2.04.98 Drug Testing in Pain Management and Substance Use Disorder Treatment			
Original Policy Date:	April 15, 2015	**Effective Date:**	January 1, 2022
Section:	2.0 Medicine	**Page:**	Page 1 of 22

Policy Statement

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

I. Baseline screening before initiating treatment or at the time treatment is initiated (i.e., induction phase), when **all** of the following conditions are met:
   A. An adequate clinical assessment of patient history and risk of substance use disorder is performed and documented
   B. There is a documented plan in place regarding how to use test findings clinically
   C. Drug testing is ordered by a clinician during an office visit (this policy does not apply to the inpatient or emergency department settings)

Note: Urine or oral fluids (saliva) are the preferred sources for testing. The use of other matrices such as breath, blood or hair for testing may only be considered **medically necessary** when urine or saliva testing is not possible or reasonable (see Policy Guidelines section) as documented in the medical record.

I. Stabilization, maintenance or monitoring phase when either of the following conditions are met:
   A. Using an appropriate test, matrix, and frequency of testing for the risk level of the individual and the substance(s) being used (see Policy Guidelines section)
   B. Documentation in the medical record explains **all** of the following (see Policy Guidelines section):
      1. Rationale for the specific test(s) ordered
      2. Patient's history of substance use
      3. How drug testing results will guide medical decision-making

Definitive (i.e., confirmatory) drug testing, in outpatient pain management or substance use disorder treatment, may be considered **medically necessary** under **either** of the following circumstances:

I. When immunoassays for the relevant drug(s) are indicated but not commercially available
II. In specific situations for which definitive drug levels are required for clinical decision making, one or more of the following presumptive urine drug screen results must be present and documented when not expected by history and physical exam:
   A. Positive for a prescription drug that is not prescribed to the patient
   B. Negative for a prescription drug that is prescribed to the patient
   C. Positive for an illicit drug

Note: Confirmatory testing is considered **not medically necessary** when presumptive testing results were expected based on the patient history and physical exam.

Note: Medical records should support the need for testing for the specific substance(s) of interest by documentation regarding the diagnosis, history and physical examination and/or behavior of the patient. Medical records should also justify the test that is being used and describe how results of testing will guide medical decision-making. If a definitive panel test (including several substances) is requested, the need for the use of a panel instead of more focused (individual) testing needs to be supported in the medical records.

Presumptive and definitive drug testing in outpatient pain management and/or outpatient substance use disorder treatment monitoring, are considered **investigational** for **all** indications outside of the medical necessity criteria, including but not limited to the following:

I. Routine screenings, including definitive panels, performed as part of a clinician's protocol for treatment
II. Standing orders resulting in testing that is not individualized or not used in the management of the patient's specific medical condition
III. Validity testing not included as part of drug testing, when used as a separate evaluation (see Policy Guidelines section)

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

I. Emergency rooms
II. Ambulatory surgery
III. Inpatient services
IV. An abrupt change in mental status (i.e., to rule out substance intoxication or delirium)
V. Drug or alcohol exposure during pregnancy
VI. To rule out a fetal withdrawal syndrome by testing the mother for drug use.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Notes:

- Patients who have unusually high numbers of tests ordered need medical review to confirm that the previous and current tests meet medical necessity.
- This policy does not apply to testing required by third parties such as, but not limited to **any** of the following:
  - testing for a medico-legal purpose such as child custody
  - testing for pre-employment or random testing for employment
  - testing for athletics
- Validity testing includes pH, specific gravity, nitrates, chromates, and creatinine, which are performed on the same specimen that is being drug tested. Validity testing is an internal process to affirm that the reported results are accurate and valid, and/or to confirm the sample is from the appropriate source (e.g., urine). Validity testing when done is included as part of the testing process and not as a separate evaluation/test (often billed as a urinalysis).

Pain Management

The risk level for an individual patient should include both a global assessment of risk factors and monitoring for the presence of aberrant behavior. Standardized risk-assessment tools are available, such as the 24 item Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP®-R)(https://www.helpisherede.com/Content/Documents/SOAPP-Tool.pdf), or the 5-item Opioid Risk Tool (ORT) (http://www.drugabuse.gov/nidamed-medical-health-professionals).

