

# Medical Necessity Considerations for Clinical Drug Testing

## Key highlights

- Many guidelines and policies exist that outline appropriate use for testing based on a specific clinical need
- Ordering providers should only order those tests that they believe are medically necessary for each individual patient, as documented in the patient's medical record
- Labcorp is not in a position to make an independent decision about the medical necessity of the tests being ordered

## Clinical Utility of Drug Testing

Drug testing provides physicians with information relevant to the treatment of patients who are prescribed controlled substances, including opioid pain medications, antianxiety medications, stimulants and drugs to treat substance use disorder. While urine drug testing can be a critical component in patient care, Medicare and commercial managed care payers have become concerned about inappropriate utilization. Many guidelines and policies exist that outline appropriate use for testing based on a specific clinical need. These guidelines typically reflect a risk-based approach to medical necessity, with specific coverage criteria applicable to patients who are on chronic opioid therapy or being treated for substance-use disorders with medication-assisted treatment.

## Drug Testing in Medication-Assisted Treatment (MAT)

Treatment for opioid use disorder, like any other chronic disease, requires ongoing evaluation and modification of the treatment plan as needed. Urine drug testing plays an important role in supporting the care of patients in MAT programs. Treatment professionals agree that monitoring drug use during MAT can be a powerful incentive for abstinence, and it can also provide an early indication of a return to drug use.

*Scope of testing:* Use of a routine panel based on the most commonly used illicit and prescription drugs in a given treatment population is generally acceptable. However, providers should also consider the individual patient's clinical needs and self-reported substance use. In addition, providers should consider regional patterns of use.<sup>1</sup>

*Frequency:* More frequent testing at the initiation of therapy is advised. The American Society of Addiction Medicine (ASAM) recommends weekly testing in early recovery and less frequent testing, but no less than monthly, as the patient becomes more stable. Unannounced, randomized testing is important.<sup>1</sup>

*Methodology considerations:* Presumptive testing should be a routine part of care in MAT. Definitive testing may be beneficial to confirm a presumptive result if a patient disputes the findings or to detect a specific substance not adequately identified by presumptive methods. Definitive testing may also be necessary if the provider needs information such as specific substance and/or quantity of a given drug class.<sup>1</sup>

## Drug Testing in Chronic Opioid Therapy

Outside of the MAT setting, there are many prescribed medications for which a healthcare provider may want to use drug testing to monitor patient compliance. Medical drug monitoring (MDM) is an important tool in evaluating drug therapy in pain management, behavioral health, psychiatry and many other practices where clinicians prescribe controlled substances. Polypharmacy and use of multiple providers across disciplines often complicates the evaluation of these patients.

*Scope of testing:* Due to the risk of drug to drug interactions, drug testing to identify the use of relevant over-the-counter medications, prescribed and non-prescribed drugs and illicit substances is recommended in pain management settings. Many guidelines recommend tiered testing based on patient risk stratification, geographical tendencies and individual patient considerations.<sup>2</sup>

*Frequency:* Baseline testing is recommended before prescribing opioids for chronic pain. In addition, random urine drug monitoring or ongoing testing for these patients should be considered at least annually for low risk patients. Testing two or more times per year for moderate-risk patients, and three or more times per year for high-risk patients, is appropriate.<sup>2-4</sup>

*Methodology considerations:* Definitive testing is recommended and preferred due to superior sensitivity and specificity. However, immunoassay (IA) testing offers some clinical utility. Physicians using presumptive testing should understand the capabilities and limitations for each specific drug/drug class on immunoassay.<sup>2,5,6</sup>

### Individualized Risk-based Medical Necessity Approach

In addition to the clinical need for testing, policies frequently establish indications for coverage based on the documented clinical assessment of the individual patient. Acceptable testing methods and frequency may vary depending on the clinical assessment of the patient. Elements of medical necessity to be identified and documented in the medical record may include the following:

- Patient history, physician exam, and previous lab findings
- Current treatment plan
- Prescribed medication(s)
- Risk assessment plan

An example of payer guidance on frequency is included in tables 1 and 2.<sup>7</sup>

Table 1

Urine Drug Testing for Substance Abuse or Dependence		
Patient's Day of Abstinence	Frequency Presumptive Testing	Frequency Definitive Testing
0-30 consecutive days	Not to exceed 3 per rolling 7 days	Not to exceed 3 per rolling 7 days
31-90 consecutive days	Not to exceed 3 per rolling 7 days	Not to exceed 3 per rolling 30 days
>90 consecutive days	Not to exceed 3 per rolling 30 days	Not to exceed 3 per rolling 90 days

Table 2

Urine Drug Testing for Patients on Chronic Opioid Therapy (COT)		
Risk Group	Baseline	Frequency of Testing
Low risk	Prior to initiation of COT	Presumptive and definitive testing not to exceed 2 times in a rolling 365 days
Moderate risk	Prior to initiation of COT	Presumptive and definitive testing not to exceed 2 times in a rolling 180 days
High risk	Prior to initiation of COT	Presumptive and definitive testing not to exceed 2 times in a rolling 90 days

### Patient Risk Assessment

Patient risk assessment should be conducted prior to initiating COT and throughout treatment. The U.S. Centers for Disease Control and Prevention (CDC) outlines several steps that may be used to evaluate a patient's risk potential for misuse and diversion. Some of these steps include evaluating known risk factors and utilizing screening tools.<sup>3</sup>

