


<b>MEDICAL POLICY</b>	<b>Drug Testing for Therapeutic or Substance Use Monitoring (All Lines of Business Except Medicare)</b>	
<b>Effective Date: 1/1/2021</b>   1/1/2021	Section: LAB	Policy No: 361
	Medical Policy Committee Approved Date: 11/15; 4/16; 12/16; 3/17; 5/17; 12/17; 8/18; 10/18; 12/18; 5/19; 7/19; 10/19; 11/19; 5/2020; 12/2020	
Medical Officer	Date	

**See Policy CPT/HCPCS CODE section below for any prior authorization requirements**

**SCOPE:**

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

**APPLIES TO:**

All lines of business except Medicare

**BENEFIT APPLICATION**

Medicaid Members

*Oregon:* Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**POLICY CRITERIA**

**Urine Drug Testing**

**Note:** Please see Providence Health Plans Payment Policy 28.0, Urine Drug Testing, for additional payment and coding restrictions.

Presumptive Urine Drug Testing

I. Presumptive urine drug testing using codes: 80305, 80306, or 80307 (see Billing Guideline Section), may be considered **medically necessary and covered**, for pain management or substance use treatment, when **all** of the following (A.-C.) criteria are met:

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- A. Drug misuse, use or diversion is suspected; **and**
- B. Clinical documentation indicates how test results will impact treatment planning; **and**
- C. Testing is ordered by the treating provider.

II. Presumptive urine drug testing is considered **not medically necessary and is not covered** when criterion I., above is not met.

Definitive Urine Drug Testing

III. Definitive urine drug testing using codes G0480 (see Billing Guideline Section) may be considered **medically necessary and covered** when **all** of the following (A.-E.) criteria are met:

- A. Drug misuse or use is suspected; **and**
- B. Clinical documentation indicates how test results will impact clinical decision making and treatment planning; **and**
- C. Testing is ordered by the treating provider; **and**
- D. An unexpected presumptive test warrants further, specific definitive testing; **and**
- E. Definitive testing must be performed within 48 hours after the aberrant presumptive test.

IV. Definitive urine drug testing is considered **not medically necessary and is not covered** when criterion III. above is not met.

V. Definitive urine drug testing of more than 7 drug classes, or broad-spectrum definitive testing, (e.g., 0051U, G0481, G0482, G0483, G0659) is considered **not medically necessary and is not covered**.

**Non-Covered Services**

VI. The following urine drug testing is considered **not medically necessary and is not covered**:

- A. Mandated drug testing (e.g., testing required by a court-order, employment drug screening, or screening for a commercial driver’s license)
- B. Residential monitoring
- C. Specimen validity testing

VII. The use of oral fluid or hair samples for drug testing is considered **not medically necessary and is not covered** for all indications.

Link to [Policy Summary](#)

**BILLING GUIDELINES**

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- The following laboratory codes are not to be used for testing of drug analytes and are therefore NOT appropriate to use for urine drug testing:
  - 82541 - 82544
  - 83789
  
- The following codes may not be billed individually, as this is not the least costly alternative for drug screening:
  - 80323 - 80335
  - 80337 - 80350
  - 80352 - 80374

**Presumptive Testing**

- Presumptive testing must precede definitive testing. Definitive testing must be performed within 48 hours after the aberrant presumptive test.
- Only 1 of the 3 presumptive tests may be billed per day.
- Only 1 unit per date of service may be billed.

**Definitive Testing**

- Definitive testing should be used to confirm an aberrant presumptive test and should be specific and targeted to each patient’s clinical scenario. Therefore, broad-spectrum definitive testing of more than 7 classes of drugs is not medically necessary and is not covered.
- Only 1 unit per date of service may be billed.

**CPT/HCPCS CODES**

<b>All Lines of Business Except Medicare</b>	
No Prior Authorization Required	
<b>Presumptive Urine Drug Testing</b>	
80305	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
80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures (eg, immunoassay); read by instrument assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service

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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
<b>Definitive Urine Drug Testing</b>	
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 (eg, 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)
Not covered	
0006U	Prescription drug monitoring, 120 or more drugs and substances, definitive tandem mass spectrometry with chromatography, urine, qualitative report of presence (including quantitative levels, when detected) or absence of each drug or substance with description and severity of potential interactions, with identified substances, per date of service
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
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
0020U	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, with specimen verification including DNA authentication in comparison to buccal DNA, per date of service
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
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

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0093U	Prescription drug monitoring, evaluation of 65 common drugs by LC-MS/MS, urine, each drug reported detected or not detected
0116U	Prescription drug monitoring, enzyme immunoassay of 35 or more drugs confirmed with LC-MS/MS, oral fluid, algorithm results reported as a patient-compliance measurement with risk of drug to drug interactions for prescribed medications
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
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
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
0146U	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
0147U	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
0148U	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
0149U	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
0150U	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
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
G0481	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily

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	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 (eg, 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; 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 (eg, 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 (eg, 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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes
H0003	Alcohol and/or drug screening; laboratory analysis of specimens for presence of alcohol and/or drugs

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**DESCRIPTION**

**Background**

According to the Centers for Disease Control and Prevention, 91 Americans die every day from an opioid overdose and this number has quadrupled since 1999.<sup>1</sup> Furthermore, the American Society of Intervention Pain Physicians (ASIPP) estimates that one-third of chronic pain patients misuse or use prescription opioids. Several societies and guidelines recommend monitoring patients in pain management and substance use programs. Testing biological substances, most commonly urine, for the presence or absence of drugs is the most common strategy for monitoring these patients.

