Introduction

Urine drug testing is generally done for people in a pain management program or in substance use disorder treatment. Pain management programs work to control pain and improve function while minimizing the use of potentially addictive medications. In substance use disorder treatment the goal is to stop using, and remain free of addictive prescribed or illegal drugs. Usually a patient may be tested for drug use as treatment begins. Testing may also be done intermittently during treatment. After a urine sample is provided, the urine is tested to detect if a particular drug has been used within a set time frame. Results can also show the absence of specific substances. This policy describes when urine drug testing as part of pain management and substance use disorder treatment programs may be considered medically necessary. Drug testing from body sources other than urine is usually considered investigational and therefore not covered.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
### Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Testing</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Presumptive (ie, screening) urine drug testing</strong></td>
<td>Presumptive urine drug testing is testing that uses a method with low sensitivity and/or specificity (usually immunoassay), which establishes preliminary evidence regarding the presence or absence of drugs, metabolites, or a class of drugs.</td>
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</tbody>
</table>

**In the outpatient pain management setting, presumptive urine drug testing is considered medically necessary for any of the following reasons:**

- As part of the initial evaluation upon admission to the program
- At any time that there is suspicion of non-compliance with prescribed treatment
- At any time that there is suspicion of unreported drug use or abuse
- At any time that interval history or symptoms suggest use of non-prescribed medications or illegal substances
- At any time that there is a report of, suspicion of, or evidence of aberrant behavior such as:
  - Lost prescriptions
  - Repeated requests for early refills
  - Prescriptions from multiple providers
  - Unauthorized dose escalation
  - Apparent intoxication
  - Other unusual findings
- For periodic monitoring to check treatment compliance and to check for unauthorized drug use:
  - The frequency is determined by risk stratification according to a standard risk assessment tool such as the Opioid Risk Tool (ORT) or the Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R), or based on clinical risk factors (eg, history of or current substance use disorder, history of overdose, use of high opioid doses, concurrent benzodiazepine use):
    - Low risk: every 12 months
<table>
<thead>
<tr>
<th>Testing</th>
<th>Medical Necessity</th>
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</table>
| ▪ Moderate risk: every 6 months  
▪ High risk or opioid dose >120 MED/day: every 3 months |

**In substance use disorder treatment settings, presumptive urine drug testing is considered medically necessary for any of the following reasons:**

- As part of the initial evaluation upon admission to the program
- Intermittently while in ambulatory (outpatient, intensive outpatient, partial hospitalization) substance use disorder or dual disorders (substance use and mental health) treatment:
  - One to two times/week during the stabilization phase of treatment
  - One time/month during the maintenance phase of treatment
  - One time/week during the maintenance phase of treatment for patients residing in a recovery residence
  - One time/month for patients in office-based medication-assisted treatment (MAT)
  - At any time that there is a report of, suspicion of, or evidence of use or abuse of non-prescribed drugs, illicit drugs, or drugs that have not been authorized or agreed to by the treatment program
  - At any time that there is a report of, suspicion of, or evidence of relapse
  - Repeat testing following a positive test for non-prescribed controlled medications(s) or illicit drug(s), until test is no longer positive or patient is dismissed from the program
- Intermittently while in inpatient or residential substance use disorder or dual disorders (substance use and mental health) treatment:
  - One time only, as part of the initial admission evaluation (because the patient is then in a 24/7 contained setting)
  - At any time that there is reason to suspect that the patient has taken a non-prescribed or illicit drug that the patient or someone else smuggled in
  - At any time that there is reason to suspect that the patient
<table>
<thead>
<tr>
<th>Testing</th>
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</tr>
</thead>
<tbody>
<tr>
<td>has taken a non-prescribed or illicit drug while out of the facility on a pass</td>
<td>Presumptive urine drug testing is considered to be not medically necessary when the criteria above are not met. Alcohol breath testing (breathalyzer) may be considered medically necessary in lieu of urine testing only when there is reason (documented in the medical record) to suspect alcohol ingestion within the past 24 hours and there are no obvious clinical signs or symptoms of alcohol ingestion or intoxication. The use of presumptive testing panels is considered not medically necessary unless all components of the panel meet the medically necessary criteria listed above. Note: A specific individual component of a panel may be considered medically necessary when criteria above are met, and when only the specific individual component is tested for.</td>
</tr>
</tbody>
</table>

### Medical Record Documentation Necessary for Presumptive Testing

- The medical record documents the clinical necessity for presumptive testing based on the criteria above, and documents the medical necessity for each drug or drug class tested, based on individual patient clinical needs, and also documents the information that is expected to be obtained from the testing. Testing that is a program's or facility's or provider's routine or standard testing that is not based on individual patient clinical needs is considered to be not medically necessary.

