Medical Policy

Urine Drug Testing in Pain Management and Substance Abuse Treatment Settings

Table of Contents
- Policy: Commercial
- Policy: Medicare
- Authorization Information
- Coding Information
- Description
- Policy History
- Information Pertaining to All Policies
- References

Policy Number: 674
BCBSA Reference Number: 2.04.98

Related Policies
- Biofeedback as a Treatment of Chronic Pain, #210
- Methadone Treatment and Intensive Detoxification or Ultra-Rapid Detoxification for Opiate Addiction, #274
- Intravenous Anesthetics for the Treatment of Chronic Pain, #291

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

In the outpatient pain management setting, qualitative (ie, immunoassay) urine drug testing may be MEDICALLY NECESSARY for:
- Baseline screening before initiating treatment or at the time treatment is initiated, when the following conditions are met:
  - An adequate clinical assessment of patient history and risk of substance abuse is performed;
  - Clinicians have knowledge of test interpretation;
  - There is a plan in place regarding how to use test findings clinically
- Subsequent monitoring of treatment at a frequency appropriate for the risk-level of the individual patient.

In the outpatient substance abuse treatment setting, in-office or point-of-care qualitative (ie, immunoassay) urine drug testing may be MEDICALLY NECESSARY under the following conditions:
- Baseline screening before initiating treatment or at the time treatment is initiated (ie, induction phase), 1 time per program entry, when the following conditions are met:
  - An adequate clinical assessment of patient history and risk of substance abuse is performed;
  - Clinicians have knowledge of test interpretation;
  - There is a plan in place regarding how to use test findings clinically
- Stabilization phase - targeted weekly qualitative screening for a maximum of 4 weeks
- Maintenance phase – targeted qualitative screening once every 1 to 3 months.
Quantitative (i.e., confirmatory) urine drug testing, in the pain management or substance abuse setting, may be *MEDICALLY NECESSARY* under the following circumstances:

- When immunoassays for the relevant drug(s) are not commercially available.
- In specific situations for which quantitative drug levels are required for clinical decision making.

In the outpatient pain management setting and outpatient substance abuse setting, urine drug testing is **NOT MEDICALLY NECESSARY** when the above criteria are not met including but not limited to routine qualitative or quantitative urine drug testing (e.g., testing at every visit, without consideration for specific patient risk factors or without consideration for whether quantitative testing is required for clinical decision making).

**Medicare HMO BlueSM and Medicare PPO BlueSM Members**

**Indications:**

"Although technology has provided the ability to measure many toxins, most toxicological diagnoses and therapeutic decisions are made based on historical or clinical considerations: (1) laboratory turnaround time can often be longer than the critical intervention time course of an overdose; (2) the cost and support of maintaining the instruments, staff training, and specialized labor involved in some analyses are prohibitive; (3) for many toxins there are no established cutoff levels of toxicity, making interpretation of the results difficult." "Although comprehensive screening is unlikely to affect emergency management, the results may assist the admitting physicians in evaluating the patient if the diagnosis remains unclear." Qualitative screening panels should be used when the results will alter patient management or disposition. (Richardson et al, 2007).

A qualitative drug screen may be indicated with a symptomatic patient when the history is unreliable, with a multiple-drug ingestion, with a patient in delirium or coma, for the identification of specific drugs, and to indicate when antagonists may be used. The clinical utility of drug screens in the emergency setting may be limited because patient management decisions are unaffected, since most therapy for drug poisonings is symptom directed and supportive.

Medicare will consider performance of a qualitative drug screen medically reasonable and necessary when a patient presents with suspected drug overdose and one or more of the following conditions:

- Unexplained coma;
- Unexplained altered mental status in the absence of a clinically defined toxic syndrome or toxidrome;
- Severe or unexplained cardiovascular instability (cardiotoxicity);
- Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome;
- Seizures with an undetermined history;
- For monitoring patient compliance during active treatment for substance abuse or dependence.

A qualitative drug screen is considered medically reasonable and necessary in patients on chronic opioid therapy:

- In whom illicit drug use, non-compliance or a significant pre-test probability of non-adherence to the prescribed drug regimen is suspected and documented in the medical record; and/or
- In those who are at high risk for medication abuse due to psychiatric issues, who have engaged in aberrant drug-related behaviors, or who have a history of substance abuse.

