IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Patients in pain management programs and substance abuse treatment may misuse prescribed opioids and/or may use non-prescribed drugs. Thus, these patients are often assessed before treatment and monitored while they are receiving treatment. Urine drug screening is most often used in coordination with a multifaceted intervention approach.

Background

According to an evidence assessment by the American Society of Interventional Pain Physicians (ASIPP), approximately one-third of chronic pain patients do not use opioids as prescribed or may abuse them.[1] Moreover, studies report that a substantial proportion of chronic pain patients inaccurately report nonadherence to prescribed medications and use of illicit drugs.[2]

According to the National Pharmaceutical Council (NPC) and Joint Commission on Accreditation of Healthcare Organizations (JCAHO) guideline regarding current understanding of assessment, management, and treatment of pain, the primary drugs used to treat pain may be categorized into three classes:[3]

- **Nonopioid analgesics (nonopioids):** acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs), including aspirin and other salicylic acid derivatives.
• **Opioid analgesics (opioids):** mu opioid agonists (i.e., morphine-like agonists) and agonist-antagonist opioids.

• **Adjuvant analgesics or co-analgesics:** a diverse group of drugs, with primary indications for conditions other than pain, with analgesic properties relevant to some conditions. Commonly used adjuvant analgesics include antiepileptic drugs (AEDs), tricyclic antidepressants (TCAs), and local anesthetics (LAs).

The NPC notes that, “variations of this classification system exist, and terminology in the field is also evolving.”

**Monitoring Drug Use**

Various strategies are available to monitor patients in pain management and substance abuse treatment. Multicomponent interventions are often used which may include patient contracts, risk assessment screening instruments and tracking of aberrant behaviors. One strategy for monitoring patients is testing of biological specimens for the presence or absence of drugs. Currently, urine is the most commonly used biological substance. Advantages of urine sampling are that it is readily available, and there are standardized techniques for detecting drugs in urine. Other biological specimens (e.g., blood, oral fluids, hair and sweat) can also be tested and may gain popularity over time as techniques for collecting and analyzing these specimens become more standardized.

**Urine Drug Testing**

There are various approaches to incorporating urine drug screening into pain management and substance abuse treatment settings. Most commonly, patients undergo urine drug screening before beginning treatment to verify current drug use. Some clinicians believe that urine drug screening 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 healthcare 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.

Full informed consent is a requirement before urine drug testing. 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 as one factor in the overall assessment of patients’ ability to adhere to treatment.[4]

There are two primary categories of urine drug testing:

I. **Presumptive Immunoassay (Qualitative) Testing**

These tests can be performed either in a laboratory or at point-of-service with Certification of Waiver or a Medical Test Site Accredited License. Presumptive 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.

Presumptive 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 crossreactivity, i.e., an antibody’s reactivity with a compound other than the target of the test, varies widely among immunoassays.

Presumptive 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.

Imunoassays generally have a rapid turnaround time, within minutes for onsite tests and 1 to 4 hours for laboratory-based tests.[5]

II. Definitive Confirmatory (Quantitative) Testing to Identify a Specific Drug

Confirmatory tests are performed in a laboratory or by a provider with Certificate of Registration, Compliance of Accreditation or Medical Test Site Categorized License or Accredited License. Gas chromatography/mass spectrometry (GC/MS) is considered to be the criterion standard for confirmatory testing. This technique involves using GC to separate the analytes in a specimen and 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. 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 generally requires 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 testing.[6]

Urine Drug Test Accuracy

An issue with both types of urine drug testing 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 onsite testing of sample characteristics including urine temperature, creatinine concentration, and specific gravity).

In addition, correct interpretation of urine drug testing 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 have this degree of hydrocodone if high amounts of oxycodone were also present.

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

Regulatory Status

GC/MS tests and some immunoassays are performed in laboratory settings. Clinical laboratories may develop and validate in house (i.e., laboratory-developed) tests and market them as a service. Laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Act (CLIA).

A CLIA waiver is available for use of certain point-of-care immunoassays. Tests eligible for a CLIA waiver are those considered to be simple, with low risk of error and low potential for harm. The U.S. Food and Drug Administration (FDA) is tasked with approving manufacturers’ applications for test system waivers. There are commercially available CLIA-waived tests for drugs such as cocaine, methadone, morphine/opiates and oxycodone.

NOTE: This policy does not address the use of urine drug testing in the following circumstances:

- Emergency department testing, including for the detection of potential overdose or poisoning.
- Screening for commercial drivers licensing, or any other job related testing.
- State/legally mandated drug testing.