**AND**

- Urine drug testing is done at no more than the frequencies indicated above for presumptive testing. For urine drug testing that exceeds the indicated frequencies, the medical record documents the specific clinical need for the additional testing based on individual patient clinical needs, and documents the information that is expected to be obtained from the testing. Additional testing that is a program's or facility's or provider's routine or standard testing that is not based on individual patient clinical needs is considered to be not medically necessary.
<table>
<thead>
<tr>
<th>Testing</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definitive (ie, confirmatory) urine drug testing</td>
<td>Definitive urine drug testing is testing that uses a method with high sensitivity and specificity (usually gas or liquid chromatography combined with mass spectrometry), that is able to identify specific drugs, their metabolites, and/or drug quantities.</td>
</tr>
<tr>
<td></td>
<td>Definitive urine drug testing is considered medically necessary in the following situations:</td>
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<tr>
<td></td>
<td>• Presumptive urine drug testing was previously done for a medically necessary reason and the presumptive test result was concerning for one or more of the following reasons:</td>
</tr>
<tr>
<td></td>
<td>o Negative for prescribed medications (indicating possible non-compliance and/or diversion; or may indicate that the patient’s drug level was below the threshold detected by the presumptive testing)</td>
</tr>
<tr>
<td></td>
<td>o Positive for a prescription drug with abuse/addiction potential (controlled medication) that is not being prescribed for the patient</td>
</tr>
<tr>
<td></td>
<td>o Positive for an illicit drug</td>
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<td></td>
<td>o There is reason (documented in the medical record) to suspect that a presumptive testing result is erroneous (false positive or false negative)</td>
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<td></td>
<td>o The patient disputes the results of the presumptive testing</td>
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<td></td>
<td>o There is clinical need (documented in the medical record) to quantify the level of substance that is present</td>
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<tr>
<td>OR</td>
<td>Presumptive testing identified a class of drugs but not a specific drug or drugs, and the patient will not disclose the unauthorized or illicit specific drug or drugs, or, the specific drug or drugs need confirmation to verify compliance</td>
</tr>
<tr>
<td>OR</td>
<td>There is reason (documented in the medical record) to suspect use of a substance that is inadequately detected or inconsistently detected or not detected by presumptive testing, such as:</td>
</tr>
<tr>
<td></td>
<td>o heroin</td>
</tr>
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<td>o synthetic opioids:</td>
</tr>
<tr>
<td><strong>Testing</strong></td>
<td><strong>Medical Necessity</strong></td>
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<td>-------------</td>
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</tr>
<tr>
<td></td>
<td>▪ fentanyl, methadone, meperidine, propoxyphene</td>
</tr>
<tr>
<td></td>
<td>o semi-synthetic opioids:</td>
</tr>
<tr>
<td></td>
<td>▪ oxycodone, oxymorphone, hydrocodone, hydromorphone, buprenorphine</td>
</tr>
<tr>
<td><strong>AND</strong></td>
<td>The medical record documents the clinical necessity for testing for each drug tested, based on individual patient clinical needs, documents the information that is expected to be obtained from the testing, and documents how test results will guide clinical management</td>
</tr>
<tr>
<td></td>
<td><strong>Repeating definitive urine drug testing for the same presumptive testing result is considered not medically necessary.</strong></td>
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<tr>
<td></td>
<td><strong>Definitive urine drug testing is considered not medically necessary when the criteria above are not met.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Definitive urine drug testing that is a program’s or facility’s or provider’s routine or standard testing that is not based on individual patient clinical needs, and is not done for one of the specific reasons noted above, is considered not medically necessary.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>The use of definitive testing panels is considered not medically necessary unless all components of the panel meet the medically necessary criteria listed above.</strong></td>
</tr>
</tbody>
</table>
|             | **Note:** A specific individual component of a panel may be considered medically necessary when criteria above are met, and when only the specific individual component is tested for.
Other Testing | Investigational
--- | ---
Hair / oral fluid / nail / sweat drug testing | Hair drug testing, oral fluid drug testing, nail drug testing, and sweat drug testing are considered investigational in all clinical settings due to insufficient current evidence to support their usefulness in treatment settings.

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
</tbody>
</table>
| 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  
NOTE: Proprietary Laboratory Analysis Code (PLA) for the test ToxProtect from Genotox Laboratories LTD |
| 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  
NOTE: Proprietary Laboratory Analysis Code (PLA) for the test UCompliDx from Elite Medical Laboratory Solutions |
<p>| 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 |
| 0143U | Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, comments including sample validation, per date of service (new code effective 1/1/20) |
| 0144U | Drug assay, definitive, 160 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, comments including sample validation, per date of service (new code effective 1/1/20) |
| 0145U | Drug assay, definitive, 65 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, comments including sample validation, per date of service (new code effective 1/1/20) |</p>
<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0146U</td>
<td>Drug assay, definitive, 80 or more drugs or metabolites, urine, by quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, comments including sample validation, per date of service (new code effective 1/1/20)</td>
</tr>
<tr>
<td>0147U</td>
<td>Drug assay, definitive, 85 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, comments including sample validation, per date of service (new code effective 1/1/20)</td>
</tr>
<tr>
<td>0148U</td>
<td>Drug assay, definitive, 100 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, comments including sample validation, per date of service (new code effective 1/1/20)</td>
</tr>
<tr>
<td>0149U</td>
<td>Drug assay, definitive, 60 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, comments including sample validation, per date of service (new code effective 1/1/20)</td>
</tr>
<tr>
<td>0150U</td>
<td>Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, comments including sample validation, per date of service (new code effective 1/1/20)</td>
</tr>
<tr>
<td>80305</td>
<td>Drug test(s), presumptive, any number of drug classes, any number of devices or procedures (eg, immunoassay); capable of being read by direct optical observation only (eg, dipsticks, cups, cards, 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 (eg, immunoassay); read by instrument assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service</td>
</tr>
<tr>
<td>80307</td>
<td>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</td>
</tr>
<tr>
<td>HCPCS</td>
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</table>
| 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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (eg, to control for matrix
<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td></td>
<td>effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (eg, 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</td>
</tr>
<tr>
<td>G0481</td>
<td>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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (eg, to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (eg, 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</td>
</tr>
<tr>
<td>G0482</td>
<td>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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (eg, to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (eg, 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</td>
</tr>
<tr>
<td>G0483</td>
<td>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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (eg, to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (eg, 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</td>
</tr>
<tr>
<td>G0659</td>
<td>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 without method or drug-</td>
</tr>
</tbody>
</table>
### Pain Management

Aberrant behavior during treatment of pain with opioids is defined by one or more of the following:

- Multiple lost or stolen prescriptions
- Multiple requests for early refills
- Obtaining opioids from multiple providers
- Unauthorized dose escalation
- Apparent intoxication during office visits
- Reports of apparent intoxication during ER visits
- Reports of intoxication from other reliable sources
- Arrests or citations by law enforcement for intoxication
- Diversion of prescribed opioids to other persons
Substance Use Disorder Treatment

**Stabilization Phase**

The stabilization phase (also referred to as the initial phase or early in recovery) is the initial period of substance use disorder treatment during which treatment generally focuses on the following:

- Eliminating use of the substance(s) for which substance use disorder is diagnosed
- Ameliorating any remaining withdrawal symptoms (as distinct from post-acute withdrawal symptoms or PAWS, which can persist for days to months)
- Eliminating use of any other illicit and non-prescribed substances
- Eliminating inappropriate use or abuse of any prescribed psychoactive substances
- Reducing the intensity of cravings
- Evaluating and decreasing the intensity of any co-occurring mental and medical disorders
- Developing a plan to address social, legal, family, employment, and other problems associated with substance use
- Satisfying basic needs for food, clothing, shelter, and safety (when in ambulatory levels of treatment)
- Initiating and stabilizing the dose of medication-assisted treatment (MAT) when MAT is utilized

If a patient re-enters treatment for substance use after a period of abstinence, treatment re-starts with the stabilization phase.

