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Prescription Medication and Illicit Drug Testing in the Outpatient Setting

I. Policy Description

Abuse of both prescription and illicit drugs is extremely common. Drugs of abuse (DOA) may be defined as "a drug, chemical, or plant product that is known to be misused for recreational purposes," which can include drugs such as pain relievers that have legitimate prescriptions. Drug tests may be performed for a variety of reasons, such as compliance with treatment program or medical regimen. Numerous biological substances, such as blood, hair, or saliva may be tested, but urine is the most commonly tested biological substance in drug tests.[1]

This policy addresses clinical toxicology in the outpatient setting and does not address forensic testing or therapeutic drug monitoring (TDM). Forensic drug testing is used for legal proceedings and requires secondary confirmatory testing.[2] TDM "involves sampling of plasma or serum drug levels to determine optimal drug dosing."[3]

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

This policy concerns only coverage criteria and does not describe or define the legal responsibility of providers. Providers should refer to state and federal laws for such guidance.

This policy does not address the use of drug testing in the following circumstances:

A. *State, federally regulated, and legally mandated drug testing (i.e., court-ordered drug screening, forensic examinations).*

B. *Non-forensic testing for commercial driver's licensing or any other job-related testing (i.e., as a prerequisite for employment or as a means for continuation of employment).*

As a component of care rendered in an urgent/emergency situation.

PRESUMPTIVE DRUG SCREENING USING URINE SAMPLES

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1) Presumptive drug screening using urine samples (qualitative, semi-quantitative or quantitative) **MEETS COVERAGE CRITERIA** in **any** of the following situations:

   a) To assess an individual being treated for chronic, non-cancer pain when clinical evaluation of the individual (history/signs/symptoms) suggests the use of non-prescribed medications or illegal substances:

      i) Prior to initiating chronic opioid pain therapy in chronic non-cancer pain to determine if the individual has been exposed to controlled substances or potentially confounding illicit drugs.

      ii) To verify an individual's compliance with treatment or identify undisclosed drug abuse as part of routine monitoring for individuals who are receiving treatment for non-cancer chronic pain with prescription opioid pain medication. The random testing interval and drugs selected for testing should be based on the individual's history, condition, and treatment, as documented in the medical record.

         (a) Monitoring of low risk (as defined by a risk assessment tool) individuals on chronic opioid therapy, up to one time per year after initiation of therapy.

         (b) Monitoring of moderate risk (as defined by a risk assessment tool) individuals on chronic opioid therapy, up to two times per year after initiation of therapy.

         (c) Monitoring of high risk (as defined by a risk assessment tool) individuals on chronic opioid therapy, up to four times per year after initiation of therapy.

         (d) For individuals with aberrant behavior (lost prescriptions, multiple requests for early refills, and opioids from multiple providers, unauthorized dose escalation, apparent intoxication, etc.), testing at the time of visit meets coverage criteria.

   b) In pregnant individuals at high-risk for substance abuse in whom the suspicion of drug use exists based on the answers to substance abuse screening questions or as indicated by information from the prescription drug monitoring program (PDMP), as documented in the medical record.

   c) In newborns when there is a history of maternal substance abuse or agitated/altered mental status in the birthing parent.

   d) In candidates for organ transplant who have a history of substance abuse (to demonstrate abstinence prior to transplant).

e) In individuals with a suspicion of or a diagnosis of mental illness (e.g., anxiety disorders, schizophrenia, major depressive disorder, mood disorders, suicidal ideations, substance abuse disorder).

f) In individuals with attention-deficit hyperactivity and disruptive behavior disorders.

g) In cancer patients on opioid pain medication.

h) In individuals with epilepsy.

i) For the management and compliance monitoring of an individual under treatment for substance abuse or dependence at the following frequency (after baseline at initial evaluation) and must be documented in the patient's medical record:

   i) For patients with zero to ninety consecutive days of abstinence, random qualitative drug testing at a frequency of one to two per week.

   ii) For patients with greater than ninety consecutive days of abstinence, random qualitative drug testing at a frequency of one to three per month.

j) In individuals where substance abuse is in the differential diagnosis of the presenting conditions.