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

- Multiple lost prescriptions
- Multiple requests for early refill
- Obtained opioids from multiple providers
- Unauthorized dose escalation
- Apparent intoxication during previous visits

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

- Low risk by ORT: Once a year

- Moderate risk by ORT: Twice a year
- High risk or opioid dose greater than 120 morphine milligram equivalents/day (mg MED/d): 3 to 4 times a year
- Recent history of aberrant behavior: Each visit

Note that the ORT is a copyrighted instrument. The Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain does not include specific screening frequencies but states that an individual patient's risk for opioid misuse and addiction should be considered when deciding when to order a urine drug screen.

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

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

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

Selecting an Appropriate Matrix
Urine, exhaled breath (for alcohol) and oral fluid (saliva) can be used for point of care testing. Blood, sweat, and hair are matrices also used in drug testing, but require being sent to a lab for testing. Urine or saliva are the preferred matrices, but all matrices have advantages and disadvantages with respect to sensitivity and specificity over different time windows, time to obtain results, different susceptibility to sample tampering, and ease of collection.

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

Selecting an Appropriate Frequency of Testing
Patients who have unusually high numbers of tests ordered need medical review to confirm that the tests meet medical necessity.

Appropriate frequency of testing depends on many factors:
- Tests' detection capabilities and windows of detection
- Patient factors such as severity and chronicity of addiction
- Substance(s) used
- Phase of treatment
    - During the stabilization phase, drug testing may be scheduled more frequently. Testing is commonly done weekly for the first 4 weeks.
    - During the maintenance phase, drug testing may be scheduled less frequently. Testing is commonly done once every 1 to 3 months.

The rationale for unusually frequent testing should be supported in the medical record, and may need medical review to assess medical necessity.

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

Table PG1. Limitations in Availability of Presumptive Immunoassays

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

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

The following drugs are available for presumptive testing:

- Alcohol (ethanol)
- Ethyl Glucuronide (alcohol metabolite)
- Amphetamines
- Barbiturates (class IA)
- Benzodiazepines (class IA)
- Buprenorphine
- Cocaine
- Fentanyl
- Heroin
- 3,4-Methylenedioxymethamphetamine (MDMA)
- Methadone
- Methamphetamine
- Nicotine
- Opiates (class IA)
- Oxycodone
- Phencyclidine (PCP)
- Tetrahydrocannabinol (THC)
- Tramadol

Guidance on Definitive (Confirmatory) Testing

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

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

Notes:
(1) Confirmatory testing is not appropriate for every specimen and should not be done routinely. This type of test should be performed in a setting of unexpected results and not on all specimens. The rationale for each confirmatory test must be supported by the ordering clinician's documentation. The record must show that an inconsistent positive finding was noted on the presumptive testing or that there was not an available presumptive test to evaluate the presence of semi-synthetic or synthetic opioid in a patient.

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

(3) Currently, urine is the most commonly used biological substance. Advantages of urine sampling are that it is readily available, and standardized techniques for detecting drugs in urine exist. Other biological specimens, e.g., blood, oral fluids, hair and sweat, can also be tested and may gain in popularity over time as techniques for collecting and analyzing these specimens become more standardized.

Table PG2, on interpreting unexpected results of urine drug tests, is adapted from a table developed by the Canadian National Opioid Use Guideline Group that was cited by the American Society of Interventional Pain Physicians in its guideline on prescribing opioids for chronic non-cancer pain.

Table PG2. Interpreting Unexpected Urine Drug Tests Results

Unexpected Result	Possible Explanations	Possible Actions for the Physician
Test is negative for prescribed opioid	• False-negative • Noncompliance • Diversion	• Conduct confirmatory testing, specifying the drug of interest (e.g., oxycodone often missed by immunoassay) • Take a detailed history of patient's medication use for the preceding 7 days (e.g., could learn that patient ran out several days before test) • Ask patients if they've given the drug to others • Monitor compliance with pill counts
Test is positive for nonprescribed opioid or benzodiazepines	• False-positive • Patient acquired opioids from other sources (double-doctoring, "street")	• Repeat urine drug testing regularly • Ask patients if they accessed opioids from other sources • Assess for opioid misuse/addiction • Review/revise treatment agreement
UDS positive for illicit drugs (e.g., cocaine, cannabis)	• False-positive • Patient is occasional user or addicted to the illicit drug • Cannabis is positive for patients taking certain medications (e.g., dronabinol)	• Repeat urine drug test regularly • Assess for abuse/addiction and refer for addiction treatment as appropriate

UDS: urine drug screen.

