Applicable To:

- ☑ Medicare - excluding KY
- ☑ Medicaid - excluding AZ and KY
- ☑ CMS Health Plan - CHIP

Claims and Payment Policy: Drug Testing

Policy Number: CPP-115

Original Effective Date: 12/5/2013

Revised Effective Date(s): 5/1/2014; 5/22/2015, 12/16/2015, 4/7/2016; 3/2/2017; 2/21/2018; 5/3/2018; 8/8/2018; 10/24/18; 8/22/2019; 10/31/2019; 3/11/2020

BACKGROUND

Per CMS Local Coverage Determinations (LCDs), urine drug testing provides objective information to assist clinicians in identifying the presence or absence of drugs or drug classes in the body and making treatment decisions. Established maximum frequencies of testing is essential for safe medication management of prescribed substances in risk stratified pain management patients and/or in identifying and treating substance use disorders.

There are two major categories of drugs of abuse monitoring and testing. The first is known as Substance Abuse Disorder (SUD) and occurs when a person's use of alcohol or another substance (drug) leads to health issues or problems at work, school, or home. The second is known as Chronic Opioid Therapy (COT) and is recognized as the use of opioids or substances that act on the opioid receptors that produce morphine-like effects for a period of 90 days or more.

Presumptive/Qualitative drug testing is used when medically necessary to determine the presence or absence of drugs or drug classes (SUD or COT) in a urine sample; results are expressed as negative or positive or as a numerical result.

Definitive/Quantitative/Confirmation is used when medically necessary to identify specific medications, illicit substances and metabolites (SUD or COT); and reports the results of analytes absent or present typically in concentrations such as ng/mL.

Presumptive Versus Definitive UDT

Presumptive testing typically involves testing for multiple analytes based on the beneficiary's clinical history and risk assessment, and must be documented in the medical record.

Presumptive Urine Drug Testing (UDT) may be ordered by the clinician caring for a beneficiary when it is necessary to rapidly obtain and/or integrate results into clinical assessment and treatment decisions. Definitive UDT is reasonable and necessary for the following circumstances:

- Identify a specific substance or metabolite that is inadequately detected by a presumptive UDT;
- Definitively identify specific drugs in a large family of drugs;

- Identify a specific substance or metabolite that is not detected by presumptive UDT such as fentanyl, meperidine, synthetic cannabinoids and other synthetic/analog drugs;
- 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);
- Identify a negative, or confirm a positive, presumptive UDT result that is inconsistent with a patient's self-report, presentation, medical history, or current prescribed pain medication plan;
- Rule out an error as the cause of a presumptive UDT result;
- Identify non-prescribed medication or illicit use for ongoing safe prescribing of controlled substances; and
- Use in a differential assessment of medication efficacy, side effects, or drug-drug interactions.

Definitive UDT 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 UDT and the tests ordered must be documented in the patient's medical record

Additional Medical Necessity Guidance

Clinical literature and State regulatory pain management policies are not uniform in the recommendations associated with drug testing. What can be gleaned from this literature is the trend toward the use of clinical drug testing of new patients (to assess the presence or absence of drugs in the patient system before initiating opioid therapy), as well as random follow-up testing used to monitor the patient's adherence to/compliance with the treatment plan.

For these reasons, it is imperative that the ordering clinician must have freedom of choice in ordering laboratory tests and carefully assess an individual patient's situation and need for drug testing (drug classes and frequency of testing); this information must, according to this policy, be documented in the medical record so that medical necessity may be properly evaluated.

Appropriate documentation must follow current clinical guidelines and State pain regulations or policies governing the initial assessment of the patient and medical need for the use of controlled medications to treat pain, as well as a validated risk assessment process (interview or questionnaire), proper risk stratification, and patient monitoring, which should include use of prescription drug monitoring database information where available.

