Qualitative Drug Testing for Indications Other Than Mental Health

Guideline Number: MPG264.07
Approval Date: April 14, 2021

Overview
A qualitative/presumptive drug screen is used to detect the presence of a drug in the body. A urine or blood sample may be used. Urine is the best specimen for broad qualitative screening, as blood is relatively insensitive for many common drugs, including stimulants, opioids, and psychotropic agents.

Methods of drug analysis include immunoassay, spectrometry, chromatography, and chemical (“spot”) tests. Analysis is comparative, matching the properties or behavior of a substance with that of a valid reference compound (a laboratory must possess a valid reference agent for every substance that it identifies). Drugs or classes of drugs are commonly assayed by a qualitative/presumptive screen. A test may be followed by confirmation with a second method, only if there is a positive or negative inconsistent finding from the qualitative/presumptive test in the setting of a symptomatic patient. When a presumptive test is negative for a patient on a prescribed medication, a definitive drug test may be performed.

Some examples of drugs or classes of drugs that are commonly assayed by qualitative/presumptive tests, followed by confirmation with a second method, are: alcohols, amphetamines, antipsychotics, antihistamines, barbiturates/sedatives, benzodiazepines, cardiovascular drugs, cocaine and metabolites, methadone, stimulants, opioid analgesics, salicylates, cyclic antidepressants, and others. Focused drug screens, most commonly for illicit drug use, may be more useful clinically.

Qualitative/presumptive screening panels should be used when the results will alter patient management or disposition. A qualitative/presumptive drug screen may be indicated with a symptomatic patient when the history is unreliable, with multiple-drug ingestion, with a patient in delirium or coma, for the identification of specific drugs, and to indicate when antagonists may be used. The clinical utility of drug screens in the emergency setting may be limited because patient management decisions are unaffected, since most therapy for drug poisonings is symptom directed and supportive.

Guidelines
Qualitative/presumptive drug screen is reasonable and necessary when a patient presents with signs or symptoms of substance use toxicity, when the history is unreliable for a symptomatic patient, when there has been a suspected multiple-drug ingestion, and for patients with suspected drug overdose and one or more of the following conditions:
● Seizures with an undetermined history;
● Unexplained coma;
● Severe or unexplained cardiovascular instability (cardiotoxicity);
● Unexplained altered mental status in the absence of a clinically defined toxic syndrome or toxidrome;
● Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome;
● For monitoring patient compliance during active treatment for substance abuse or dependence.

A qualitative/presumptive drug screen is considered reasonable and necessary in patients on chronic opioid therapy:
● In whom illicit drug use, non-compliance or a significant pre-test probability of non-adherence to the prescribed drug regimen is suspected and documented in the medical record; and/or
● In those who are at high risk for medication abuse due to psychiatric issues, who have engaged in aberrant drug-related behaviors, or who have a history of substance abuse.

A qualitative/presumptive drug screen is considered reasonable and necessary in patients with chronic pain to:
● Determine the presence of other substances prior to initiating pharmacologic treatment
● Detect the presence of illicit drugs
● Monitor adherence to the plan of care

A qualitative/presumptive drug screen is not reasonable or necessary to screen for the same drug with both a blood and a urine specimen simultaneously.

Only one presumptive service may be billed per patient, per encounter, regardless of the provider.

Medicare regards drug screening for medico-legal purposes (e.g., court-ordered drug screening) or for employment purposes (e.g., as a pre-requisite for employment or as a requirement for continuation of employment) as not medically necessary.

### Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>80305</td>
<td>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</td>
</tr>
<tr>
<td>80306</td>
<td>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</td>
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<tr>
<td>80307</td>
<td>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</td>
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*CPT® is a registered trademark of the American Medical Association

### Diagnosis Codes

See related [Local Coverage Determinations](#).
Definitions

The following terminology relates to the basic forms of Urine Drug Testing (UDT).

**Qualitative/Presumptive Drug Testing:** To determine the presence or absence of drugs or drug classes in a urine sample

**Quantitative/Definitive/Confirmation:** To identify specific medications, illicit substances and metabolites; reports the results of analytes absent or present typically in concentrations such as ng/mL

References

**CMS National Coverage Determinations (NCDs)**

*NCD 190.24 Digoxin Therapeutic Drug Assay*

**CMS Local Coverage Determinations (LCDs) and Articles**

<table>
<thead>
<tr>
<th>LCD</th>
<th>Article</th>
<th>Contractor</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
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<tbody>
<tr>
<td>L34645 Drug Testing</td>
<td>A56915 Billing and Coding: Drug Testing</td>
<td>WPS</td>
<td>AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY</td>
<td>IA, IN, KS, MI, MO, NE</td>
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<td>L35724 Lab: Controlled Substance Monitoring and Drugs of Abuse Testing</td>
<td>A54799 Billing and Coding: Lab: Controlled Substance Monitoring and Drugs of Abuse Testing</td>
<td>Palmetto</td>
<td>AL, GA, TN, NC, SC, VA, WV</td>
<td>AL, GA, TN, NC, SC, VA, WV</td>
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<td>L35006 Controlled Substance Monitoring and Drugs of Abuse Testing</td>
<td>A56645 Billing and Coding: Controlled Substance Monitoring and Drugs of Abuse Testing</td>
<td>Novitas</td>
<td>AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX</td>
<td>AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX</td>
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<td>L36037 Urine Drug Testing</td>
<td>A56761 Billing and Coding: Urine Drug Testing</td>
<td>NGS</td>
<td>CT, IL, MA, ME, MN, NH, NY, RI, VT, WI</td>
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<td>L36393 Controlled Substance Monitoring and Drugs of Abuse Testing</td>
<td>A57077 Billing and Coding: Controlled Substance Monitoring and Drugs of Abuse Testing</td>
<td>First Coast</td>
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<tr>
<td>L36029 Controlled Substance Monitoring and Drugs of Abuse Testing</td>
<td>A56818 Billing and Coding: Controlled Substance Monitoring and Drugs of Abuse Testing</td>
<td>CGS</td>
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<td>L36668 Controlled Substance Monitoring and Drugs of Abuse Testing</td>
<td>A55001 Billing and Coding: Lab: Controlled Substance Monitoring and Drugs of Abuse Testing</td>
<td>Noridian</td>
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CMS Claims Processing Manual

Chapter 16; §70 Clinical Laboratory Improvement Amendments (CLIA) Requirements

CMS Transmittal(s)

Transmittal 3439, Change Request 9502, Dated 01/15/2016 (Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits)
Transmittal 3471, Change Request 9549, Dated 02/26/2016 (April 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS))
Transmittal 3701, Change Request 9946, Dated 02/03/2017 (Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits)
Transmittal 4169, Change Request 10958, Dated 11/15/2018 (New Waived Tests)
Transmittal 4195, Change Request 11080, Dated 01/11/2019 (New Waived Tests)

MLN Matters

Article MM9502, Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
Article MM9549, April 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS)
Article MM9946, Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
Article SE1105, Revised, Medicare Drug Screen Testing
Article SE18001, Proper Coding for Specimen Validity Testing Billed in Combination with Drug Testing

UnitedHealthcare Commercial Policy

Drug Testing Policy

Other(s)

CMS Clinical Laboratory Fee Schedule

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Summary of Changes</th>
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<tbody>
<tr>
<td>04/14/2021</td>
<td>Supporting Information</td>
</tr>
<tr>
<td></td>
<td>Updated References section to reflect the most current information; no change to guidelines</td>
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<tr>
<td></td>
<td>Archived previous policy version MPG264.06</td>
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Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.
UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

**Terms and Conditions**

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.