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

Confirmation of drug screens is only indicated when the result of the drug screen is different than that suggested by the patient's medical history, clinical presentation or patient's own statement.
Limitations:
A qualitative drug screen is not medically reasonable or necessary to screen for the same drug with both a blood and a urine specimen simultaneously.

Medicare regards drug screening for medico-legal purposes (e.g., court-ordered drug screening) or for employment purposes (e.g., as a pre-requisite for employment or as a requirement for continuation of employment) as not medically necessary.

Local Coverage Determination (LCD) for Qualitative Drug Screening (L28145):

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.

| Plan Type                              | Prior Authorization
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>No</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>No</td>
</tr>
<tr>
<td>Medicare HMO Blue℠</td>
<td>No</td>
</tr>
<tr>
<td>Medicare PPO Blue℠</td>
<td>No</td>
</tr>
</tbody>
</table>

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

**CPT Codes**

<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>80100</td>
<td>Drug screen, qualitative; multiple drug classes chromatographic method, each procedure</td>
</tr>
<tr>
<td>80101</td>
<td>Drug screen, qualitative; single drug class method (eg, immunoassay, enzyme assay), each drug class</td>
</tr>
<tr>
<td>80102</td>
<td>Drug confirmation, each procedure</td>
</tr>
<tr>
<td>80104</td>
<td>Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure</td>
</tr>
</tbody>
</table>

**HCPCS Codes**

<table>
<thead>
<tr>
<th>HCPCS codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0431</td>
<td>Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter</td>
</tr>
<tr>
<td>G0434</td>
<td>Drug screen, other than chromatographic; any number of drug classes, by CLIA waved test or moderate complexity test, per patient encounter</td>
</tr>
</tbody>
</table>
**Description**
Patients in pain management programs and substance abuse treatment may misuse prescribed opioids and/or may use nonprescribed drugs. Thus, patients in these settings are often assessed before treatment and monitored while they are receiving treatment. Urine drug screening is a monitoring strategy; it is most often used as part of a multifaceted intervention that includes other components such as patient contracts.

**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)

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

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

Another 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 standardized techniques for detecting drugs in urine exist. Other biological specimens eg, 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.

**Urine drug testing**
There are 2 primary categories of urine drug testing.

**Immunoassay testing (ie, qualitative testing, screening):** These tests can be performed either 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 to an opiate immunoassay can be due to morphine or hydromorphone. The degree of crossreactivity, ie, an antibody’s reactivity with a compound other than the target of the test, varies widely among immunoassays.

Immunoassay findings are generally reported qualitatively as either positive (drug level above a prespecified threshold) or negative (drug level below a prespecified threshold). Raising or lowering the threshold thus changes the proportion of positive tests. A negative test is interpreted as a level below the threshold and does not necessarily mean that the drug or metabolite is absent.
Immunoassays generally have a rapid turnaround time, within minutes for onsite tests and 1 to 4 hours for laboratory-based tests. (3)

**Specific drug identification (ie, quantitative testing, confirmatory testing):** Confirmatory tests are always performed in a laboratory. 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. (4)

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 eg, 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.

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.

Existing protocols vary for use of qualitative versus quantitative tests. Some settings conduct 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 immunoassays.

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 1 factor in the overall assessment of patients’ ability to adhere to treatment. (5)

**Summary**
There is limited published evidence on the diagnostic accuracy and clinical utility of urine drug testing in the pain management and substance abuse treatment settings. There are no randomized controlled trials (RCTs) that isolate the potential effect of urine drug testing on patient management/health outcomes in the pain management setting. One RCT was identified on urine drug testing of patients in
substance abuse treatment; that trial focused on the specific situation of testing to determine eligibility for take-home methadone. Based on the available evidence and clinical input, urine drug testing may be considered medically necessary under specific conditions listed in the policy statements.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/2014</td>
<td>Medicare local coverage determination for Qualitative Drug Screening (L28145) added.</td>
</tr>
<tr>
<td>7/2014</td>
<td>New medical policy describing medically necessary and not medically necessary indications. Effective 7/1/2014.</td>
</tr>
</tbody>
</table>

**Information Pertaining to All Blue Cross Blue Shield Medical Policies**

Click on any of the following terms to access the relevant information:

- [Medical Policy Terms of Use](#)
- [Managed Care Guidelines](#)
- [Indemnity/PPO Guidelines](#)
- [Clinical Exception Process](#)
- [Medical Technology Assessment Guidelines](#)

**References**