POSITION STATEMENT

In accordance with CMS substance abuse disorder and chronic opioid disorder monitoring and testing policies (Local Coverage Determinations), Wellcare supports the established maximum unit limitations for drug testing. Wellcare (or its designee) may conduct pre-payment reviews of a provider's records related to services rendered to Wellcare members. When conducting reviews of claims Wellcare may request medical records, itemized bills, invoices or other substantiating documentation to support the charges billed. In a pre-pay review, if additional documentation is needed for Wellcare to accurately adjudicate the claim, the claim may be initially denied and a request sent to the Provider to submit medical records to support payment of the services billed.

Frequency and Max Unit

Type of UDT	Description of Frequency/Unit	Wellcare Denial Code(s) if Frequency/Unit Exceeded

SUDP	• The daily frequency for 80305, 80306, or 80307 set to 1 unit per day in any combination of codes. • The monthly frequency for 80305 set to 2 units per every 30 days, and • The monthly frequency for codes 80306 or 80307 set at 1 unit per every 30 days. • The yearly frequency for 80305 should be set at 24 units per every 365 days. • The yearly frequency for 80306 or 80307 should be 12 units per every 365 days.	**LT313**: Med records required to support drug test over limit
SUDD	• Any combination of definitive testing codes G0480, G0481, G0482, G0483, and G0659 is applicable • Limit those codes to 1 unit per day, 1 unit per every 30 days and 12 units per every 365 days	

[redacted]

COTP	• Any combination of presumptive testing codes 80305, 80306, and 80307 is applicable • Limits on those codes to 1 unit per day, 1 unit per every 30 days, and 12 units per every 365 days	**LT313**: Med records required to support drug test over limit
COTD	• Any combination of definitive testing codes G0480, G0481, G0482, G0483, and G0659 is applicable • Limit any combination of those codes to 1 unit per day, 1 unit per every 30 days and 12 units per every 365 days	
High Acuity COTD/SUDD	• Wellcare may request medical record review of high acuity drug tests (G0482 and G0483)	**LTUDT**: Medical records required to support UDT claim billed

Required Documentation

The following documentation is required as part of the member's medical record once the number of allowable units has been exceeded**.**

- Pages should be legible and include member identification (e.g., name, dates of service(s)) and any providers (including non-physicians) involved in the member's care.
- For member files requested for review, the member's medical record should support the use of the selected code(s). Submitted CPT/HCPCS code should describe the service performed. Also, demonstrating the medical necessity for performing a qualitative and/or quantitative drug test should be included. Tests shall be ordered in writing by the treating provider, indicating drugs and drug classes to be included.
- Medical record documentation (e.g., history and physical, progress notes) maintained by the ordering provider/treating provider must indicate the medical necessity for performing a presumptive and/or definitive drug 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 Member's medical record.
- If the provider of the service is not the ordering/referring provider, the rendering provider must maintain printed copy documentation of the lab results, along with printed copies of the ordering/referring provider's order for the qualitative or presumptive drug test. The provider must include the clinical indication/medical necessity in the order for the qualitative and/or quantitative drug test.

Considerations

- A full panel screen should only be considered for initial testing only when appropriate or when the Member's behavior suggests the use of drugs not identified on the original screening. Medical documentation must support the justification for conducting a full panel screening. Subsequent testing should only be conducted for those substances identified on the Member's initial profile.

- The preferred method of urine drug testing for a Member with a history of poly-substance abuse during the monitoring period is by utilization of a multi-drug screening kit (qualitative analysis by multiplex method for 2-15 drugs or drug classes).

- Drug confirmation by a second method is indicated when either of the following has occurred:
  - The result of the screen is positive and the patient disputes the findings; **OR**
  - The result is negative and the negative finding is inconsistent with the patient's medical history.

- For coverage of confirmatory testing, the test results must be necessary for treatment planning and be requested by the ordering physician. Written orders are required.