DEFINITIVE DRUG TESTING

2) Confirmatory/definitive qualitative or quantitative drug testing (up to seven drug classes) **MEETS COVERAGE CRITERIA** when laboratory-based definitive drug testing is specifically requested, the rationale is documented by the patient's treating physician, and any of the following conditions are met:

   a) The result of the presumptive drug screen is different than that suggested by the patient's medical history, their clinical presentation, or patient's own statement (e.g., test was negative for prescribed medications, test was positive for prescription drug with abuse potential, which was not prescribed, test was positive for an illegal drug).

      - **Presumptive Optical Testing – Annual Limit not to exceed 24,**
      - **Presumptive Instrument-Based Testing – Annual Limit not to exceed 12**

   b) For diagnosing and monitoring individuals with substance use disorder or dependence, when accurate and reliable results are necessary for treatment decisions:

      i) Individuals with zero to thirty consecutive days of abstinence, random definitive drug testing at a frequency not to exceed one test per week.

ii) Individuals with thirty-one to ninety consecutive days of abstinence, random definitive drug testing at a frequency of one to three test(s) per month. No more than three definitive drug tests in one month will be allowed.

iii) Individuals with greater than ninety consecutive days of abstinence, definitive drug testing at a frequency of one to three test(s) every three months. No more than three definitive drug tests in a three-month period will be allowed.

- **Definitive Testing – Annual Limit not to exceed 12**

c) For monitoring of individuals on opioid therapy (to ensure adherence to the therapeutic plan, for treatment planning, and for detection of other, non-prescribed opioids).

d) A presumptive test does not exist or does not adequately detect the specific drug or metabolite to be tested (e.g., specific drugs within the amphetamine, barbiturate, benzodiazepine, tricyclic antidepressants, and opiate/opioid drug classes, as well as synthetic/analog or "designer" drugs).

e) To definitively identify specific drugs in a large family of drugs.

f) To identify drugs when a definitive concentration of a drug is needed to guide management.

3) When laboratory-based definitive drug testing is requested for larger than seven drug classes panels, confirmatory/definitive qualitative or quantitative drug testing **DOES NOT MEET COVERAGE CRITERIA**.

4) Confirmatory/definitive qualitative or quantitative or presumptive (qualitative, semi-quantitative or quantitative) drug testing using proprietary tests (e.g., CareView360) **DOES NOT MEET COVERAGE CRITERIA**.

SPECIMEN VALIDITY TESTING

5) Specimen validity testing (e.g., urine specific gravity, urine creatinine, pH, urine oxidant level, genetic identity testing [e.g., NextGen Precision™ Testing]) **DOES NOT MEET COVERAGE CRITERIA**.

GENERAL

6) In all other situations not addressed above, presumptive drug screening and definitive drug testing **DO NOT MEET COVERAGE CRITERIA.**

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NOTES:

Documentation Requirements

The patient's medical record must contain documentation that fully supports the medical necessity for drug testing. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

III. Reimbursement

1. The following IS reimbursed (see complete Coverage Criteria in Letters A and B, Section III above) for:
    a. Presumptive drug screening based upon appropriate clinical criteria (qualitative, semi-quantitative or quantitative);
    b. Definitive drug testing (qualitative or quantitative) for up to seven drug classes when the presumptive drug screening meets one of the following criteria:
        i. The test was negative for prescribed medications, or
        ii. Positive for a prescription drug with abuse potential which was not prescribed, or
        iii. Positive for an illegal drug, or
        iv. A presumptive test does not exist or does not adequately detect the specific drug or metabolite to be tested
    c. Blood specimens in patients with anuric Chronic Renal Failure.
2. The following **IS NOT REIMBURSED**:
    a. Same-day testing of the same drug or metabolites from two different samples (e.g. both a blood and a urine specimen) by either presumptive or definitive analyses
    b. Blanket orders or routine standing orders for all patients in the physician's practice
3. Only urine or oral fluid specimens will be covered except blood specimen will be covered for patients with anuric Chronic Renal Failure.
4. Confirmatory/definitive testing should be supported by documentation of rationale in the patient's medical record.

