

OHCA Guideline

Medical Procedure Class:	Controlled Substance Monitoring and Drugs of Abuse Testing
Initial Implementation Date:	January 1, 2015
Last Review Date:	August 3, 2020
Effective Date:	April 13, 2021
Next Review/Revision Date:	April 2024
* This document is not a contract, and these guidelines do not reflect or represent every conceivable situation. Although all items contained in these guidelines may be met, this does not reflect, or imply, any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.	
<input type="checkbox"/> New Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria	
Summary	
Purpose:	To provide guidelines to assure medical necessity and consistency in the prior authorization process.
Definitions	
<p><u>PRESUMPTIVE DRUG TESTING:</u> Presumptive drug testing is used to identify possible use or non-use of a drug or drug class. A presumptive test may be followed by a definitive test in order to specifically identify drugs or metabolites. Urine is the best specimen for presumptive screening as blood is relatively insensitive for many common drugs, including psychotropic agents, opioids and stimulants. When obtained, results can be expressed as a negative/positive result or as a numerical result. Multiple methods can be utilized to perform presumptive testing, including direct optical observation, instrument assisted direct optical observation or utilization of chemical analyzers.</p> <p><u>DEFINITIVE DRUG TESTING:</u> Definitive drug tests are qualitative or quantitative and may be used to identify possible use or non-use of a specific drug. These tests identify specific drugs and associated metabolites, if performed. A presumptive test is not always required in order to proceed to definitive drug testing. Definitive drug testing is performed when it is medically necessary to identify specific medications, illicit substances and metabolites. Urine is typically the sample used to obtain these results. Results are reported as absent or present and listed in concentrations of nanograms per milliliter (ng/ml). Testing methods are limited to gas chromatography-mass spectrometry (GC-MS) or Liquid chromatography-mass spectrometry (LC-MS, or HPLC-MS).</p> <p><u>THERAPEUTIC DRUG ASSAYS:</u> Therapeutic assays are used to monitor clinical responses to a known, prescribed medication. These assays are usually quantitative tests and the <i>specimen is whole blood, serum, plasma or cerebrospinal fluid</i>. Routine testing of <i>therapeutic</i> drug levels when there is no impact to the patient's treatment plan is not allowed. The use of these codes for drug testing is inappropriate and not allowed. Therapeutic drug assays do not require prior authorization, but are only allowed when the member is being treated with a specific medication listed in the assay section.</p> <p><u>SPECIMEN VALIDITY TESTING</u> - is used to determine if a specimen is diluted or has been adulterated or substituted. Most basic urine immunoassays have specimen validity checks built into the screening process</p>	

and allow for basic determination of sample tampering. Specimen validity testing (SVT), consisting of pH, specific gravity, oxidants, creatinine, or other test, is considered to be a quality measure and **coverage is excluded**. If the physician believes the patient has produced adulterated or substituted urine, and no alternative matrix sampling is available (i.e., blood), the treating provider should consider witnessed urine collection.

Description

Drug testing provides objective information to assist clinicians in identifying the absence or presence of drugs or drug classes in the body to assist with making treatment decisions. Testing for drugs of abuse to monitor treatment compliance should be included in the treatment plan for pain management when chronic opioid therapy is involved. Some indications for testing for patients on Chronic Opioid Therapy (COT) include:

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

CPT Codes Covered Requiring Prior Authorization (PA)

G0480 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 GC/MS (any type, single or tandem) and LC/NS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase); qualitative or quantitative, all sources, includes specimen validity testing, per day, 1-7 drug class(es), including metabolites (s) if performed.

G0481 8-14 drug class(es)

G0482 15-21 drug class(es)

G0483 22 or more drug class(es)

Approval Criteria

I. GENERAL

Drug screening and testing is indicated in several populations, including but not limited to neonates suspected prenatal drug exposure; symptomatic patients with possible multiple drug ingestion or unreliable history (usually seen in the emergency room); those patients undergoing substance abuse treatment; or patients in chronic pain management with chronic opioid therapy.

Note: THIS GUIDELINE IS APPLICABLE TO DRUG SCREENING/TESTING IN THOSE PATIENTS IN CHRONIC PAIN MANAGEMENT WITH CHRONIC OPIOID THERAPY (COT).

SUBJECT: Presumptive Drug Testing (80305, 80306, 80307)
Definitive Drug Testing (G0659; G0480-G0483)
Therapeutic Drug Assays (80150-80299)

NOTE: Drug testing may not be limited to codes listed above; thus, all codes/tests submitted for drug testing on laboratory specimens must meet medical necessity requirements per OHCA policy, or as determined by OHCA physician review.