MEDICAL POLICY CRITERIA

*NOTE: Presumptive immunoassay (qualitative) and/or definitive confirmatory (quantitative) urine drug testing will not be covered as required for, or in conjunction with, participation in a substance abuse facility. Urine drug testing is considered included in the facility reimbursement.

Presumptive Immunoassay (Qualitative) Urine Drug Testing

I. Presumptive immunoassay (qualitative) urine drug testing with codes 0007U, 80305, 80306, or 80307 (only 1 of the 4 immunoassay codes may be billed per day with one unit per code) may be considered medically necessary* at any one level of care per day for pain management or substance abuse treatment when either of the following criteria (A or B) are met:

A. Testing does not exceed 15 presumptive codes per year; or

B. Testing exceeds 15 presumptive codes per year and clinical documentation indicates both of the following criteria are met:

1. Abuse, misuse or diversion is suspected; and

2. Documentation indicates how test results will impact management.
II. Presumptive immunoassay (qualitative) urine drug testing for pain management or substance abuse treatment, is considered **not medically necessary** when the above criteria (I) are not met.

**Definitive Confirmatory (Quantitative) Urine Drug Testing**

III. Definitive confirmatory (quantitative) urine drug testing with codes G0480, G0481, G0482, G0483, or G0659 (only 1 of the 5 definitive G codes may be billed per day with one unit per code) may be considered **medically necessary** at any one level of care per day for pain management or substance abuse treatment when either of the following criteria (A or B) are met:

A. Testing does not exceed 15 definitive codes per year; or

B. Testing exceeds 15 definitive codes per year and clinical documentation indicates both of the following criteria are met:
   1. Abuse, misuse or diversion is suspected; and
   2. Documentation indicates how test results will impact management.

IV. Definitive confirmatory (quantitative) urine drug testing for pain management or substance abuse treatment, is considered **not medically necessary** when the above criteria (III) are not met.

**SCIENTIFIC EVIDENCE**

Assessment of diagnostic testing typically focuses on 3 main principles:

1. The analytic validity of the test, which refers to the technical accuracy of the test in detecting a mutation that is present or in excluding a mutation that is absent;
2. The clinical validity of the test, which refers to the diagnostic performance of the test (sensitivity, specificity, positive and negative predictive values) in detecting clinical disease; and
3. The clinical utility of the test, i.e., how the results of the diagnostic test will be used to change management of the patient and whether these changes in management lead to clinically important improvements in health outcomes.

The focus of the following literature appraisal is on evidence related to the clinical utility of urine drug testing to:

- Provide clinically relevant information beyond other strategies for monitoring drug use in pain management and substance abuse treatment patients, and
- Alter treatment decisions and improve health outcomes as a result of confirmatory testing and/or presumptive immunoassay testing compared to clinical evaluation techniques.

**Literature Appraisal**

**Managing Patients with Routine Urine Drug Testing Versus Confirmatory Urine Drug Testing**

Confirmatory tests provide quantitative measurements of a wider range of medications and their metabolites compared to immunoassay testing and are considered effective for confirming an
unexpected immunoassay result. Numerous studies were identified which evaluated the use of confirmatory urine drug testing to distinguish patients who are abusing prescription drugs from those who are complying with a prescribed dosing regimen.[7-12] However, no studies were identified that assessed how results from confirmatory testing improved patient management decisions or health outcomes compared to patients managed using routine immunoassay urine drug tests.

**Clinical Practice Guidelines**

**Centers for Disease Control and Prevention**

In 2016, Centers for Disease Control and Prevention (CDC) guidelines on opioids for chronic pain was published.[13] 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.”

**Washington State Agency Medical Directors’ Group**

The Agency Medical Directors’ Group (AMDG) of Washington State updated guidelines on opioid dosing for chronic non-cancer pain were first published in 2010, and revised with the broadened scope of opioids for pain in 2015.[14,15] Regarding the use of urine drug testing (UDT), the WA AMGD made the following statements:

“The purpose of drug testing is to identify aberrant behavior, undisclosed drug use and/or abuse and verify compliance with treatment. If a decision has been made to prescribe opioids for chronic non-cancer pain, the prescriber should get a baseline UDT and screen all patients for risk level to develop an appropriate monitoring plan as well as a basis for consultation or referral. Although UDT and other screening tools are helpful in identifying aberrant behavior, it is also important for prescribers to use their clinical judgment in the development of a monitoring plan. The Prescriber should repeat random UDT based on the patient’s risk category. There are several validated screening tools available to assess risk of aberrant behavior. The Opioid Risk Tool (ORT) provides a brief questionnaire that can easily be used in the primary care setting”