5. More than one presumptive test result per patient per date of service regardless of the number of billing providers **IS NOT REIMBURSED**:

    a. It is not reasonable or necessary for a provider to perform qualitative point-of-care testing and also order presumptive testing from a reference laboratory on the same specimen.

    b. It is not reasonable or necessary for a provider to perform presumptive immunoassay testing and also order presumptive immunoassay testing from a reference laboratory with or without reflex testing on the same specimen.

IV. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: https://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

V. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or 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; read by instrument assisted direct optical observation (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service

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CPT	Code Description
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without 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
80320–80377	AMA Definitive Drug Class Codes
0007U	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, includes specimen verification including DNA authentication in comparison to buccal DNA, per date of service Proprietary test: ToxProtect Lab/Manufacturer: Genotox Laboratories LTD
0011U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites Proprietary test: Cordant CORE™ Lab/Manufacturer: Cordant Health Solutions
0051U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service Proprietary test: UCompliDx Lab/Manufacturer: Elite Medical Laboratory Solutions, LLC (LDT)
0054U	Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service Proprietary test: AssuranceRx Micro Serum Lab/Manufacturer: Firstox Laboratories, LLC
0079U	Comparative DNA analysis using multiple selected single-nucleotide polymorphisms (SNPs), urine and buccal DNA, for specimen identity verification Proprietary test: ToxLok™ Lab/Manufacturer: InSource Diagnostics

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CPT	Code Description
0082U	Drug test(s), definitive, 90 or more drugs or substances, definitive chromatography with mass spectrometry, and presumptive, any number of drug classes, by instrument chemistry analyzer (utilizing immunoassay), urine, report of presence or absence of each drug, drug metabolite or substance with description and severity of significant interactions per date of service Proprietary test: NextGen Precision™ Testing Lab/Manufacturer: Precision Diagnostics LBN Precision Toxicology, LLC
0093U	Prescription drug monitoring, evaluation of 65 common drugs by LC-MS/MS, urine, each drug reported detected or not detected Proprietary test: ComplyRX Lab/Manufacturer: Claro Labs
0227U	Drug assay, presumptive, 30 or more drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, includes sample validation Proprietary Test: Comprehensive Screen Lab/Manufacturer: Aspenti Health
0328U	Drug assay, definitive, 120 or more drugs and metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), includes specimen validity and algorithmic analysis describing drug or metabolite and presence or absence of risks for a significant patient-adverse event, per date of service Proprietary test: CareView360 Lab/Manufacturer: Newstar Medical Laboratories, LLC
0517U	Therapeutic drug monitoring, 80 or more psychoactive drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally and maximally effective dose of prescribed and non-prescribed medications Proprietary test: PrecisView® CNS, Phenomics Health™ Inc Lab/Manufacturer: Phenomics Health™ Inc
0518U	Therapeutic drug monitoring, 90 or more pain and mental health drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally effective range of prescribed and non-prescribed medications

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CPT	Code Description
	Proprietary test: SyncView® Pain Lab/Manufacturer: Phenomics Health™ Inc
0519U	Therapeutic drug monitoring, medications specific to pain, depression, and anxiety, LCMS/MS, plasma, 110 or more drugs or substances, qualitative and quantitative therapeutic minimally effective range of prescribed, non-prescribed, and illicit medications in circulation Proprietary test: SyncView® PainPlus Lab/Manufacturer: Phenomics Health™ Inc
0520U	Therapeutic drug monitoring, 200 or more drugs or substances, LCMS/MS, plasma, qualitative and quantitative therapeutic minimally effective range of prescribed and non-prescribed medications Proprietary test: SyncView® Rx Lab/Manufacturer: Phenomics Health™ Inc
G0480	Drug test(s), definitive, utilizing (1) 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)), (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	Drug test(s), definitive, utilizing (1) 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)), (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),

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CPT	Code Description
	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; 8-14 drug class(es), including metabolite(s) if performed
G0482	Drug test(s), definitive, utilizing (1) 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)), (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; 15-21 drug class(es), including metabolite(s) if performed
G0483	Drug test(s), definitive, utilizing (1) 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)), (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; 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

CPT	Code Description
	specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

VI. Evidence-based Scientific References

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