Description

Patients in pain management programs and substance use disorder treatment may misuse prescribed opioids and/or may use nonprescribed drugs. Thus, these patients are often assessed before treatment and monitored while receiving treatment. Drug testing can be part of this

monitoring strategy; it is most often used as part of a multifaceted intervention that includes other components, such as patient contracts.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

The U.S. Food and Drug Administration (FDA) regulates drugs of abuse tests that are sold to consumers or health care professionals in the U.S. The FDA reviews many of these tests before they are sold for use. In its review, the FDA evaluates the design and performance of tests and sample collection systems to help ensure that they produce accurate results. The FDA does not review drugs of abuse tests intended for employment and insurance testing provided they include a statement in their labeling that the device is intended solely for use in employment and insurance testing. The FDA review does not include test systems intended for federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration, the Department of Transportation, and the U.S. military.)

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

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

Rationale

Background
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.[1] 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.[2,] Additionally, studies have found that a substantial proportion of chronic pain patients inaccurately report nonadherence to prescribed medications and the use of illicit drugs.[3,]

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

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

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

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

Testing Matrices
Another strategy for monitoring patients is testing of biologic specimens for the presence or absence of drugs. Currently, urine is the most commonly used biologic substance. Advantages of urine drug testing (UDT) are that it is readily available and standardized techniques for detecting drugs in urine exist. Other biologic specimens (e.g., blood, oral fluids, hair, sweat) can also be tested. All matrices have advantages and disadvantages with respect to sensitivity and specificity over different time windows, time to obtain results, different susceptibility to sample tampering, and ease of collection.

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

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

Immunoassay tests vary in the type of compounds they can detect. Some detect specific drugs and may fail to recognize similarly structured drugs within the same class. Other immunoassays

identify only classes of drugs and thus results cannot be used to determine which drug a patient is taking. For example, a positive result of an opiate immunoassay can be due to morphine or hydromorphone. The degree of crossreactivity (i.e. an antibody's reactivity with a compound other than the target of the test) varies widely among immunoassays.

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

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

Confirmatory (Specific Drug Identification)
Confirmatory tests are always performed in a laboratory. Gas chromatography/mass spectrometry (GC/MS) and liquid chromatography/mass spectrometry (LC/MS) are considered to be the criterion standard for confirmatory testing. These techniques involve using GC or LC to separate the analytes in a specimen and for MS to identify the specific molecular structures of the drug and its metabolites. The tests are able to quantify the amount of drug or metabolite present in the urine sample. Definitive quantitative tests can be used to confirm the presence of a specific drug identified by a screening test and can identify drugs that cannot be isolated by currently available immunoassays. Results are reported as the specific levels of substances detected in the urine. GC/MS and LC/MS generally require the specification of the drug or drugs to be identified. Alternatively, "broad-spectrum screens" can be conducted. There is a several-day turnaround time for GC/MS and LC/MS testing.[5,]

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

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

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

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

Full informed consent is a requirement before UDT. Patients should be informed of the specific drug testing protocol before treatment and should provide written agreement with the plan for monitoring. As stated in a joint U.S. Veterans Affairs/Department of Defense guideline, patients' refusal to consent to urine testing should be considered a factor in the overall assessment of patients' ability to adhere to treatment. [6,]

Oral Fluid Drug Testing
Oral fluid (liquid samples obtained from the oral cavity) can potentially be used to test for drug use. Oral fluid contains secretions from several different sources, including secretions from the 3 pairs of major salivary glands (parotid, sublingual, and submandibular), secretions from the minor salivary glands, oro-nasopharyngeal secretions, and cellular debris. The mixture of fluids obtained varies depending on the collection method used (e.g., spitting, suctioning, draining, or collection on some type of absorbent material). Drug concentrations can be affected by the collection method and by the use of saliva stimulation methods. Several collection devices are commercially available in the U.S.[1,] and they generally involve collection on an absorbent material, such as foam pads; pads are then placed in a container with a stabilizing buffer solution. Drug concentrations may also depend on how the oral fluid is recovered from the collection device (e.g., by centrifugation or by applying pressure). Drug concentrations may not reflect blood levels because of residual amounts of a drug (specifically those ingested or smoked) remaining in the oral cavity after recent use.

