medical necessity and reviewed by the clinician in the management of prescribing/renewing a controlled substance for every risk group outlined below.

Risk Group	Baseline	Frequency of Testing

Low Risk	Prior to Initiation of COT	Presumptive and definitive UDT not to exceed 2 times each in a rolling 365 days for prescribed medications, non- prescribed medications that may pose a safety risk if taken with prescribed medications, and illicit substances based on patient history, clinical presentation, and/or community usage.
Moderate Risk	Prior to Initiation of COT	Presumptive and definitive UDT not to exceed 2 times each in a rolling 180 days for prescription medications, non- prescribed medication that may pose a safety risk if taken with prescribed medications, and illicit substances, based on patient history, clinical presentation, and/or community usage.
High Risk	Prior to Initiation of COT	Presumptive and definitive UDT not to exceed 3 times each in a rolling 90 days for prescribed medications, non-prescribed medications that may pose a safety risk if mixed with prescribed and illicit substances based on patient history, clinical presentation and/or community usage.

*Note: Any additional definitive UDT beyond recommendations above must be justified by the clinician in the medical situations in which changes in prescribed medications may be needed, such as:

- Patient response to prescribed medication suddenly changes;
- Patient side effect profile changes;
- To assess for possible drug-drug interactions;
- Change in patient's medical condition;
- Patient admits to use of illicit or non-prescribed controlled substance.

Opioid Risk Tool:

The patient's risk category must be clearly defined in the medical record and is essential in determining number of UDTs billed over time and medical necessity.

This TOOL is to be used as a suggestion for defining Risk and this document is just an example and other tools accepted by the Opioid Use treating community may be used. Example, accepted by SAMHSA (Substance Abuse and Mental Health Services Administration)

The Opioid Risk Tool (ORT)[16] is a brief, self-report screening tool designed for use with adult patients in primary care settings to assess risk for opioid abuse among individuals prescribed opioids for treatment of chronic pain.[13,14] Patients categorized as high-risk are at increased likelihood of future abusive drug-related behavior.[12] The ORT can be administered and scored in less than 1 minute and has been validated in both male and female patients, but not in non-pain populations. This tool should be administered to patients upon an initial visit prior to beginning opioid therapy for pain management. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse.[13,16]

Mark each box that applies	Female	Male
Family history of substance abuse		
Alcohol		
Illegal drugs		
Rx drugs		
Personal history of substance abuse		
Alcohol		
Illegal drugs		
Rx drugs		
Age between 16-45 years		
History of preadolescent sexual abuse		
Psychological disease		
ADD, OCD, bipolar, schizophrenia		
Depression		
Scoring totals		

Other Covered Services

1. Reflex Testing by Reference Laboratories – since reference laboratories do not have access to patient-specific data, reflex testing under the following circumstances is reasonable and necessary:
    a. To verify a presumptive positive UDT using definitive methods that include but are not limited to GC-MS or LC-MS/MS before reporting the presumptive finding to the ordering clinician and without an additional order from the clinician; or
    b. To confirm the absence of prescribed medications when a negative result is obtained by presumptive UDT in the laboratory for a prescribed medication listed by the ordering clinician.
2. When medical record documentation that is individualized for a particular patient satisfies medical necessity requirements found elsewhere in this LCD (e.g., risk assessment, frequency), direct to definitive UDT without a presumptive UDT may be reasonable and necessary.
3. Definitive testing to confirm a negative presumptive UDT result, upon the order of the clinician, is reasonable and necessary in the following circumstances:
    a. The result is inconsistent with a patient's self-report, presentation, medical history, or current prescribed medication plan (should be present in the sample);
    b. Following a review of clinical findings, the clinician suspects use of a substance that is inadequately detected or not detected by a presumptive UDT; or
    c. When there is an unexpected negative presumptive UDT result, and it is clinically imperative to know if it is truly positive or negative; the medical record should state such.
4. Definitive testing to confirm a presumptive UDT positive result, upon the order of the clinician, is reasonable and necessary when the result is inconsistent with the expected result, a patient's self-report, presentation, medical history, or current prescribed medication plan.