**Urine Drug Testing (UDT)**

Urine drug testing is performed to detect the use of prescription medication and illegal substances of concern for use. Urine drug testing should not routinely include a panel of all drugs of use. Testing should focus on the detection of specific drugs. Testing should be done at the lowest level to detect the presence of drugs.

Presumptive Versus Definitive Testing

Drugs or classes of drugs are commonly assayed by presumptive testing. Presumptive, UDT identifies if a particular substance (analyte) is present in the specimen.<sup>2</sup> Presumptive test may be followed by confirmation with a second method (definitive), only if there is a positive finding.

Definitive UDT identifies how much (the quantity) of an analyte is present. “After the presence of an analyte has been established (which may involve a second, confirmatory test), the amount of the analyte present in the sample then may be measured. For example, you could test for the presence of alcohol in the blood (presumptive), and/or may test for the actual blood alcohol level (definitive).”<sup>2</sup> Immunoassay, the measurement of the presence of a molecule in a solution, is the most common analytic method for presumptive UDT. Chromatography is the most common analytic mechanism for confirmatory UDT. This process involves passing a dissolved mixture that is in a mobile phase through a stationary phase; thus isolating different molecules by type. These isolated molecules can then be identified and measured.

All urine drug testing should be performed on a frequency appropriate for clinical needs. Adherence to substance use treatment is best measured through random testing rather than scheduled testing.

**Table 1. Comparison of Presumptive and Definitive Urine Drug Testing<sup>3</sup>**

	Presumptive	Definitive
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<b>Analytic Technique</b>	Immunoassay	Gas Chromatography-Mass Spectrometry (GC-MS) or High Performance Liquid Chromatography (HPLC)
<b>Sensitivity</b>	Low or none when testing for semi-synthetic or synthetic opioids	High
<b>Specificity</b>	Varies based on assay used- can result in false positives and false negatives	High
<b>Use</b>	Presumptive analysis; detects classes of drugs	Definitive analysis; identifies the quantity of a specific drug

**Oral Fluid Drug Testing**

Oral fluid drug testing utilizes saliva samples as a means for therapeutic or substance use monitoring.<sup>4</sup> The use of these tests has increased considerably due to their quick and non-invasive approach, and the ability to conduct them outside of the lab. Additionally, the use of screening cartridges and devices that provide an instantaneous electronic readout are available and widely used.

**Hair Sample Drug Testing**

A hair follicle drug test involves the removal of a small amount of hair to evaluate drug use in the last 90 days.<sup>5</sup> Enzyme-linked immunosorbent assay is used first, and if a positive result is seen, confirmatory testing is performed. The sampling can be taken in a health care setting, workplace, or at home, but the analysis must be performed in the lab.

**REVIEW OF EVIDENCE**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of presumptive and confirmatory urine drug testing, oral fluid drug testing, and hair sample drug testing. Below is a summary of the available evidence identified through June of 2020.

Several studies were identified which evaluated the analytic validity (i.e., sensitivity and specificity) of urine drug testing.<sup>6-18</sup> However, no studies were identified which assessed the clinical utility of urine drug testing for monitoring patients in pain management and substance use programs. Therefore, no reliable conclusions can be drawn regarding urine drug testing and its possible impact on health outcomes in these patient populations.

**CLINICAL PRACTICE GUIDELINES**

Oregon Health Evidence Review Commission (HERC)

In 2018, HERC published a coverage guidance for urine drug testing. The coverage guidance recommended the following:



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“Urine drug testing (UDT) using presumptive testing is recommended for coverage (weak recommendation) when the results will affect treatment planning.

Definitive testing is recommended for coverage as a confirmatory test only when the result of the presumptive testing is inconsistent with the patient’s history, presentation, or current prescribed medication plan, and the results would change management.

Definitive testing other than to confirm the results of a presumptive test as specified above is not recommended for coverage (weak recommendation), unless the clinician suspects use of a substance that is inadequately detected by presumptive UDT (e.g., fentanyl).

Definitive testing is recommended for coverage for no more than seven substances per day.

In patients receiving treatment for a substance use disorder, random UDT is recommended for coverage (weak recommendation). Up to 36 presumptive tests and 12 definitive tests are recommended per year. These limits must be applied in accordance with mental health parity law.