- Urine drug testing for medical conditions may be covered. Documentation of medical necessity must be demonstrated and when treatment planning by the requesting provider is dependent upon the test results. Rationale may include, but is not limited to:
  - Altered mental status;
  - Medical or psychiatric condition where drug toxicity may be a contributing factor;
  - Fetal withdrawal syndrome;
  - Possible exposure of the fetus to illicit drugs taken by the mother;
  - To assess and treat Members with a substance abuse disorders;
  - To assess a Member's adherence to prescribed medications.

- Drug testing should be performed at an appropriate frequency based on clinical needs. Substance Use Disorder treatment adherence is often best measured through random testing rather than frequent scheduled testing.
- Reports or clinical information derived from the result of laboratory data (e.g., mathematically calculated) – this information is considered part of the test procedure and therefore not a separately reportable service.

- Medical records must justify each test ordered and must include the rationale of the ordering provider. This may include, but is not limited to the medical necessity of the test ordered, the justification for the billed CPT or HCPCS Code, and the reason why other appropriate tests were not utilized.

- **Should a provider receive a claim denial for exceeding quantity limits, providers have the option to dispute the claim by submitting medical records to justify the medical necessity of additional testing.**

State Specific Criteria

GEORGIA

The State of Georgia's Medicaid contract with Wellcare reads as follows: "*Court-Ordered Evaluations and Services (4.11.6).* In the event a Member requires Medicaid-covered services ordered by a State or federal court, the Contractor shall fully comply with all court orders while maintaining appropriate Utilization Management practices."

SOUTH CAROLINA

Effective for dates of service beginning Jan. 1, 2016, the South Carolina Department of Health and Human Services (SCDHHS) will cover the following presumptive and definitive drug testing classifications. SCDHHS **will reimburse for a maximum of one screening per procedure code per date of service, not to exceed 18 screenings per 12 every 30 day period.** Providers should bill the most appropriate Healthcare Common Procedure Coding System (HCPCS) code for the service rendered.

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.

Drug test(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers utilizing immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry), includes sample validation when performed, per date of service.

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 and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed.

CODING & BILLING

Covered ICD-10 Codes
These diagnoses are specific to **Substance Abuse Disorder Presumptive (SUDP) and Definitive (SUDD).**

SUDP/SUDD	Code Description
F10.11	Alcohol abuse, in remission
F10.20	Alcohol dependence, uncomplicated
F12.11	Cannabis abuse, in remission

F13.11	Sedative, hypnotic or anxiolytic abuse, in remission
F14.11	Cocaine abuse, in remission
F15.11	Other stimulant abuse, in remission
F16.11	Hallucinogen abuse, in remission
F18.10	Inhalant abuse, uncomplicated
F18.11	Inhalant abuse, in remission
F18.120	Inhalant abuse with intoxication, uncomplicated
F18.90	Inhalant use, unspecified, uncomplicated
F19.11	Other psychoactive substance abuse, in remission
F19.20	Other psychoactive substance dependence, uncomplicated
F55.0	Abuse of antacids
F55.1	Abuse of herbal or folk remedies
F55.2	Abuse of laxatives
F55.3	Abuse of steroids or hormones
F55.4	Abuse of vitamins
F55.8	Abuse of other non-psychoactive substances

These diagnoses are specific to **Chronic Opioid Disorder Presumptive (COTP) and Definitive (COTD).**

COTP/COTD	Code Description
F11.11	Opioid abuse, in remission
F11.20	Opioid dependence, uncomplicated
F11.220	Opioid dependence with intoxication, uncomplicated
F11.221	Opioid dependence with intoxication delirium
F11.222	Opioid dependence with intoxication with perceptual disturbance
F11.229	Opioid dependence with intoxication, unspecified
F11.23	Opioid dependence with withdrawal
F11.24	Opioid dependence with opioid-induced mood disorder
F11.250	Opioid dependence with opioid-induced psychotic disorder with delusions
F11.251	Opioid dependence with opioid-induced psychotic disorder with hallucinations
F11.259	Opioid dependence with opioid-induced psychotic disorder, unspecified
F11.281	Opioid dependence with opioid-induced sexual dysfunction
F11.282	Opioid dependence with opioid-induced sleep disorder
F11.288	Opioid dependence with other opioid-induced disorder
F11.29	Opioid dependence with unspecified opioid-induced disorder

