



## **MEDICAL POLICY**

**Subject:** Urine Drug Testing (UDT) for Chronic Opioid Therapy (COT) and Pain Management

**Effective:** 01/01/2017 (Published May 2017)

The use of urine drug testing (UDT) in the management of patients being treated with medications, in particular opioids, for the diagnosis of chronic pain is recognized as an adjunct to monitoring along with clinical exams and pill counts.

### **PURPOSE FOR UDT**

- Monitor compliance of prescribed substances
- Identify use of non-prescribed or illicit substances
- Detect adulterated urine samples and/or diversion

### **INDICATIONS**

- Prior to initiating therapy or when opioids are being considered for treatment of chronic pain
- Prescribed drug has a high potential for abuse or addiction
- Positive risk addiction screening
- Suspected aberrant behavior or misuse
- Acute changes in physical and mental status
- Suspected drug overdose

### **TESTING METHODS**

- Presumptive Drug Testing
- Definitive Drug Testing

# Billing Codes and Processing/Utilization Guidelines

## I. Presumptive Drug Testing

### A. Updated Billing Codes Effective 1/1/2017:

\* Procedure codes 80305 and 80306 are considered point of contact (POC) testing codes. A POC is typically administered in the office and provides a rapid feedback assessment to the prescribing provider for initiating or resuming COT. Procedure code 80306 requires documentation of the instrument used to perform the higher level POC test.

- \*80305: Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g. immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service
- \*80306: Drug test(s), presumptive, any number of drug classes; qualitative, any number of devices or procedures, (e.g. immunoassay) read by instrument-assisted direct optical observation (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service

**\*\*Procedure code 80307 is performed in a clinical laboratory setting. Results are not immediate.**

- \*\*80307: Drug test(s), presumptive, any number of drug classes; qualitative, any number of devices or procedures by instrumented chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF), includes sample validation when performed, per date of service

### B. Processing/Utilization Guidelines:

#### 1. POC Presumptive drug testing:

- The value of POC testing, with immediate results, used in determining a plan of care is recognized. It may be considered reasonable and necessary to perform POC testing (Codes 80305 and 80306) up to 12 times annually. More than 12 times annually requires pre-authorization.
- Testing should be performed randomly. Routine testing at each office visit is not considered random and may result in denial of payment.
- A POC UDT does not have to be associated with an office visit.

#### 2. Laboratory Setting Presumptive drug testing:

- A clinical laboratory presumptive screening test (80307) may be utilized to test for compounds not detected or inadequately detected by a POC. Over (4) presumptive 80307 tests annually requires pre-authorization. Services not pre-authorized may be denied if not deemed medically necessary.
- A POC presumptive test and a laboratory setting presumptive test is not allowed within the same 30-day screening period. **The second submitted test will be denied or considered overpaid if processed.**

- Definitive testing billed in conjunction with procedure 80307 requires pre-authorization to determine the necessity of both procedures and why a direct to definitive test is not indicated.

## II. Definitive Drug Testing

### A. Updated Billing Codes Effective 1/1/2017:

**\* Per the Centers for Medicare & Medicaid Services (CMS) Calendar Year 2017 Clinical Laboratory Fee Schedule Final Determinations - Procedure code G0659 was created to recognize laboratories that are performing a less sophisticated version of a definitive urine drug test. As noted in the Medicare Learning Network (MLN) # MM9946 the updated code description for G0659 is intended to be billed by providers who perform the test “in a single machine run without drug or class specific calibrations...” Drug tests that include but are not limited to - universally recognized internal standards in all samples with methods or drug-specific calibration and matrix-matched quality control material may be billed under codes G0480 through G0483. Documentation of the analyzer used to perform the test is required.**

**\*\*Please refer to the updated code descriptors detailed below.**

- 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 (eg IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase), performed in a single machine run without drug or class specific calibrations; qualitative or quantitative, all sources, includes specimen validity testing, per day.
- G0480: Drug test(s) definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomer), 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: same as G0480 except 8-14 drug classes
- G0482: same as G0480 except 15-21 drug classes
- G0483: same as G0480 except 22 or more drug classes

### B. Processing/Utilization/Pre-Authorization Guidelines

- The value of definitive testing used in the surveillance of COT and pain management patients is recognized. It is considered reasonable and necessary to perform up to 2 definitive tests annually under codes G0659 or G0480. Testing cycles are expected to be random and individualized. Routine testing of all patients in a practice beyond recommended frequency is not considered medically necessary.

- Over (2) definitive G0659 or G0480 tests performed annually requires pre-authorization for payment. Services not pre-authorized may be denied.
- Procedure codes G0481 through G0483 require pre-authorization.
- Maximum of one definitive code is allowed per test date.