**Maintenance Phase**

The maintenance phase (also referred to as stable in treatment or stable in recovery) is the period of substance use disorder treatment following the stabilization phase during which treatment generally focuses on the following:

- Further reducing the intensity of cravings
- Recognizing and developing skills to deal with relapse triggers
• Developing a relapse prevention plan
• Developing a support system
• Involving family when available and amenable in relapse prevention planning
• Developing skills for coping with, and initiating plans for addressing, major life problems, eg, medical, social, legal, family, employment, and other problems
• Assisting with or providing referrals for help with legal, educational, employment, medical, financial, or other problems that could interfere with treatment retention
• Promoting participation in constructive activities such as employment, education, vocational training, increased parenting activities, volunteer work
• Promoting and assisting with obtaining a sponsor when appropriate
• Providing information about, promoting participation in, and assisting with engagement with, outside/community support groups such as AA, NA, other 12-Step groups, or other similar groups
• Adjusting the dose of medication-assisted treatment (MAT) as needed

**Immunoassay Availability and Diagnostic Capacity**

The following information on immunoassay availability and diagnostic capacity is included in the Washington Agency Medical Directors Group (AMDG) Inter-Agency Guideline on Prescribing Opioids for Pain (2015):

**Natural Opioids (eg, codeine, morphine)**

“Immunoassays for ‘opiates’ are responsive for morphine and codeine but do not distinguish which is present. Confirmatory testing is required to reliably identify drug(s) present. Since codeine is metabolized to morphine and small quantities to hydrocodone, these drugs may be found in the urine. Also, morphine may metabolize to produce a small amount (<10%) of hydromorphone.”
Semisynthetic Opioids (eg, hydrocodone, hydromorphone, oxycodone, oxymorphone)

“‘Opiates’ immunoassays may also detect semisynthetic opioids depending on their crossreactivity pattern. However, a negative result does not exclude use of semisynthetic opioids. Confirmatory testing (GC/MS or LC/MS/MS [liquid chromatography tandem mass spectrometry]) is required to verify compliance with the prescribed semisynthetic opioid(s).

Since hydrocodone is metabolized in small amounts to hydromorphone, both may be found in the urine. Likewise, oxycodone is metabolized to oxymorphone, so these may both be present in the urine of oxycodone users. However, the reverse is not true. In other words, hydromorphone and oxymorphone use does not result in positive screens for hydrocodone and oxycodone, respectively.”

Synthetic Opioids (eg, fentanyl, meperidine, methadone, propoxyphene)

“Current ‘opiates’ immunoassays do not detect synthetic opioids. Thus confirmatory testing (GC/MS or LC/MS/MS) is needed to identify these drugs. If the purpose is to document compliance with treatment, the laboratory can be instructed to remove the cutoff concentration so that the presence of lower concentrations can be identified.”

Interpreting Unexpected Urine Drug Tests Results

The following table on interpreting unexpected results of urine drug tests was adapted from one developed by the Canadian National Opioid Use Guideline Group that was cited by in the American Society of Interventional Pain Physicians guideline on prescribing opioids for chronic noncancer pain.

<table>
<thead>
<tr>
<th>Unexpected Results</th>
<th>Possible Explanations</th>
<th>Possible Actions For the Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test is negative for prescribed opioid</td>
<td>• False negative</td>
<td>• Conduct confirmatory testing, specifying the drug of interest (eg, oxycodone often missed by immunoassay)</td>
</tr>
<tr>
<td></td>
<td>• Noncompliance</td>
<td>• Take a detailed history of a patient’s medication use for the predicting 7 days (eg, could learn that the patient ran out several days before test)</td>
</tr>
<tr>
<td></td>
<td>• Diversion</td>
<td>• Ask patient if they’ve given the drug to others</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Monitor compliance with pill counts</td>
</tr>
</tbody>
</table>
### Unexpected Results

<table>
<thead>
<tr>
<th>Possible Explanations</th>
<th>Possible Actions For the Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test is positive for non-prescribed opioid or benzodiazepines</td>
<td>• Repeat urine drug testing regularly</td>
</tr>
<tr>
<td>• False positive</td>
<td>• Ask patients if they accessed opioids from other sources</td>
</tr>
<tr>
<td>• Patient acquired opioids from other sources (double doctoring, “street”)</td>
<td>• Assess for opioid misuse/addiction</td>
</tr>
<tr>
<td></td>
<td>• Review/revise treatment agreement</td>
</tr>
<tr>
<td>UDS positive for illicit drugs (eg, cocaine, cannabis)</td>
<td>• Repeat urine drug test regularly</td>
</tr>
<tr>
<td>• False positive</td>
<td>• Assess for abuse/addiction and refer for addiction treatment as appropriate.</td>
</tr>
<tr>
<td>• Patient is occasional user or addicted to the illicit drug</td>
<td></td>
</tr>
<tr>
<td>• Cannabis is positive for patients taking certain medications (eg, dronabinol)</td>
<td></td>
</tr>
</tbody>
</table>

UDS: urine drug screen.

### Benefit Application

Drug testing or screening for employment issues may be addressed in the member contract. Please refer to the member's benefits for further information.