Analysis techniques must be able to detect drugs present in low concentration and in a small volume of fluid (often <1 mL). Immunoassay techniques are available to detect drugs in oral fluid; they require a small sample volume (≈25 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 (i.e., within the past 7 days) cannot be detected; difficulty in detecting very light drug use (e.g., a single episode); and drug levels can be affected by environmental exposure. In addition, variation in hair texture as well as cosmetic hair treatments can affect drug incorporation into hair and the accuracy of drug tests on hair samples. As with other types of samples, hair can be initially tested using immunoassay techniques, with confirmation by MS-based methods. Hair testing has been used in a variety of situations where detection of drug use during the previous several months is desired (e.g., pre-employment screening, post-drug-treatment verification of relapse).

Literature Review
Guidelines with evidence reviews of published peer-reviewed scientific literature suggest that the evidence of benefit on health outcomes for drug testing for both patients in chronic pain using opioids and patients with substance use disorder is limited and usually confounded with drug testing as part of a multifaceted intervention of risk mitigation or contingency

management. There is also no clear evidence in the literature regarding the most effective frequency of testing. [7,6,]

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

Thus a traditional evidence review will not be performed and relevant national and regional clinical practice guidelines were sought to inform the review. The guidelines are reviewed in the Supplementary Information section of the review.

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

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

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

Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests from Blue Cross Blue Shield Association, input was received from 5 physician specialty societies and 8 academic medical centers in 2014. There was near-consensus among reviewers that, in outpatient pain management, presumptive (i.e. qualitative) urine drug testing may be considered medically necessary for patients who meet the stated criteria and that the frequency of repeat drug testing should depend on the risk level of the individual. There was also near-consensus among reviewers that, in substance abuse treatment, baseline presumptive drug testing may be considered medically necessary for patients who meet the stated criteria and that targeted weekly qualitative screening for a maximum of 4 weeks may be considered medically necessary during the stabilization phase. There was mixed input on the frequency of presumptive drug testing that may be considered medically necessary during the maintenance phase of substance abuse treatment. In addition, clinical input was mixed on confirmatory definitive (i.e. quantitative) drug testing and particularly on whether definitive drug testing should only be performed on a drug-specific basis.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given

to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Pain Management
Nuckols et al (2014) published a systematic review of guidelines that addressed the management of opioid use for chronic pain.[8] Reviewers included guidelines from national organizations and specialty societies, as well as guidelines from state agencies and specific health systems. Moreover, reviewers identified 9 guidelines with recommendations on urine drug testing (UDT). Recommendations varied widely; 2 recommended mandatory testing for all patients, another recommended testing only patients at increased risk of a medication use disorder, and 2 stated that testing patients at low-risk of abuse is not cost-effective. If UDT is used, the recommended frequency of follow-up testing was at least quarterly in 1 guideline, at least yearly in another, and randomly in 2.

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

American Society of Interventional Pain Physicians
In 2017, the American Society of Interventional Pain Physicians issued guidelines for responsible, safe, and effective opioid prescribing for chronic non-cancer pain.[10] The guidelines included the following recommendations on UDT (see Table 1).

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

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

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

Centers for Disease Control and Prevention
In 2016, the Centers for Disease Control and Prevention published guidelines on opioids for chronic pain.[11] The guidelines included the following recommendation on UDT: "When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs."