### III. DOCUMENTATION

- Medical record documentation should make evident the reason(s) that a presumptive test is required.
- Medical record documentation should make evident the reason(s) that a definitive test is required. This includes documentation to support all classes of drugs requested for testing.
- The need for an increased frequency of testing must be supported by clear and legible medical record documentation. The medical record should clearly document a confirmed inconsistent finding was identified and investigated. It should also clearly document the action plan or change in treatment plans to address the non-compliance.
- Documentation of the CLIA certification number is required for all lab charges.
- Documentation of the analyzer/instrument used to perform the test is required for procedure codes 80306, 80307, G0659, and G0480 through G0483.
- For codes G0481 through G0483 the medical record documentation must indicate the medical necessity for performing more than a 7-drug class test. All tests must be ordered in writing by the treating provider and all drugs/drug classes to be tested must be indicated in the order. A detailed list of all drugs the patient is taking, dosages, instructions, and last time of use (including over-the-counter drugs and herbal preparations) should be clearly documented in the medical record and must be included in the lab order.
- UDT may only be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license) who uses the results in the management of patient care.

### IV. RISK PROFILE CATAGORIES

- Low Risk: *Clinical findings*; Pathology is identifiable with objective and subjective symptoms to support a diagnosis. There is an absence of psychiatric comorbidity.
- Moderate Risk: The patient generally has objective and subjective signs and symptoms of an identifiable diagnostic problem but may have some but not all of the identifiers found under the “high risk” category. This includes patients undergoing prescribed opioid changes without success, patients with a stable addiction disorder, patients in unstable and/or dysfunction social situations, and patients with comorbid psychiatric conditions. Some authors indicate that individuals with treated, or non-active, substance abuse issues or significant family history of this, fall into this category.

- High Risk: Minimal objective findings are documented to explain pain. Symptom magnification can be noted. Hyperalgesia may be present. Underlying pathology can include diseases associated with substance abuse including HIV, hepatitis B and C, and pathology associated with alcoholism or drug abuse. Patients with suicidal risks or poorly controlled depression may be at higher risk for intentional overdose when prescribed opioids for chronic pain. Results of administered screening tests show inconsistencies or there is evidence of elevated risks for substance abuse including personal and/or family history, comorbid psychiatric disease, and/or childhood trauma. Indications of addiction or misuse to suggest high risk may include evidence of adverse consequences/behavior, impaired control over medication use, craving and preoccupation. This category generally includes individuals with active substance abuse disorders or have demonstrated non-compliance. Many authors only include individuals with current active substance abuse or who have demonstrated noncompliance in the “high risk” category.

## **V. Options for requesting Pre-Authorization:**

- E-Services web site (with an established account login) [www.ceiwc.com](http://www.ceiwc.com)
- To set up an eService account: <https://wcis.ceiwc.com/eServices/Register/createAccountProfile>
- Fax request to 410-339-4071

**- Medical Justification For The Requested Service Must Accompany The Request.**

**- Generic Form Letters Are Not Considered Valid And Will Prompt Denial Of The Request**

### **Reference Sources:**

Chesapeake Employers Medical Policy 1/1/2011

CMS Calendar Year (CY) 2017 Clinical Laboratory Fee Schedule – Final Determinations

CMS MLN Matters Number: MM9909

CMS MLN Matters Number: MM9946

Novitas Solutions (L35006)

Palmetto GBA (L35724)

Palmetto GBA (MM0128, V4)

Official Disability Guidelines, Pain, (1/12/16)

## CHESAPEAKE/ IWIF URINE DRUG TESTING BILLING SUMMARY TABLE

### **PRESUMPTIVE – random testing**

- Testing at each office visit is not considered random
- Both POC and laboratory setting testing is not allowed within the same 30-day screening period
- Medical documentation making evident the reason for testing and frequency is required
- Both are subject to denial (refer to policy)

### **POINT OF CARE TESTING (POC) DRUG TESTING- typically administered in office with immediate results**

80305	Direct optical observation	More than 12 times annually requires pre-authorization
80306	Ready by instrument assisted direct optical observation Requires documentation of the POC instrument certification	More than 12 times annually requires pre-authorization

### **CLINICAL LABORATORY SETTING- results are not immediate**

80307	Instrumental chemistry analyzers performed in a clinical laboratory setting Test for compounds not detected or inadequately detected by a POC	More than 4 times annually requires pre-authorization
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### **DEFINITIVE DRUG TESTING- utilizing drug identification methods**

- Expected to be random
- Services not pre-authorized when indicated may be denied
- Documentation must make evident the reason for testing and support for the classes of drugs being tested

G0659	Performed in a single machine run without drug or class specific calibrations	Up to 2 definitive tests yearly	More than 2 requires pre-authorization. Services not pre-authorized may be denied.
G0480	1-7 drug classes	Up to 2 definitive tests yearly	More than 2 requires pre-authorization. Services not pre-authorized may be denied.
G0481	8-14 drug classes	Requires pre-authorization	<ul style="list-style-type: none"> <li>- Documentation must indicate the medical necessity for performing more than a seven-drug class test. All tests must be ordered in writing by the treating provider and all drugs/drug classes to be tested must be indicated in order.</li> <li>- Detailed list of all drugs including dosage, instructions, and the last time of use should be clearly documented in the medical record and the LAB order.</li> </ul>
G0482	15-21 drug classes	Requires pre-authorization	
G0483	22 or more drug classes	Requires pre-authorization	