### Evidence Review

**Opioids**

According to a 2012 evidence assessment by the American Society of Interventional Pain Physicians, approximately one-third of chronic pain patients do not use opioids as prescribed or may abuse them.\(^1\) In 2016, the International Narcotics Control Board reported that between 1999 and 2010, the number of deaths related to the use of prescription opioid painkillers increased 5-fold among United States women and increased by a factor of 3.6 among United States men.\(^2\) Additionally, studies have found that a substantial proportion of chronic pain patients inaccurately report nonadherence to prescribed medications and use of illicit drugs.\(^3\)

Various strategies are available to monitor patients in pain management and substance abuse treatment settings, and multicomponent interventions are often used. Many settings require patients to sign a contract before they are given a prescription for opioids. The contracts
generally involve obtaining patients’ agreement on behaviors they will engage in during the treatment period (eg, taking medication as prescribed) and not engage in (eg, selling prescribed medication and/or obtaining additional prescriptions from other physicians).

Confirming whether patients follow these behavioral guidelines can be a challenge. Risk-assessment screening instruments, such as the Screener and Opioid Assessment for Patients with Pain-Revisited (SOAPP-R), and the Opioid Risk Tool (ORT), can aid in the assessment of patients’ risk for inappropriate drug use. In addition, the presence of “aberrant behaviors” can be used as a marker for patients who are at high risk for deviating from treatment protocols. Aberrant behaviors include multiple lost prescriptions, obtaining prescriptions from other practitioners, and displaying evidence of acute intoxication during office visits.

Another strategy for monitoring patients is testing of biological specimens for the presence or absence of drugs. Currently, urine is the most commonly used biological substance. Advantages of urine sampling are that it is readily available, and standardized techniques for detecting drugs in urine exist. Other biological specimens (eg, blood, oral fluids, hair and sweat) can also be tested and may gain in popularity over time as techniques for collecting and analyzing these specimens become more standardized. In addition to urine testing, this review will address testing of oral fluids and hair.

**Urine Drug Testing**

The two primary categories of urine drug testing (UDT) are explained below.

**Immunoassay Testing (ie, Presumptive Testing, Screening)**

These tests can be performed either in a laboratory or at point of service. Immunoassay tests are based on the principle of competitive binding and use antibodies to detect a particular drug or drug metabolite in a urine sample. With competitive binding, a fixed amount of a labeled drug is added to the urine sample, and the drug or metabolite in the sample competes with the labeled drug for binding sites on the antibody. The amount of labeled antigen that binds with the antibody is inversely proportional to the amount of the drug or metabolite in the sample.

Immunoassay tests vary in the type of compounds they can detect. Some detect specific drugs and may fail to recognize similarly structured drugs within the same class. Other immunoassays identify only classes of drugs and thus results cannot be used to determine which drug a patient is taking. For example, a positive result to an opiate immunoassay can be due to morphine or
hydromorphone. The degree of crossreactivity, ie, an antibody’s reactivity with a compound other than the target of the test, varies widely among immunoassays.

Immunoassay findings are generally reported qualitatively as either positive (drug level above a prespecified threshold) or negative (drug level below a prespecified threshold). Raising or lowering the threshold thus changes the proportion of positive tests. A negative test is interpreted as a level below the threshold and does not necessarily mean that the drug or metabolite is absent.

Immunoassays generally have a rapid turnaround time, within minutes for onsite tests and 1 to 4 hours for laboratory-based tests.³

**Specific Drug Identification (ie, Quantitative Testing, Confirmatory Testing, Definitive Testing)**

Confirmatory tests are always performed in a laboratory. Gas chromatography/mass spectrometry (GC/MS) is considered to be the criterion standard for confirmatory testing. This technique involves using GC to separate the analytes in a specimen and MS to identify the specific molecular structures of the drug and its metabolites. The tests are able to quantify the amount of drug or metabolite present in the urine sample. Quantitative tests can be used to confirm the presence of a specific drug identified by a screening test and can identify drugs that cannot be isolated by currently available immunoassays. Results are reported as the specific levels of substances detected in the urine. GC/MS generally requires specification of the drug or drugs to be identified. Alternatively, “broad spectrum screens” can be conducted. There is a several day turnaround time for GC/MS testing.⁴

An issue with both types of urine drug testing is the possibility of sample tampering to mask the presence of illegal drugs. A variety of products and techniques are available to patients, and can be as simple as drinking a large amount of water to dilute the sample. There are also commercial dilution and cleaning products, additives and urine substitutes. Some of these techniques can be detected by visual inspection of the sample eg, color, or by onsite testing of sample characteristics including urine temperature, creatinine concentration, and specific gravity.

In addition, correct interpretation of urine drug testing results is very important. Knowledge of drug metabolites is essential for accurate interpretation. Accurate interpretation of test results also requires knowledge of the drug manufacturing process. For example, due to manufacturing impurities, a small amount of hydrocodone may be present in urine samples from patients
prescribed oxycodone. Thus, it would be acceptable to have this degree of hydrocodone if high amounts of oxycodone were also present.

There are various approaches to incorporating urine drug screening into pain management and substance abuse treatment settings. Most commonly, patients undergo urine drug screening before beginning treatment to verify current drug use. Some clinicians believe that urine drug screening should be routinely used to establish baseline information about substance use, but the optimal frequency and interval of testing remains uncertain. A universal approach to screening may uncover more inappropriate use, and may reduce patients’ sense that testing is being performed due to a lack of trust. However, routine universal screening may place an unnecessary burden on the healthcare system and on the doctor-patient relationship. An alternative approach is selective testing of patients who are judged to be at increased risk for drug misuse.

Existing protocols vary for use of qualitative versus quantitative tests. Some settings conduct routine confirmation of positive qualitative tests with quantitative testing. Others use selective confirmation of positive qualitative tests, such as when an unexpected immunoassay result is not adequately explained by the patient. There is also a mixed approach, with routine conformation of qualitative tests only for drugs with poor-performing immunoassays.