Department of Veterans Affairs and Department of Defense
In 2017 , the Department of Veterans Affairs and Department of Defense updated clinical practice guidelines for managing opioid therapy for the treatment of chronic pain.[6] The recommendations on risk mitigation to prescribed opioids include obtaining a UDT (with patient consent) before initiating opioid therapy, and then randomly at a follow-up to confirm appropriate use. Other strategies recommended include clinical assessment such as random pill counts and use of prescription drug monitoring programs.

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

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

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

The guideline states that gaining consent is required prior to a UDT; if a patient declines consent, "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.[12] The guidelines included recommendations on UDT. Recommendations on testing frequency differed depending on the patient risk of opioid addiction and opioid dosage, as listed below:

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

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

Substance Use Disorder Treatment
American Society of Addiction Medicine
The American Society of Addiction Medicine (ASAM) has published several documents on drug testing: a public policy statement (2010),[13] a white paper (2013), which provided background on the science and current practices of drug testing[14], and guidelines (2017) on the effective use of drug testing.[7,15]

The ASAM's public policy statement asserts that: "Urine drug testing is a key diagnostic and therapeutic tool that is useful for patient care and in monitoring of the ongoing status of a person who has been treated for addiction. As such, it is a part of medical care, and should not face undue restrictions."[13] The ASAM recommended drug testing where medically appropriate in clinical diagnostic settings and clinical treatment settings. The term "drug testing" in this document was a broad term that included urine or other body fluids or tissues.

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

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

The ASAM (2017) guidance on appropriate drug testing in clinical addiction medicine advises health care providers that before choosing the type of drug test, they should first identify the questions they are seeking to answer and be aware of the benefits and limitations of the various drug tests. Table 2 summarizes the characteristics of urine, oral fluid, and hair drug tests that may inform the decision of what type of drug test to use.[7.]

Table 2. Summary of Drug Testing Characteristics

Characteristics	Urine	Oral Fluid	Hair
General detection period	Hours to days	Minutes to hours	Weeks to months
Point-of-care testing	Yes	Yes	No
Primarily detects	Drug metabolite	Parent drug compound	Parent drug compound
Best use in treatment setting	Intermediate-term detection in ongoing treatment	Short-term detection in ongoing treatment	Long-term monitoring, 3-month history
Ease of collection	Requires restroom	Easily collected	Easily collected
Resistance to tampering	Low	High, with some uncertainty	High when chemically untreated
Retesting same sample	Possible	Difficult	Easy

Adapted from Jarvis et al (2017).[7.]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

References

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical, and/or consultation reports and progress notes including:
  - Reason for performing test
  - Patient history and risk of substance abuse
  - Signs/symptoms/test results related to reason for urine drug testing
  - How test result will impact clinical decision making
  - Physician order for urine drug testing
- Name and description of urine drug test
- Name of laboratory that is performing or has performed the test
- Any available evidence supporting the clinical validity/utility of the specific test
- CPT codes billed for the particular urine drug test

Post Service (in addition to the above, please include the following):

- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement

policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	0082U	Drug test(s), definitive, 90 or more drugs or substances, definitive chromatography with mass spectrometry, and presumptive, any number of drug classes, by instrument chemistry analyzer (utilizing immunoassay), urine, report of presence or absence of each drug, drug metabolite or substance with description and severity of significant interactions per date of service
	0093U	Prescription drug monitoring, evaluation of 65 common drugs by LC-MS/MS, urine, each drug reported detected or not detected
	0116U	Prescription drug monitoring, enzyme immunoassay of 35 or more drugs confirmed with LC-MS/MS, oral fluid, algorithm results reported as a patient-compliance measurement with risk of drug to drug interactions for prescribed medications
	0117U	Pain management, analysis of 11 endogenous analytes (methylmalonic acid, xanthurenic acid, homocysteine, pyroglutamic acid, vanilmandelate, 5-hydroxyindoleacetic acid, hydroxymethylglutarate, ethylmalonate, 3-hydroxypropyl mercapturic acid (3-HPMA), quinolinic acid, kynurenic acid), LC-MS/MS, urine, algorithm reported as a pain-index score with likelihood of atypical biochemical function associated with pain
	0143U	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
	0144U	Drug assay, definitive, 160 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
	0145U	Drug assay, definitive, 65 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
	0146U	Drug assay, definitive, 80 or more drugs or metabolites, urine, by quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
	0147U	Drug assay, definitive, 85 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
	0148U	Drug assay, definitive, 100 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service