In addition, the WA AMDG noted that immunoassays are the most commonly used method of testing, although no standard UDT is suitable for all purposes and settings. The WA AMDG made the following recommendations regarding when confirmatory testing may be beneficial:

**Natural Opioids (e.g., codeine, morphine)**

“Immuoassays for “opiates” are responsive for morphine and codeine but do not distinguish which is present. Confirmatory testing is required to reliably identify drug(s) present. Since codeine is metabolized to morphine and small quantities to hydrocodone, these drugs may be found in the urine. Also, morphine may metabolize to produce a small amount (<10%) of hydromorphone.”

**Semisynthetic Opioids (e.g., hydrocodone, hydromorphone, oxycodone, oxymorphone)**

“‘Opiates’ immunoassays may also detect semisynthetic opioids depending on their crossreactivity pattern. However, a negative result does not exclude use of semisynthetic opioids.
Confirmatory testing (GC/MS or LC/MS/MS [liquid chromatography tandem mass spectrometry]) is required to verify compliance with the prescribed semisynthetic opioid(s).

Since hydrocodone is metabolized in small amounts to hydromorphone, both may be found in the urine. Likewise, oxycodone is metabolized to oxymorphone, so these may both be present in the urine of oxycodone users. However, the reverse is not true. In other words, hydromorphone and oxymorphone use does not result in positive screens for hydrocodone and oxycodone, respectively.”

Synthetic Opioids (e.g., fentanyl, meperidine, methadone, propoxyphene)

“Current “opiates” immunoassays do not detect synthetic opioids. Thus confirmatory testing (GC/MS or LC/MS/MS) is needed to identify these drugs. If the purpose is to document compliance with treatment, the laboratory can be instructed to remove the cutoff concentration so that the presence of lower concentrations can be identified.”

Opinions vary on the optimal frequency of urine drug screening to monitor patients on opioid therapy for chronic pain. The WA AMDG UDT algorithm for monitoring opioid treatment in chronic non-cancer pain includes test frequency recommendations, summarized as follows:

- Low risk by Opioid Risk Tool (ORT): 1 per year
- Moderate risk by ORT: 2 per year
- High risk or opioid dose >120 MED/d: 3 to 4 per year
- Aberrant: At time of visit

Note that the ORT is a copyrighted instrument.[16]

American Society of Addiction Medicine (ASAM)

In October of 2013, ASAM published a white paper reviewing the use of drug testing as a primary prevention, diagnostic, and monitoring tool to, “identify the presence or absence of drug abuse or therapeutic agents related to addition management in multiple settings.”[17] ASAM recommends random drug testing is preferable to scheduled testing for addiction treatment. In addition, the ASAM position paper indicates that the frequency of testing should be higher at the start of treatment and then lowered as the patient attains a substantial abstinence from drug use. Specifically, ASAM makes the following statement regarding the frequency of testing:

“Even though drug testing is a central component of years-long monitoring programs for licensed health professionals, there is no agreed-to standard among states regarding frequency or duration of testing in such programs. In general, most PHPs set the frequency of random testing at once a week early in their monitoring. The frequency of testing is reduced to twice a month and then once a month after long-term sobriety is achieved.”

American Society of Interventional Pain Physicians

In 2012, the American Society of Interventional Pain Physicians (ASIPP) issued guidelines on responsible opioid prescribing for chronic noncancer pain.[1] The evidence supporting the recommendations below was not clearly described in either the guidance document or the accompanying
evidence assessment document. The guidelines include the following recommendations on urine drug testing:

- “Comprehensive assessment and documentation is recommended before initiating opioid therapy.
  
  (Evidence was rated as “good” indicating it includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes with at least 2 consistent, higher-quality randomized controlled trials (RCTs) or studies of diagnostic test accuracy.)

- Despite limited evidence for reliability and accuracy, screening for opioid use is recommended, as it will identify opioid abusers and reduce opioid abuse.
  
  (Evidence as rated as “limited” indicating that it is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.)

- Urine drug testing must be implemented from initiation along with subsequent adherence monitoring, in an in-office setting with immunoassay and confirmation for accuracy with chromatography in select cases, to identify patients who are non-compliant or abusing prescription drugs or illicit drugs, and urine drug testing may decrease prescription drug abuse or illicit drug use when patients are in chronic pain management therapy.
  