Full informed consent is a requirement before urine drug testing. Patients should be informed of the specific drug testing protocol before treatment and should provide written agreement with the plan for monitoring. As stated in a joint U.S. Veterans Affairs/Department of Defense guideline, patients’ refusal to consent to urine testing should be considered as 1 factor in the overall assessment of patients’ ability to adhere to treatment.5

**Oral Fluid Drug Testing**

Oral fluid, liquid samples obtained from the oral cavity, can potentially be used to test for drug use. Oral fluid contains secretions from several different sources, including secretions from the 3 pairs of major salivary glands (parotid, sublingual, and submandibular), secretions from the minor salivary glands, oro-naso-pharyngeal secretions and cellular debris. The mixture of fluids obtained varies depending on the collection method used eg spitting, suctioning, draining or collection on some type of absorbent material. In addition, drug concentrations can be affected by the collection method, as well as by whether or not saliva stimulation methods were used. Several collection devices are commercially available in the United States and these generally involve collection on absorbent material (eg, foam pad). Pads are then placed in a container with a stabilizing buffer solution. Drug concentrations may also vary depending on how the oral fluid
is recovered from the collection device (eg, by centrifugation or by applying pressure). Another issue is that drug concentrations may not reflect blood levels because of residual amounts of drug (specifically those ingested or smoked) remaining in the oral cavity after recent use.

Analysis techniques must be able to detect drugs present in low concentration and in a small volume of fluid (often <1 mL). Immunoassay techniques are available to detect drugs in oral fluid; these require a small sample volume (≈25 μL). Immunoassays tend to be relatively sensitive techniques but they tend to have low specificity. Confirmation analysis is generally performed using mass spectrometry (MS) based methods. In recent years, advancements have been made in MS analysis techniques, including the development of multianalyte liquid chromatography-mass spectrometry (LC-MS) methods.

A practical advantage of oral fluid collection compared with urine is that samples can be obtained under direct supervision and without loss of privacy. It has been used in forensic situations where urine sampling is impractical, such as testing drivers during traffic stops. Oral fluid sampling also has the potential to be useful in the pain management or substance abuse treatment settings, particularly when substitution or tampering with urine drug samples is suspected. However, it is not yet practical in these settings because of inconsistency of results for reasons noted above.

**Hair Testing**

Hair is made up of protein that traps chemicals in the blood at the time the hair was made in the hair follicle. Hair on the human head grows at the rate of approximately one-half inch per month. Thus, a 1.5-inch hair sample could be used to reveal drug use during the previous 90 days. Potential advantages of hair as a drug testing source include that it collection is noninvasive, it is easy to collect, store and ship, sufficient samples are generally available for testing and retesting and it is difficult to substitute or adulterate. Potential disadvantages are that hair analysis cannot detect recent drug use (ie, within past 7 days), it is difficult to detect very light drug use (eg, a single episode), drug levels can be due to environmental exposure as well as use. In addition, variation in hair texture as well as cosmetic hair treatments can affect drug incorporation in hair and the accuracy of drug tests on hair samples. As with other types of samples, hair can be initially tested using immunoassay techniques, with confirmation by MS-based methods. Hair testing has been used in a variety of situations where detection of drug use during the previous several months is sought, such as pre-employment screening or post-drug-treatment verification of relapse. However, it is not yet practical in treatment settings for reasons noted above.
Summary of Evidence

**Urine Drug Testing**

For individuals who have chronic pain treated with opioids who receive UDT, the evidence includes nonrandomized comparative studies and systematic reviews. Relevant outcomes are test accuracy and validity, health status measures, and resource utilization. The evidence on the diagnostic accuracy of urine immunoassay tests, as confirmed by gas- or liquid-chromatography/mass spectrometry, shows sensitivities ranging from about 80% to 93% for both opiates and oxycodone. No randomized controlled trials (RCTs) evaluating clinical utility were identified. Several nonrandomized comparative studies have been conducted, though interventions and outcomes have varied across the studies. Most interventions included patient contracts along with UDT, and therefore, the effect of UDT alone could not be determined. Most studies did not provide details on the frequency of UDTs and whether the testing was random or scheduled. As a result, these studies provided inconclusive evidence on whether UDT in the pain management setting improves patient outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have a drug addiction who are in substance use disorder treatment who receive UDT, the evidence includes two RCTs. Relevant outcomes are test accuracy and validity, health status measures, and resource utilization. No studies were identified that evaluated the accuracy of UDT compared with a valid reference standard in individuals undergoing substance abuse treatment. One small RCT focused specifically on UDT to determine eligibility for take-home methadone. The second RCT found that UDT identified drug use in a substantial number of patients who denied illicit usage; the impact on treatment success was not addressed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Based on the available evidence and clinical input, urine drug testing may be considered medically necessary under specific conditions listed in the policy statements.

**Oral Fluid Drug Testing**

For individuals who have chronic pain treated with opioids or with a drug addiction in substance use disorder treatment who receive oral fluid drug testing, the evidence includes diagnostic accuracy studies using UDT as the reference standard. Relevant outcomes are test accuracy and validity, health status measures, and resource utilization. The limited number of studies on the
diagnostic accuracy of oral fluid testing compared with UDT have varied findings. No studies were identified assessing the impact of oral fluid testing on health outcomes compared with UDT or no drug testing. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Hair Drug Testing**

For individuals who have chronic pain treated with opioids or with a drug addiction in substance use disorder treatment who receive hair drug testing, the evidence includes a diagnostic accuracy study in the psychiatric treatment setting. Relevant outcomes are test accuracy and validity, health status measures, and resource utilization. Hair testing cannot detect recent drug use (ie, in the past few days), and thus has limited applicability to pain management or substance abuse treatment settings, except, perhaps, for initial intake. There are no studies comparing the diagnostic accuracy of hair testing with UDT in either setting. One relatively small study tested the hair and urine of known drug users recruited from a psychiatric clinic. The study looked for drug use over the past several months rather than the shorter timeframe generally needed in pain management or drug treatment settings. No studies were identified on the clinical utility of hair testing in pain management or substance abuse.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02345655</td>
<td>On-site Evaluation of Substances Consumption on Opiate Maintenance (ESUB-MG)</td>
<td>136</td>
<td>April 2019</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 5 physician specialty societies and 8 academic medical centers while this policy was under review in 2014. There was near-consensus among reviewers that, in outpatient pain management, presumptive (ie, qualitative) urine drug testing may be considered medically necessary for patients who meet the stated criteria and that the frequency of repeat drug testing should depend on the risk level of the individual. There was also near-consensus among reviewers that, in substance abuse treatment, baseline presumptive drug testing may be considered medically necessary for patients who meet the stated criteria and that targeted weekly qualitative screening for a maximum number of weeks (most experts indicated 4 weeks) may be considered medically necessary during the stabilization phase for patients in ambulatory treatment. There was mixed input on the frequency of presumptive drug testing that may be considered medically necessary during the maintenance phase of substance abuse treatment. In addition, clinical input was mixed on confirmatory definitive (ie, quantitative) drug testing and particularly on whether definitive drug testing should only be performed on a drug-specific basis. The specific conditions and frequencies listed in the policy statements derive to a significant extent from the guidelines of the Washington State Agency Medical Directors’ Group (AMDG) and of the American Society of Addiction Medicine (ASAM), which have emerged as pre-eminent authoritative guidelines.