Type	Code	Description
	0149U	Drug assay, definitive, 60 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
	0150U	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
	0227U	Drug assay, presumptive, 30 or more drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, includes sample validation
	80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
	80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; read by instrument assisted direct optical observation (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
	80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; by instrument chemistry analyzers (e.g., utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (e.g., GC, HPLC), and mass spectrometry either with or without chromatography, (e.g., DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service
	82077	Alcohol (ethanol); any specimen except urine and breath, immunoassay (e.g., IA, EIA, ELISA, RIA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)
HCPCS	G0480	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 1-7 drug class(es), including metabolite(s) if performed
	G0481	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and

Type	Code	Description
		variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 8-14 drug class(es), including metabolite(s) if performed
	G0482	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 15-21 drug class(es), including metabolite(s) if performed
	G0483	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 22 or more drug class(es), including metabolite(s) if performed
	G0659	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
04/15/2015	BCBSA medical policy adoption
06/30/2015	Administrative Update (Policy statement clarification)
01/01/2016	Coding update
10/01/2016	Coding update

Effective Date	Action
11/01/2016	Policy title change from Urine Drug Testing in Pain Management and Substance Abuse Treatment. Policy revision without position change.
02/01/2017	Policy revision without position change
02/01/2018	Coding update
03/01/2018	Policy revision without position change
02/01/2019	Coding update
06/01/2019	Coding update. Administrative Update (Policy Guidelines clarification).
11/01/2019	Coding update
12/16/2019	Policy title change from Drug Testing in Pain Management and Substance Abuse Treatment. Policy revision with position change.
03/01/2020	Coding update
04/01/2020	Annual review. No change to policy statement.
02/01/2021	Annual review. Policy statement, guidelines and literature updated. Coding update.
01/01/2022	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Drug Testing in Pain Management and Substance Use Disorder Treatment 2.04.98 **Policy Statement:** In outpatient pain management or substance use disorder treatment, laboratory, in-office or point-of-care presumptive (e.g., immunoassay) drug testing may be considered **medically necessary** for **either** of the following conditions: I. Baseline screening before initiating treatment or at the time treatment is initiated (i.e., induction phase), when **all** of the following conditions are met: A. An adequate clinical assessment of patient history and risk of substance use disorder is performed and documented B. There is a documented plan in place regarding how to use test findings clinically C. Drug testing is ordered by a clinician during an office visit (this policy does not apply to the inpatient or emergency department settings) **Note**: Urine or oral fluids (saliva) are the preferred sources for testing. The use of other matrices such as breath, blood or hair for testing may only be considered **medically necessary** when urine or saliva testing is not possible or reasonable (see Policy Guidelines section) as documented in the medical record. I. Stabilization, maintenance or monitoring phase when **either** of the following conditions are met: A. Using an appropriate test, matrix and frequency of testing for the risk level of the individual and the substance(s) being used (see Policy Guidelines section) B. Documentation in the medical record explains **all** of the following (see Policy Guidelines section): 1. Rationale for the specific test(s) ordered 2. Patient's history of substance use 3. How drug testing results will guide medical decision-making	**Drug Testing in Pain Management and Substance Use Disorder Treatment 2.04.98** **Policy Statement:** In outpatient pain management or substance use disorder treatment, laboratory, in-office or point-of-care presumptive (e.g., immunoassay) drug testing may be considered **medically necessary** for **either** of the following conditions: I. Baseline screening before initiating treatment or at the time treatment is initiated (i.e., induction phase), when **all** of the following conditions are met: A. An adequate clinical assessment of patient history and risk of substance use disorder is performed and documented B. There is a documented plan in place regarding how to use test findings clinically C. Drug testing is ordered by a clinician during an office visit (this policy does not apply to the inpatient or emergency department settings) **Note**: Urine or oral fluids (saliva) are the preferred sources for testing. The use of other matrices such as breath, blood or hair for testing may only be considered **medically necessary** when urine or saliva testing is not possible or reasonable (see Policy Guidelines section) as documented in the medical record. I. Stabilization, maintenance or monitoring phase when either of the following conditions are met: A. Using an appropriate test, matrix, and frequency of testing for the risk level of the individual and the substance(s) being used (see Policy Guidelines section) B. Documentation in the medical record explains **all** of the following (see Policy Guidelines section): 1. Rationale for the specific test(s) ordered 2. Patient's history of substance use 3. How drug testing results will guide medical decision-making