II. INDICATIONS

POLICY

OHCA will reimburse for *medically indicated laboratory services*. Medical necessity criteria is defined in **OAC 317:30-3-1(f)**. Drug screening for medico-legal purposes (e.g., court-ordered drug screening) and for employment purposes (e.g., as a pre-requisite for employment or as a requirement for continuation of employment) is **not considered medically necessary** by OHCA. Testing is not covered for patient sample/sources such as saliva, oral fluids, and hair. Urine is the preferred biologic specimen for testing because of the ease of collection, storage, and cost-effectiveness. Urine drug testing cannot detect the amount of drug ingested/used, the time of use, or the means of delivery. **There is no coverage of testing of two different specimen types (blood and urine) from the same patient on the same date of service.**

PRESUMPTIVE DRUG TESTING is allowed once per day without authorization utilizing one of the 3 CPT codes 80305, 80306, or 80307. This test is billed depending on the methodology used for the test, regardless of the number of classes tested. This testing is used when there is a medical need to determine the presence or absence of drugs or drug classes in a sample. Reasons providers perform presumptive drug testing include:

- To identify an absence of a prescribed medication and potential for abuse, misuse and diversion;
- To identify non disclosed substances, such as alcohol, unsanctioned prescriptions or illicit substances;
- To identify substances that could contribute to adverse reactions or drug-drug interactions;
- To assist the provider with assessing compliance of the patient with his/her treatment plan.

DEFINITIVE DRUG TESTING may be reasonable and necessary based on patient specific indications, including historical use, medication response, and clinical assessment, when accurate results are necessary to make clinical decisions. The clinician's rationale for the definitive drug testing and the tests ordered must be documented in the patient's medical record. Definitive drug testing may be medically indicated for the following:

- To Identify a specific substance or metabolite that is inadequately detected or not detected by a presumptive drug test, such as fentanyl, meperidine, synthetic cannabinoids or other synthetic/analog drugs;
- To definitively identify specific drugs in a large family of drugs;
- To identify drugs when a definitive concentration of a drug is needed to guide management (e.g., discontinuation of THC use according to a treatment plan);
- To identify a negative, or confirm a positive, presumptive drug test result that is inconsistent with a patient's self-report, presentation, medical history, or current prescribed pain medication plan;
- To rule out an error as the cause of a presumptive drug test result;

- To identify non-prescribed medication or illicit use for ongoing safe prescribing of controlled substances when medically necessary, as evidenced by risk assessment, PMP database search results, random pill counts, aberrant behavior and overall clinical presentation; and
- For use in a differential assessment of medication efficacy, side effects, or drug-drug interactions.

In all cases, drugs or drug classes for which *definitive* testing is performed should reflect only those likely to be present, based on the patient's medical history, current clinical presentation and illicit drugs that are in common use. In other words, it is NOT medically necessary or reasonable to routinely test for substances (licit or illicit), which are not used in the patient treatment population or, in the instance of illicit drugs, in the community at large. The ordering/referring provider must issue a written order for all drugs to be tested individualized to the patient. Copies of the test results alone without a proper clinician order for the test are not sufficient documentation to support a claim for the testing services.

Based on the patient-specific treatment, clinicians must select and order the specific drug(s) or drug classes for testing. The rationale for this selection must be documented and available in the patient record. **Routine definitive testing or non-specific panel testing for all of the drugs/drug classes is excluded from coverage as not medically indicated. Automatic definitive testing for any drug is not reasonable and necessary without patient specific indications. The test must be utilized only if it is going to affect patient care.** If a previous presumptive drug test is negative, no further testing is necessary unless the clinician provides documentation of aberrant behavior to support the medical necessity of performing subsequent definitive testing. It is generally not appropriate to order definitive testing of a drug if the presumptive drug screen result is negative for an illicit substance.

Only patient-specific orders documented in the medical record are considered reasonable and necessary.

Nonspecific orders, aka “standing orders,” are not considered reasonable and necessary for patient management.

When presumptive drug testing is performed at a site other than the point of contact (physician office), and an unexpected drug(s) or metabolite(s) is observed on a single procedure (single solid/mobile phase procedure), the **LABORATORY IS REQUIRED** to contact the ordering physician to obtain an order for definitive drug testing.

If the physician determines the drug/metabolite has clinical significance for the management of the given patient, definitive drug testing may be necessary. Not all incidental drug(s) or metabolite(s) require quantitation or further testing. Standing orders for identification of incidental drug(s) or metabolite(s) are not allowed by OHCA.

DOCUMENTATION

When patients are under the care of a physician for chronic pain management and/or opioid treatment, the medical record *should* include the following information; however, not all documents may be included in the medical documentation and the nurse reviewer should utilize clinical judgment in what is pertinent to the provider’s request:

- Treatment plan which adheres to the appropriate state regulatory requirements;
- Patient history and physical;
- Review of previous medical records if treated by other previous physician for pain management;
- Review of all radiographs and/or laboratory studies, pertinent to the patient's condition;
- Current treatment plan;
- Opioid agreement and informed consent of drug testing;
- List of prescribed medications;
- Risk assessment, as identified by use of a validated risk assessment interview or questionnaire tool, with appropriate risk stratification noted and utilized;
- Documentation of review of prescription drug monitoring data or pharmacy profile as warranted;
- Office/provider monitoring protocols, such as random pill counts, etc.
- Necessary follow up treatment plan or action taken for inconsistent drug test results.