Practice Guidelines and Position Statements

Pain Management Treatment Setting

In 2014, Nuckols et al. published a systematic review of guidelines that addressed management opioid use for chronic pain. The authors included guidelines from national organizations and specialty societies, as well as guidelines from state agencies and specific health systems. The authors identified nine guidelines with recommendations on UDT. The recommendations varied widely; two guidelines recommended mandatory testing for all patients, one recommended testing only patients at increased risk of medication abuse, and two stated that testing patients at low risk of abuse is not cost-effective. If UDT is used, the recommended frequency of follow-
up testing was at least quarterly in one guideline, at least yearly in one guideline and randomly in two guidelines.

**Centers for Disease Control and Prevention**

In 2016, Centers for Disease Control and Prevention (CDC) guidelines on opioids for chronic pain were published. The guidelines included the following recommendation on UDT: “When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.”

**American Society of Interventional Pain Physicians (ASIPP)**

In 2017, the American Society of Interventional Pain Physicians issued guidelines for responsible, safe, and effective opioid prescribing for chronic non-cancer pain. The guidelines included the following recommendations on UDT (see Table 2).

### Table 2. Recommendations on Urine Drug Testing for Chronic Non-Cancer Pain

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>LOE</th>
<th>SOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Comprehensive assessment and documentation is recommended before initiating opioid therapy, with documentation of comprehensive history, general medical condition, psychosocial history, psychiatric status, and substance use history.”</td>
<td>I</td>
<td>Strong</td>
</tr>
<tr>
<td>“Screening for opioid abuse is recommended, as it will potentially identify opioid abusers and reduce opioid abuse.”</td>
<td>II-III</td>
<td>Moderate</td>
</tr>
<tr>
<td>“Presumptive UDT is implemented at initiation of opioid therapy, along with subsequent use as adherence monitoring, using in-office point of service testing, followed by confirmation with chromatography/mass spectrometry for accuracy in select cases, to identify patients who are not compliant or abusing prescription drugs or illicit drugs. UDT may decrease prescription drugs abuse of illicit drug use when patients are in chronic pain management therapy.”</td>
<td>III</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

LOE: level of evidence. SOE: strength of evidence; UDT: urine drug testing
**American Pain Society and American Academy of Pain Medicine**

In 2009, the American Pain Society and American Academy of Pain Medicine jointly published clinical guidelines on the use of opioid therapy in chronic non-cancer pain.\textsuperscript{32} The guidelines did not address UDT or other forms of monitoring adherence.

**American College of Occupational and Environmental Medicine (ACOEM)**

The latest guidelines from the American College of Occupational and Environmental Medicine (ACOEM) on the use of opioids for the treatment of acute, subacute, chronic, and postoperative pain, were published in 2014.\textsuperscript{33} The following recommendations on UDT were made for subacute (1-3 months) and chronic pain (>3 months) (see Table 3).

**Table 3. Recommendations on Opioid Use to Treat Acute, Subacute, Chronic, and Postoperative Pain**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>SOR</th>
<th>CIR</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Baseline and random urine drug screening, qualitative and quantitative, for patients prescribed opioids for the treatment of subacute or chronic pain to evaluate presence or absence of the drug, its metabolites and other substance(s) use. In certain situations, other screenings (eg, hair particularly for information regarding remote use or blood) (for acute toxicity) may be appropriate.”</td>
<td>C</td>
<td>High</td>
</tr>
</tbody>
</table>

Recommendations rating schema: A: strongly recommended; B: moderately recommended; C: recommended. CIR: confidence in recommendation; SOR: strength of recommendation.

Urine drug screening was not recommended for acute pain (up to 4 weeks) or for postoperative pain (up to 4 weeks).

As a companion to the guidelines, ACOEM developed a combined Opioid Consent Form and Opioid Treatment Agreement.\textsuperscript{34} The form provides explanations of the potential benefits and harms to be expected from opioid treatment, and asks the patient to agree to numerous terms of opioid use, which include submitting to unscheduled urine, blood, saliva, or hair drug testing at the prescriber’s request and seeing an addiction specialist if requested.
Screening was recommended for all patients at baseline, and then randomly at least twice and up to 4 times a year, and at termination. Screening should also be performed if the provider suspects abuse of prescribed medication.

**National Opioid Use Guideline Group**

The National Opioid Use Guideline Group issued guidelines in Canada in 2010 on the safe and effective use of opioids for chronic non-cancer pain that included the following recommendation on urine drug screening⁵: “When using urine drug screening (UDS) to establish a baseline measure of risk or to monitor compliance, be aware of benefits and limitations, appropriate test ordering and interpretation, and have a plan to use results. (Grade C).”

The guidelines also stated that there was no “compelling evidence” to guide physicians on identifying patients who should have UDS, or on how often they should be tested. The document stated that the following factors should be considered when deciding whether to order a urine drug screen:

- patient’s risk for opioid misuse and addiction
- aberrant drug-related behaviors
- testing availability (note: this may be a Canadian-specific issue)

**Department of Veterans Affairs and Department of Defense**

Veterans Affairs and Department of Defense In 2010, the VA and DoD issued clinical practice guidelines for managing opioid therapy for chronic pain treatment.⁵

The recommendations on assessing adherence to prescribed opioids includes, with patient consent, obtaining a urine drug test before initiating opioid therapy and randomly at follow-up to confirm appropriate use. Other strategies recommended include clinical assessment and screening aids such as random pill counts, adherence checklists and standardized instruments such as the Screener and Opioid Assessment for Patients with Pain (SOAPP).