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Definitive (i.e., confirmatory) drug testing, in outpatient pain management or substance use disorder treatment, may be considered **medically necessary** under **either** of the following circumstances: I. When immunoassays for the relevant drug(s) are indicated but not commercially available II. In specific situations for which definitive drug levels are required for clinical decision making, **one or more** of the following presumptive urine drug screen results must be present and documented when not expected by history and physical exam: A. Positive for a prescription drug that is not prescribed to the patient B. Negative for a prescription drug that is prescribed to the patient C. Positive for an illicit drug **Note**: Confirmatory testing is considered **not medically necessary** when presumptive testing results were expected based on the patient history and physical exam. **Note**: Medical records should support the need for testing for the specific substance(s) of interest by documentation regarding the diagnosis, history and physical examination and/or behavior of the patient. Medical records should also justify the test that is being used and describe how results of testing will guide medical decision-making. If a definitive panel test (including several substances) is requested, the need for the use of a panel instead of more focused (individual) testing needs to be supported in the medical records. Presumptive and definitive drug testing in outpatient pain management and/or outpatient substance use disorder treatment monitoring, are considered **investigational** for **all** indications outside of the medical necessity criteria, including but not limited to the following: I. Routine screenings, including definitive panels, performed as part of a clinician's protocol for treatment II. Standing orders resulting in testing that is not individualized or not used in the management of the patient's specific medical condition	Definitive (i.e., confirmatory) drug testing, in outpatient pain management or substance use disorder treatment, may be considered **medically necessary** under **either** of the following circumstances: I. When immunoassays for the relevant drug(s) are indicated but not commercially available II. In specific situations for which definitive drug levels are required for clinical decision making, one or more of the following presumptive urine drug screen results must be present and documented when not expected by history and physical exam: A. Positive for a prescription drug that is not prescribed to the patient B. Negative for a prescription drug that is prescribed to the patient C. Positive for an illicit drug **Note**: Confirmatory testing is considered **not medically necessary** when presumptive testing results were expected based on the patient history and physical exam. **Note**: Medical records should support the need for testing for the specific substance(s) of interest by documentation regarding the diagnosis, history and physical examination and/or behavior of the patient. Medical records should also justify the test that is being used and describe how results of testing will guide medical decision-making. If a definitive panel test (including several substances) is requested, the need for the use of a panel instead of more focused (individual) testing needs to be supported in the medical records. Presumptive and definitive drug testing in outpatient pain management and/or outpatient substance use disorder treatment monitoring, are considered **investigational** for **all** indications outside of the medical necessity criteria, including but not limited to the following: I. Routine screenings, including definitive panels, performed as part of a clinician's protocol for treatment II. Standing orders resulting in testing that is not individualized or not used in the management of the patient's specific medical condition

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
III. Validity testing not included as part of drug testing, when used as a separate evaluation (see Policy Guidelines section) Drug testing may be considered **medically necessary** in **any** of the following settings: I. Emergency rooms II. Ambulatory surgery III. Inpatient Services IV. An abrupt change in mental status (i.e., to rule out substance intoxication or delirium) V. Drug or alcohol exposure during pregnancy VI. To rule out a fetal withdrawal syndrome by testing the mother for drug use.	III. Validity testing not included as part of drug testing, when used as a separate evaluation (see Policy Guidelines section) Drug testing may be considered **medically necessary** in **any** of the following settings: I. Emergency rooms II. Ambulatory surgery III. Inpatient services IV. An abrupt change in mental status (i.e., to rule out substance intoxication or delirium) V. Drug or alcohol exposure during pregnancy VI. To rule out a fetal withdrawal syndrome by testing the mother for drug use.