  (Evidence: “good”)

American Pain Society and American Academy of Pain Medicine

In 2009, the American Pain Society (APS) and American Academy of Pain and Medicine (AAPM) issued a joint clinical practice guidelines on the use of opioid therapy in chronic noncancer pain.[18] The clinical guidelines were based upon a high quality systematic review of the current evidence which included a comprehensive literature search and transparent appraisal of the quality of evidence. The APS/AAPM guideline indicated the following:

  “Patients with chronic pain may underreport or conceal illicit drug use. Regular or periodic urine drug screening has been proposed as a method for identifying patients using illicit drugs. Most urine drug screening tests utilize immunoassays, but cross-reactivity between various drugs and chemicals can cause false positive results. Urine tests based on gas chromatography-mass spectrometry assays are considered the most specific test for identifying individual drugs and metabolites and are often used to confirm positive results on immunoassays.”

The APS/AAPM found the evidence regarding the diagnostic accuracy or urine drug screening to be limited to a single study with methodological shortcomings.

American College of Occupational and Environmental Medicine
In 2011, the American College of Occupational and Environmental Medicine (ACOEM) issued guidelines on the chronic use of opioids which contained the following recommendation on urine drug testing:\[19\]:

“Routine use of urine drug screening for patients on chronic opioids is recommended as there is evidence that urine drug screens can identify aberrant opioid use and other substance use that otherwise is not apparent to the treating physician.”

This recommendation was given a C rating to indicate, “the intervention is recommended for appropriate patients. There is limited evidence that the intervention may improve important health and functional benefits.”

In addition the ACOEM recommends screening for all patients at baseline and then randomly at least twice and up to 4 times a year and at termination. Screening should also be performed if the provider suspects abuse of prescribed medication.

Veterans Affairs and Department of Defense

In 2010, the Veterans Affairs (VA) and Department of Defense (DoD) issued clinical practice guidelines for managing opioid therapy for chronic pain treatment.\[4\] The recommendations on assessing adherence to prescribed opioids includes obtaining a urine drug test before initiating opioid therapy and randomly at follow-up to confirm appropriate use. Other strategies recommended include clinical assessment and screening aids such as random pill counts, adherence checklists and standardized instruments such as the Screener and Opioid Assessment for Patients with Pain (SOAPP).

The guideline included the following specific recommendations regarding urine drug testing:

1. “Inform patients that drug testing is a routine procedure for all patients starting or on opioid therapy (OT), and is an important tool for monitoring the safety of their treatment.
2. With patient consent, obtain a urinary drug test (UDT) in all patients prior to initiation of OT.
3. With patient consent monitor all patients on OT with periodic random UDTs to confirm adherence to the treatment plan. Increase the frequency of UDTs based on risk level for aberrant drug-related behaviors and following each dose increase.
4. Take into consideration a patient’s refusal to take a UDT as part of the ongoing assessment of the patient’s ability to adhere to the treatment plan and the level of risk for adverse outcomes.
5. When interpreting UDT results take into account other clinical information (e.g., past substance use disorder [SUD], other risk factors, aberrant drug-related behaviors, and other conditions indicating risk.)
6. Understanding of lab methods for drug testing and reporting are necessary to interpret UDT results (i.e., screen versus confirmatory test, substances tested, cut-off levels for tests). Maintain a close working relationship with the clinical laboratory to answer any questions about the UDT or for confirming the results.”

Specific recommendations regarding confirmatory urine drug testing were not included in the VA/DoD guidelines.

American Society of Addiction Medicine
In 2010, the American Society of Addiction Medicine (ASAM) issued a statement on drug testing in the substance abuse treatment programs. The guideline authors indicated that, “all positive screening test results should be verified through confirmatory testing before any adverse action based on test results is taken (e.g., sanctions applied to licensure or privileging).”

**Summary**

The research regarding the clinical utility of presumptive immunoassay (qualitative) or definitive (quantitative) confirmatory urine drug testing in pain management and substance abuse treatment is limited. However, there is consensus among clinical practice guidelines that presumptive and definitive urine drug testing may be warranted in specific cases, despite the lack of established testing standards. Therefore, presumptive immunoassay and definitive confirmatory urine drug testing may be considered medically necessary when specific criteria are met.

**REFERENCES**

8. Linares, OA, Daly, D, Stefanovski, D, Boston, RC. A new model for using quantitative urine testing as a diagnostic tool for oxycodone treatment and compliance. *Journal of pain & palliative care pharmacotherapy*. 2013 Aug;27(3):244-54. PMID: 23879213

**CROSS REFERENCES**

None

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