The guideline included the following specific recommendations regarding urine drug testing:

1. Inform patients that drug testing is a routine procedure for all patients starting or on opioid therapy, and is an important tool for monitoring the safety of their treatment.
2. With patient consent, obtain a UDT in all patients prior to initiation of OT.

3. With patient consent monitor all patients on OT with periodic random UDTs to confirm adherence to the treatment plan. Increase the frequency of UDTs based on risk level for aberrant drug-related behaviors and following each dose increase.

4. Take into consideration a patient’s refusal to take a UDT as part of the ongoing assessment of the patient’s ability to adhere to the treatment plan and the level of risk for adverse outcomes.

5. When interpreting UDT results take into account other clinical information (eg, past SUD, other risk factors, aberrant drug-related behaviors, and other conditions indicating risk.)

6. Understanding of lab methods for drug testing and reporting are necessary to interpret UDT results (ie, screen versus confirmatory test, substances tested, cut-off levels for tests). Maintain a close working relationship with the clinical laboratory to answer any questions about the UDT or for confirming the results.

**Washington State Agency Medical Directors’ Group**

In 2015, this group issued interagency guidelines on opioid dosing for chronic noncancer pain.\(^{26}\) The guidelines included recommendations on urine drug testing. Recommendations on testing frequency differed depending on patient risk of opioid addiction and opioid dosage, as listed below:

- **Low risk:** Periodic screening (up to once per year)
- **Moderate risk:** Regular screening (up to twice per year)
- **High risk or opioid dose over 120 mg MED/d:** 3-4 times per year
- **Aberrant behavior:** Each visit

No pain management guidelines were identified that had recommendations on oral fluid or hair testing.
Substance Abuse Treatment

American Society of Addiction Medicine (ASAM)

The American Society of Addiction Medicine (ASAM) has published several documents on drug testing: a public policy statement (2010), a white paper (2013), which provided background on the science and current practices of drug testing, and guidelines (2017) on the effective use of drug testing.

ASAM’s public policy statement asserts that: “Urine drug testing is a key diagnostic and therapeutic tool that is useful for patient care and in monitoring of the ongoing status of a person who has been treated for addiction. As such, it is a part of medical care, and should not face undue restrictions.” ASAM recommended drug testing where medically appropriate in clinical diagnostic settings and clinical treatment settings. The term “drug testing” in this document was a broad term that included urine or other body fluids or tissues.

The ASAM White Paper concluded that “The most important challenge in drug testing today is not the identification of every drug that we are technologically capable of detecting, but to do medically necessary and accurate testing for those drugs that are most likely to impact clinical outcomes.” The paper acknowledged that more specific guidance on drug testing was needed, which led to the development of the 2017 guidelines, described below.

The 2017 ASAM guidance on appropriate drug testing in clinical addiction medicine advises health care providers that before choosing the type of drug test, they should first identify the questions they are seeking to answer and be aware of benefits and limitations of the various drug tests. Table 4 summarizes characteristics of urine, oral fluid, and hair drug tests that may inform the decision of what type of drug test to use.

Table 4. Summary of Drug Testing Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Urine</th>
<th>Oral Fluid</th>
<th>Hair</th>
</tr>
</thead>
<tbody>
<tr>
<td>General detection period</td>
<td>Hours to days</td>
<td>Minutes to hours</td>
<td>Weeks to months</td>
</tr>
<tr>
<td>Point-of-care testing</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Primarily detects</td>
<td>Drug metabolite</td>
<td>Parent drug compound</td>
<td>Parent drug compound</td>
</tr>
<tr>
<td>Best use in treatment setting</td>
<td>Intermediate-term detection in ongoing treatment</td>
<td>Short-term detection in ongoing treatment</td>
<td>Long-term monitoring, 3-month history</td>
</tr>
<tr>
<td>Ease of collection</td>
<td>Requires restroom</td>
<td>Easily collected</td>
<td>Easily collected</td>
</tr>
<tr>
<td>Characteristics</td>
<td>Urine</td>
<td>Oral Fluid</td>
<td>Hair</td>
</tr>
<tr>
<td>----------------------</td>
<td>-------</td>
<td>-----------------------------</td>
<td>-------------------------------------------</td>
</tr>
<tr>
<td>Resistance to tampering</td>
<td>Low</td>
<td>High, with some uncertainty</td>
<td>High when chemically untreated</td>
</tr>
<tr>
<td>Retesting same sample</td>
<td>Possible</td>
<td>Difficult</td>
<td>Easy</td>
</tr>
</tbody>
</table>

Adapted from Jarvis et al (2017).38

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests (LDTs) must meet the general regulatory standards of the Clinical Laboratory Improvement Act (CLIA). Gas chromatography/mass spectrometry (GC/MS) tests and some immunoassays are performed in laboratory settings. Laboratories that offer LDTs must be licensed by CLIA for high-complexity testing. To date, the U.S. Food and Drug Administration (FDA) has chosen not to require any regulatory review of this test.

A CLIA waiver is available for use of certain point-of-care immunoassays. Tests eligible for a CLIA waiver are those considered to be simple, with low risk of error and low potential for harm. The U.S. Food and Drug Administration is tasked with approving manufacturers’ applications for test system waivers. There are commercially available CLIA-waived tests for drugs such as cocaine, methadone, morphine/opiates and oxycodone. There are also commercially available hair testing tests such as Quest Diagnostics ELISA tests for amphetamines, opiates, cocaine, marijuana metabolites, and PCP. In addition, Omega Laboratories offers hair drug screening for cocaine and cocaine metabolites.

Several oral fluid drug test collection devices have been cleared for marketing by FDA through the 510(k) process. They include:

- Intercept™ Oral Fluid Drug Test Oral Specimen Collection Device (OraSure Technologies, Bethlehem, PA)
- Oral-Eze Saliva Collection System (Quest Diagnostics, Madison NJ)
- Quantisal™ Oral Fluid Collection Device (Alere, Waltham, MA)
In addition to the oral fluid collection devices, FDA has cleared a number of assays for analysis of oral samples. For example, there are FDA-cleared assays for 9 drugs collected with the Intercept device. These are amphetamines, methamphetamine, cocaine/metabolite, opiates, marijuana/THC, phencyclidine, barbiturates, benzodiazepines, and methadone.