III. FREQUENCY

NOTE: In general, the *recommended* frequency of testing is at the initiation of opioid treatment, compliance monitoring within one – three months later, and random monitoring every 6-12 months. These recommendations are based on multiple professional literature review recommendations and medical policy decisions. However, frequency must be individualized to the patient based on personal history, risk and behaviors. The frequency of definitive drug testing is based on a complete clinical assessment of the individual's risk potential for abuse and diversion using a validated risk assessment interview or questionnaire and should include the patient's response to prescribed medications and the side effects of medications. Ongoing testing may be medically necessary based on the patient history, clinical assessment, including medication side effects or inefficacy, suspicious behaviors, self-escalation of doses, doctor-shopping, indications or symptoms of illegal drug use, evidence of diversion, or other documented clinical change in the patient's behavior.

- **Frequency of Presumptive Drug Testing:**

One unit of 80305, 80306, or 80307 is allowed per member per day. There are no annual limits set on these tests. However, it would not be appropriate to perform these tests on every visit. These tests do not require prior authorization.

- **Frequency of Definitive Drug Testing:**

HCPCS **G0659** is a definitive test utilizing methods to identify individual drugs and distinguish between structural isomers, not necessarily stereoisomers, performed without calibrations or quality control sampling, **regardless of the number of drug classes**. G0659 is not allowed as OHCA expects quality services provided to their members.

G0480, G0481, G0482 and **G0483** are based on the number of **drug classes** tested, regardless of the methodology.

The **frequency of drug testing** should be based, in part, on the assessed risk that the chronic opioid therapy patient will engage in medication-aberrant behavior (or illicit drug use behavior). Stratifying patients into

different risk categories is essential to appropriate pain management treatment and opioid prescribing. Several risk assessment tools are available for stratifying risk factors. The Opioid Risk Tool (ORT); Pain Medication Questionnaire (PMQ); Diagnosis, Intractability, Risk, Efficacy Score (DIRE); and the Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R) are widely accepted tools for opioid risk assessment. A formal psychological assessment can be used as well. Risk assessments typically categorize patients into low-, moderate-, and high-risk groups. This risk should be utilized to assist in determining the frequency of drug testing.

- **LOW RISK**, based on a validated risk assessment tool, the **frequency of periodic definitive** testing should be **every one to two years**.
- **MODERATE RISK**, based on a validated risk assessment tool, the **frequency of periodic definitive** testing should be **every six to twelve months**.
- **HIGH RISK**, based on a validated risk assessment tool, the **frequency of periodic definitive** testing should be **every three to six months**.
- Patients considered at low to moderate risk who subsequently have aberrant drug testing results or display aberrant behaviors should be moved into the high-risk category.

Once the risk assessment has been completed and the risk category has been determined, a baseline testing should be performed. **BASELINE TESTING** should be used to identify the presence of illicit substances *prior to initiating treatment* involving controlled medications, and to confirm the presence or absence of the prescribed drug/drug class where possible and in accordance with the patient's documented treatment history. Patient baseline drug testing should be conducted and reviewed prior to the initial issuance or dispensing of a controlled substance prescription if possible. When a patient enters chronic opioid therapy with a new provider, baseline testing should be performed. ***(For the purpose of this guideline, baseline testing may not be relevant to the review and the patient most likely has already had baseline testing performed. However, if a patient changes pain management providers, and has exceeded the annual limit of drug tests prompting medical review, this may be necessary to allow if the new provider cannot obtain previous laboratory results or history.)***

IV. CONTINUED MEDICAL NECESSITY

Chronic opioid therapy patients assessed at a higher risk for medication misuse and illicit drugs require more frequent testing than chronic pain patients assessed at a lower risk. In the absence of specific symptoms of medication aberrant behavior or misuse, definitive drug testing is only reasonable and necessary when titrated to patient risk potential. Patients with a history of aberrant drug-related behaviors, psychiatric co-morbidities or substance abuse may require more frequent testing.

It is important to note, drug testing is one component of treating the chronic opioid patient. Other components should include random pill counting, checking the Prescription Monitoring Program database and reviewing the patient's prescription history.

Testing should be random, not necessarily at each scheduled office visit and not necessarily for the same drug tests at each testing event. When performing drug testing on a **random basis**, drug testing should be ordered in a way that minimizes the patient's ability to prepare for the test.

As the nurse reviewer, it may be necessary to perform a claims history review to determine the frequency at which the patient has previously been tested. Claims identified as being submitted each month, or at routine intervals, for testing of the same multiple quantitative levels implies random drug testing is not being performed.

PANELS

A drug test panel is a list (or menu) of drugs or drug classes that can be tested for in a specimen. These can be ordered to identify drugs of abuse or drugs utilized in pain management. No single drug panel is suitable for all clinical uses, and test options should be adapted to clinical needs through proper exercise of clinical decision-making. Marketing test panels by independent clinical laboratories may result in medically unnecessary and unreasonable testing and should be carefully evaluated by the ordering practitioner. Nonspecific orders, aka “standing orders” or routine utilization of panels is **not** considered reasonable and necessary for patient management.

References

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7. CMS CY 2018 CLFS Final Determinations, November 2017.
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