Non-Covered Services-therefore not reasonable and necessary services

1. Blanket Orders-same orders for all patients in a health care provider's practice.
2. Reflex definitive UDT is not reasonable and necessary when presumptive testing is performed at point of care because the clinician may have sufficient information to manage the patient. If the clinician is not satisfied, he/she must determine the clinical appropriateness of and order specific subsequent definitive testing (e.g., the patient admits to using a particular drug, or the IA cut-off is set at such a point that is sufficiently low that the physician is satisfied with the presumptive test result).
3. Routine standing orders for all patients in a physician's practice are not reasonable and necessary.
4. It is not reasonable and necessary for a physician to perform presumptive POCT and order presumptive IA testing from a reference laboratory. In other words, Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers.
5. It is not reasonable and necessary for a physician to perform presumptive IA testing and order presumptive IA testing from a reference laboratory. Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers.
6. It is not reasonable and necessary for a reference laboratory to perform and bill IA presumptive UDT prior to definitive testing without a specific physician's order for the presumptive testing.
7. IA testing, regardless of whether it is qualitative or semi-quantitative (numerical), may not be used to "confirm" or definitively identify a presumptive test result obtained by cups, dipsticks, cards, cassettes, or other IA testing methods. Definitive UDT provides specific identification and/or quantification typically by GC-MS or LC-MS/MS. Semi-Quantitative is defined as a numerical estimation of the approximate concentrations.
8. Drug testing of 2 different specimen types from the same patient on the same date of service for the same drugs/metabolites/analytes.
9. UDT for medico-legal and/or employment purposes or to protect a physician from drug diversion charges.
10. Specimen validity testing including, but not limited to, pH, specific gravity, oxidants, creatinine.

Summary of Evidence

Providers should consider the prescribed medications, risk assessment, and clinical presentation when selecting which tests to order.

Analysis of Evidence (Rationale for Determination)

There are multiple validated surveys the provider can use as part of routine assessment of the individual's risk potential for abuse and diversion. These surveys typically ask the same questions that are part of the routine clinical assessment. WPS removed the validated survey requirement as this should already be part of the required clinical assessment.

Risk assessment is a widely accepted standard by expert treating entities to be used in clinical treatments and follow-up. The provider shall clearly define risk assessment as part of the reasonable and necessary criteria for UDT.

(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

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22. Wisconsin Physicians Service Insurance Corporation, Local Coverage Determination (LCD): Drug Testing (L34645), Original Effective Date 10/01/2015, Revision Effective Date 12/1/23.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 12/1/23, 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
5/1/23	3/29/23		Routine maintenance (jf) removed patients and replaced with individuals Added ref 3,14,18 Vendor Managed: Avalon With the feedback of Dr. Alexander and Dr. Lee Clinical editing. * *When ordering 8 or more drug tests (G0481, G0482, G0483), clinical documentation will be requested for review and verification of medical necessity.* 2/16/23 Received email from Dr Lee from SME's feedback to support on limit of 8 that requires medical review. Dr. John Pappas, MD (anesthesiology) from my review, practice and experience, I would opine that quantitative drug testing is patient specific, history specific and community specific. There may be times when more than 7 drug classes need to be tested (patient is on multiple medications, is a poor historian, the community has a high prevalence of illicit drug use, etc.) and times that less than 7 drug classes need to be tested (patient is not on many medications, is a good

			historian, no history or community prevalence of illicit drug use, etc.). This is similar to E and M coding where there are times that a level 2 E & M code is needed and times where a level 5 code is required. Carl Christensen MD, (addiction medicine) In that case my opinion would be that the 7 drug classes would be adequate. Also, as testing for THC continues to decrease (with legalization), that frees up one more spot to monitor for more dangerous drugs such as Kratom or Fentanyl. – Post JUMP updated inclusion section, added When testing for drug or alcohol exposure during pregnancy. – To rule out a fetal withdrawal syndrome by testing the mother for drug use. Updated Medical Policy Statement: Presumptive and definitive drug testing in the outpatient setting may be considered established when criteria are met.
5/1/24	2/20/24		Routine maintenance (jf) Vendor Managed: Avalon (aligned) LCD updated Add Ref: 5, 15

Next Review Date: 1st Qtr, 2025

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.