References


35. Washington State Agency Medical Directors’ Group. Interagency guideline on prescribing opioid dosing for pain. 2015; 3rd:

Treatment and Monitoring Programs and in other Clinical Settings. 2010; http://www.asam.org/docs/public-policy-
statements/1drug-testing---clinical-10-10.pdf?sfvrsn=0 Accessed October 2019.

(ASAM). 2013; https://www.asam.org/docs/default-source/public-policy-statements/drug-testing-a-white-paper-by-

2017;11(3):163-173. PMID 28557958


40. Washington State Agency Medical Directors’ Group. Interagency guideline on prescribing opioid dosing for pain. 2015; 3rd:

Treatment and Monitoring Programs and in other Clinical Settings. 2010; http://www.asam.org/docs/public-policy-
statements/1drug-testing---clinical-10-10.pdf?sfvrsn=0 Accessed October 2019.


43. Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, Medication-Assisted
Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP) Series, No. 43. 2005.


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tr>
<td>04/24/15</td>
<td>Annual Review. Revised last bullet point under quantitative UDT from “Testing is for no more than 6 substances” to “Testing is for no more than 6 different drugs”. Policy updated with literature review through January 2015. Reference 15 added; others renumbered. Policy statement clarified as noted. Related policy 2.01.30 removed. Coding update. The following codes were deleted effective 12/31/14, notation made: 80100-80104, 80154, 82055, 82101, 82145, 82205, 82520, 82646, 82654, 82742, 83805, 80840, 83925 and 84022. The following codes were added and are effective as of 1/1/15: 80300-80304, 80320-80326, 80339-80347, 80353, 80358, 80361-80364, 80369-80370.</td>
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<tr>
<td>03/09/16</td>
<td>Annual Review. Policy updated with literature review through November 30, 2015; references added. Statement added that, in outpatient pain management and substance abuse treatment, hair drug testing and oral fluid drug testing are considered</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>05/04/16</td>
<td>Investigational. &quot;Urine&quot; deleted from title.</td>
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<tr>
<td>03/01/17</td>
<td>Update Related Policies. Policy 3.01.02 was deleted and replaced with policy 3.01.520.</td>
</tr>
<tr>
<td>03/01/17</td>
<td>Annual Review, approved February 14, 2017. Policy updated with literature review through October 25, 2016; references 7, 14, 16, and 22 added. In policy statements and policy guidelines, &quot;qualitative&quot; changed to &quot;presumptive&quot; and &quot;quantitative&quot; changed to &quot;definitive&quot;. Coding update; removed terminated CPT and HCPCS codes. Added HCPCS codes G0480-G0483.</td>
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<tr>
<td>10/01/17</td>
<td>Coding update. Added new CPT codes 0006U, 0007U, and 0011U (effective 8/1/17).</td>
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<tr>
<td>11/07/17</td>
<td>Policy moved to new format, no changes to policy statement.</td>
</tr>
<tr>
<td>01/01/18</td>
<td>Coding update, removed CPT codes 80300, 80301, 80302, 80303, and 80304 as the codes were terminated 1/1/17.</td>
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<tr>
<td>06/26/18</td>
<td>Coding update, added CPT code 0020U and HCPCS code G0659.</td>
</tr>
<tr>
<td>08/01/18</td>
<td>Annual Review, approved July 10, 2018. Significant revision of the policy. Criteria for testing for pain management programs more clearly differentiated from testing for substance use disorder treatment programs. The specific criteria for testing for pain management programs expanded and modified to be consistent with the Washington State Agency Medical Directors’ Group (AMDG) guidelines. The specific criteria for testing for substance use disorder treatment programs expanded and modified to be consistent with American Society of Addiction Medicine (ASAM) guidelines. All limits on the number and frequency of tests for pain management programs modified to be consistent with the Washington State Agency Medical Directors’ Group (AMDG) guidelines. All limits on the number and frequency of tests for substance use disorder treatment programs modified to be consistent with American Society of Addiction Medicine (ASAM) guidelines. Added emphasis on necessary medical record documentation. Updated Coding section. Revised explanations of Stabilization Phase and Maintenance Phase. Added references. Title changed from &quot;Drug Testing in Pain Management and Substance Abuse Treatment Settings&quot; to “Drug Testing in Pain Management and Substance Use Disorder Treatment Settings”. Added CPT codes 0020U and 0051U. CPT codes 0006U, 0011U, 80184, 80320, 80322, 80323, 80324, 80325, 80326, 80339, 80340, 80341, 80342, 80343, 80344, 80345, 80346, 80347, 80353, 80358, 80361, 80362, 80363, 80364, 80369, 80370, 82542, and 83992 were removed from the policy.</td>
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<tr>
<td>10/01/18</td>
<td>Coding update, removed CPT code 0020U.</td>
</tr>
<tr>
<td>01/11/19</td>
<td>Coding update, added new CPT code 0082U (new code effective 1/1/19).</td>
</tr>
<tr>
<td>01/01/20</td>
<td>Coding update, added CPT codes 0143U, 0144U, 0145U, 0146U, 0147U, 0148U, 0149U, and 0150U (new codes effective 1/1/20).</td>
</tr>
</tbody>
</table>
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  • Qualified sign language interpreters
  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  • Qualified interpreters
  • Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at
https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S909, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information.

This notice may have important information and help in your language at no cost. You can also file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtan Iadann. Avi sila a kapab genyen enfòmasyon enfòpan konsèn pan aplikasyon w la oswa konvènt kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kék ak soy aven sèten dat limit pou ka kente kouvèti asirans sante w la oswa pou yo ka ede w avel depans yo. Se dwa w pou resesvwa enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):

Iloko (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyon wenno coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidenyo nga addang saksay dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Premera Blue Cross


Español (Spanish): Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas claras en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Український (Ukrainian): Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретній ситуації для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).