Covered CPT Codes

Presumptive Drug Testing:

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, any number of devices or procedures (eg, immunoassay); read by instrument assisted direct optical observation (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures, by instrument chemistry analyzers (e.g., utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (e.g., GC, HPLC), and mass spectrometry either with or without chromatography, (e.g., DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service-*

Covered HCPCs codes:

Definitive Drug Testing

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 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)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed
G0481	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 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, 8-14 drug class(es), including metabolite(s) if performed.
G0482	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 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, 15-21 drug class(es), including metabolite(s) if performed.)
G0483	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 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, 22 or more drug class(es), including metabolite(s) if performed.
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 (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes

Please see the appropriate ICD-10 CM and CPT/HCPCs code pairings for Substance Use Disorder and Chronic Opioid Therapy:

Diagnosis and CPT/HCPCS Pairings for **Substance Use Disorder**

Diagnosis	CPT (presumptive)	HCPCS (definitive)	Denial Code
F10.11 F10.20	80305 80306 80307	G0480 G0481 G0482 G0483	LT 313

F12.11		G0659	
F13.11			
F14.11			
F15.11			
F16.11			
F18.10			
F18.11			
F18.120			
F18.90			
F19.11			
F19.20			
F55.0			
F55.1			
F55.2			
F55.3			
F55.4			
F55.8			

Diagnosis and CPT/HCPCS Pairings for **Chronic Opioid Therapy**

Diagnosis	CPT (presumptive)	HCPCS (definitive)	Denial Code
F11.11	80305 80306 80307	G0480 G0481 G0482 G0483 G0659	LT 313
F11.20			
F11.220			
F11.221			
F11.222			
F11.229			
F11.23			
F11.24			
F11.250			
F11.251			
F11.259			
F11.281			
F11.282			
F11.288			
F11.29			

NOTE: Some codes use QW, a modifier to indicate CLIA-Waived. If a CLIA approved facility or physician is using a CLIA-Waived test they must indicate this on the code being used for reimbursement purposes. Physicians must have one of the following to qualify for CLIA status: COW – CLIA Certificate of Waiver or COA – CLIA Certificate of Accreditation.

Listing not all inclusive. Please reference CMS National and Local Coverage Determinations for specific medical necessity and coverage.

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

DEFINITIONS

Qualitative Drug Testing	Generally used to determine the presence or absence of drug or drug metabolite in the sample. The test result is expressed in non-numerical terms, with a negative or positive result.
Quantitative Drug Testing	Generally used when it is medically necessary to determine the specific quantity of drug or drug metabolite present in the sample. The test result is expressed in numerical terms.
Confirmation/Definitive Testing	Generally used to evaluate initial qualitative screening results to minimize the potential of a clinician relying on a false negative or positive result. Confirmation testing is often recommended when initial screening involves a CLIA-waived or moderate immunoassay screening, but is not medically necessary in all patient cases. A confirmation test order must be medically necessary and reasonable and patient self-report may, in some cases, reduce the need for confirmation of screen results.
Drug test panel	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 in pain management.
Chronic Opioid Therapy (COT)	Use of Opioids or substances that act on the opioid receptors that produce morphine-like effects for a period of 90 days or more.
Substance Abuse Disorder (SUD)	Substance abuse disorder occurs when a person's use of alcohol or another substance (drug) leads to health issues or problems at work, school, or home. This disorder is also called substance abuse.
COT Baseline Testing	Initial presumptive and/or definitive COT patient testing may include amphetamine/ methamphetamine, barbiturates, benzodiazepines, cocaine, methadone, oxycodone, tricyclic antidepressants, tetrahydrocannabinoid, opioids and synthetic/analog or “designer” drugs.
COT Monitoring Testing	