*Known risk factors:* Examples of known risk factors for evaluating the risk of opioid harm or misuse include<sup>3,8</sup>:

- Illegal drug use, and/or prescription drug use for nonmedical reasons
- History of substance use disorder and/or overdose, including personal or family history of alcohol and/or drug abuse
- Presence of psychiatric or mental health conditions, such as depression and/or anxiety



- Sleep-disordered breathing, including sleep apnea
- Concurrent benzodiazepine use
- Younger patient age

*Screening tools:* A few examples of screening tools to assess patient risk with COT include<sup>3,8</sup>:

- Screener and Opioid Assessment for Patients with Pain (SOAPP<sup>®</sup>)
- Opioid Risk Tool (ORT<sup>®</sup>)
- Diagnosis, Intractability, Risk, Efficacy (DIRE<sup>®</sup>)
- Mental Health Assessment to screen for psychiatric or mental health conditions

### **Methodology-based Medical Necessity Considerations**

Several coverage policies include specific coverage indications depending on the testing methodology utilized by the performing laboratory. These coverage indications are in addition to the patient risk assessment that may be performed and documented in the medical record.

Presumptive (screening) drug testing uses methods that include immunoassays and thin layer chromatography. These tests typically provide negative, positive or numeric results to identify the presence or absence of drugs or drug classes but do not identify a specific drug within a larger drug class. Presumptive testing results may be subject to methodology-specific limitations, including limited or no detection for some drugs, or potential false positives that should be considered when interpreting these results.<sup>7</sup>

Definitive (confirmation) drug testing uses methods that include mass spectrometry with chromatographic analysis, GC/MS and LC/MS-MS. Definitive testing methods typically provide qualitative or quantitative results for each individual drug and metabolite and can identify a specific drug that is present within a larger family of drugs (drug class).<sup>7</sup>

There are some specific indications for both presumptive and definitive drug testing. For example, definitive drug testing may be indicated when<sup>7</sup>:

- The result of the presumptive test is positive and inconsistent with the patient's medical history
- The result of the presumptive test is positive but is unable to identify the specific drug that is present within the drug class
- The result of the presumptive test is negative and inconsistent with the patient's medical history
- The patient risk assessment coverage criteria are met and there is no presumptive test available for the specific drug (e.g., certain synthetic or semi-synthetic opioids are not detected by presumptive tests)
- Confirmation of metabolite presence is required to identify potential drug diversion (e.g., when evaluating whether a patient is exhibiting potential "pill scraper" behavior, it may be helpful to identify whether both parent and metabolite compounds are present in the patient specimen)
- Definitive testing is usually not required for drugs where false positive results are rare (e.g., cocaine presumptive methods do not typically cross-react with other compounds or drugs, thereby reducing the occurrence of false positive results)

### **Non-covered Laboratory Testing Services<sup>7</sup>**

Many coverage policies also provide examples of services that are considered medically unnecessary and therefore are not covered. Non-covered services can include:

- Blanket orders (i.e., using the same order for every patient, every time, regardless of individual assessment or prior lab results)
- Reflex to definitive urine drug testing when presumptive testing is performed at point of care (i.e., it is not appropriate to order definitive testing prior to reviewing the presumptive test results)
- Routine standing orders for all patients

- Physician performed presumptive point of care testing (POCT) and physician ordered presumptive immunoassays testing from a reference laboratory
- Drug testing for two different specimen types from the same patient on the same date of service for the same drugs (i.e., it is not appropriate to order blood and urine testing simultaneously)

### Healthcare Provider’s Responsibility

Ordering providers should only order those tests that they believe are medically necessary for each individual patient and maintain supportive medical record documentation. Submission of testing that is considered medically unnecessary may result in coverage denials.

Please note that when ordering tests, Labcorp is not in a position to make an independent decision about the medical necessity of the tests you are ordering. The laboratory relies on the test order as supportive of medical need of the testing, as documented in the patient’s record.

### Summary

Many payer policies follow society guidelines and reflect a risk-based approach to medical necessity, with specific coverage criteria based on the clinical need for testing, individualized patient risk, and methodology considerations. Covered indications for urine drug testing may be broken into:

- Diagnosis and treatment for substance abuse or dependence (MAT)
- Treatment for patients on chronic opioid therapy including medical drug monitoring (MDM)

Within these indications, acceptable testing methods and frequency may vary. Table 3 summarizes the general differences between guidelines for these patient populations.

Table 3

Clinical Setting	Frequency	Methodology	Scope of Testing	Guideline(s) and Publications
<b>MAT</b>	Weekly to monthly	Presumptive with some definitive to identify metabolites and/or confirm disputed results	Most commonly used illicit and prescription drugs	ASAM <sup>1</sup>
<b>MDM</b>	Monthly to yearly	Definitive preferred in some instances or drugs/drug classes; and testing for many relevant drugs is only available via definitive methods	Relevant OTC drugs, prescribed and non-prescribed drugs, illicit substances	AACC, <sup>2</sup> CDC, <sup>3</sup> AAPM, <sup>4</sup> ASIPP <sup>6</sup>

### References

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