	Ongoing testing may be medically reasonable and medically necessary based on the patient history, clinical assessment, (including medication side effects or inefficacy), suspicious behaviors, self-escalation of dose, doctor-shopping, indications/symptoms of illegal drug use, evidence of diversion, or other clinician documented change in affect or behavioral pattern.
Definitive Drug Testing	A type of testing that identifies a specific drug or metabolite by use of a specific test. This type of testing is in contrast to a "screening test," which is class-based immunoassay drug testing.
Presumptive Drug Testing	Presumptive drug tests are used to detect the presence or absence of a drug or drug class; they do not typically indicate a specific level of drug but rather give a positive or negative result. A presumptive drug test may be followed with a definitive drug test in order to identify specific drugs or metabolites.
CLIA-Waived Laboratory Testing	A CLIA Waived test is categorized as a 'simple laboratory examination or procedure that has an insignificant risk of an erroneous result,' meaning the tests can be performed by untrained users at point-of-care (POC) locations across the country.

REFERENCES

1. Local coverage determination: Drugs of abuse testing (L34457). Centers for Medicare and Medicaid Services Web site. http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Effective April 2, 2015. Accessed January 7, 2020
2. Local coverage determination: Controlled substance monitoring and drugs of abuse testing (L36668). Centers for Medicare and Medicaid Services. Retrieved from: http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Effective Date: June 28, 2016. Accessed January 7, 2020.
3. South Carolina Medicaid Manual. Retrieved from: https://www.scdhhs.gov/internet/pdf/manuals/Physicians/Section%202.pdf. Accessed January 7, 2020.
4. Georgia Medicaid Manual. Retrieved from: https://www.mmis.georgia.gov/portal/PubAccessProviderInformation/ProviderManuals/tabid/54/Default.aspx. Accessed January 7, 2020.

IMPORTANT INFORMATION ABOUT THIS DOCUMENT

Claims and Payment Policies (CPPs) are policies regarding claims or claim line processing and/or reimbursement related to the administration of health plan benefits. They are not recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for diagnosing, treating, and making clinical recommendations to the member. CPPs are subject to, but not limited to, the following:

- State and federal laws and regulations;
- Policies and procedures promulgated by the Centers for Medicare and Medicaid Services, including National Coverage Determinations and Local Coverage Determinations;
- The health plan's contract with Medicare and/or a state's Medicaid agency, as applicable;
- Other CPPs and clinical policies as applicable including, but not limited to, *Pre-Payment and Post-Payment Review*.
- The provisions of the contract between the provider and the health plan; and
- The terms of a member's particular benefit plan, including those terms outlined in the member's Evidence of Coverage, Certificate of Coverage, and other policy documents.

In the event of a conflict between a CPP and a member's policy documents, the terms of a member's benefit plan will always supersede the CPP.
The use of this policy is neither a guarantee of payment, nor a prediction of how a specific claim will be adjudicated. Any coding information is for informational purposes only. No inference should be made regarding coverage or provider reimbursement as a result of the inclusion, or omission, in a CPP of a CPT, HCPCS, or ICD-10 code. Always consult the member's benefits that are in place at time of service to determine coverage or non-coverage. Claims processing is subject to a number of factors, including the member's eligibility and benefit coverage on the date of service, coordination of benefits, referral/authorization requirements, utilization management protocols, and the health plan's policies. Services must be medically necessary in order to be covered.
References to other sources and links provided are for general informational purposes only, and were accurate at the time of publication. CPPs are reviewed annually but may change at any time and without notice, including the lines of business for which they apply. CPPs are available at www.Wellcare.com. Select the "Provider" tab, then "Tools" and then "Payment Guidelines".

RULES, PRICING & PAYMENT COMMITTEE HISTORY AND REVISIONS

Date	Action
10/30/2019	RGC Approval