In patients receiving chronic opioid therapy for chronic pain, random UDT is recommended for coverage (weak recommendation), with frequency of testing depending on the patient’s risk level (using a validated opioid risk assessment tool). Definitive testing should be conducted only for confirmatory purposes as described above and should not exceed 12 tests per year:

- Low Risk: Random presumptive testing up to two times per year
- Moderate Risk: Random presumptive testing up to four times per year
- High Risk: Random presumptive testing up to 12 times per year

In patients with unexplained alteration of mental status and when knowledge of drug use is necessary for medical management (e.g., emergency department evaluation for altered mental status), UDT (presumptive and confirmatory definitive testing, if indicated) is recommended for coverage not subject to the above limitations (weak recommendation).”<sup>19</sup>

The HERC coverage guidance gives no recommendation for drug testing using oral fluid or hair samples.

Department of Veterans Affairs/Department of Defense (VA/DoD)

The 2017 VA/DoD evidence-based guideline for opioid therapy for chronic pain gave the following recommendation:

“The Work Group recommends implementing risk mitigation strategies upon initiation of long-term opioid therapy, starting with an informed consent conversation covering the risks and benefits of opioid therapy as well as alternative therapies. The strategies and their frequency should be commensurate with risk factors and include:

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- Ongoing, random urine drug testing (including appropriate confirmatory testing)
- Checking state prescription drug monitoring programs
- Monitoring for overdose potential and suicidality
- Providing overdose education
- Prescribing of naloxone rescue and accompanying education”<sup>20</sup>

(Strong for; Reviewed, New-replaced)—defined as “the work group recommends offering this option” and it is a “recommendation from a previous CPG that has been carried over to the updated CPG that has been changed following review of the evidence.”<sup>20</sup>

The guideline gives no recommendation for drug testing using oral fluid or hair samples.

Washington State Department of Labor Industries

The 2017 Washington State Department of Labor Industries guideline for prescribing opioids to treat pain in injured workers gave the following recommendations for urine drug testing:

“Use of chronic opioid therapy requires regular monitoring and documentation, such as screening for risk of co-morbid conditions with validated tools, checking the Prescription Monitoring Program database, assessing clinically meaningful improvement in function and administering random urine drug tests.”<sup>21</sup>

The Washington State Agency Medical Directors’ Group (AMDG) Interagency Guideline on Prescribing Opioids for Pain gave the following considerations regarding urine drug testing for specific classes of drugs<sup>22</sup>:

- *Opioids or “Opiates”—Natural (from opium)*
  - 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.
- *Opioids—Semisynthetic (derived from opium)*
  - “Opiates” immunoassays may also detect semisynthetic opioids depending on their cross-reactivity pattern. However, a negative result does not exclude use of semisynthetic opioids. Confirmatory testing (GC/MS or LC/MS/MS) 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

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other words, hydromorphone and oxycodone use does not result in positive screens for hydrocodone and oxycodone, respectively.

- *Synthetic Opioids*
  - 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.

The guideline gives no recommendation for drug testing using oral fluid or hair samples.

Centers for Disease Control and Prevention (CDC)

The 2016 evidence-based CDC guideline for prescribing opioids for chronic pain recommended the following:

“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 (recommendation category: B, evidence type: 4).”<sup>23</sup>

A category B recommendation is defined as “(i)ndividual decision making needed; different choices will be appropriate for different patients. Clinicians help patients arrive at a decision consistent with patient values and preferences and specific clinical situations.”<sup>23</sup> Type 4 evidence is defined as “(c)linical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations.”<sup>23</sup>

American Pain Society/College on Problems of Drug Dependence (APS/CPDD)

The 2014 APS/CPDD evidence-based clinical practice guideline for methadone safety recommended the following regarding urine drug testing:

- The panel recommends that clinicians obtain urine drug screens prior to initiating methadone and at regular intervals in patients prescribed methadone for opioid addiction (strong recommendation, low-quality evidence).
- The panel recommends that patients prescribed methadone for chronic pain who have risk factors for drug use undergo urine drug testing prior to initiating methadone and at regular intervals thereafter; it recommends that clinicians consider urine drug testing in all patients regardless of assessed risk status (strong recommendation, low-quality evidence).<sup>24</sup>

The guideline gives no recommendation for drug testing using oral fluid or hair samples.

American Pain Society and American Academy of Pain Medicine (APS/AAPM)

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The 2009 APS/AAPM evidence-based clinical practice guideline for the use of chronic opioid therapy (COT) in chronic noncancer pain recommended the following:

- Clinicians should reassess patients on COT periodically and as warranted by changing circumstances. Monitoring should include documentation of pain intensity and level of functioning, assessments of progress towards achieving therapeutic goals, presence of adverse events, and adherence to prescribed therapies (strong recommendation, low-quality evidence).
- In patients on COT who are at high risk or who have engaged in aberrant drug-related behaviors, clinicians should periodically obtain urine drug screens or other information to confirm adherence to the COT plan of care (strong recommendation, low-quality evidence).
- In patients on COT not at high risk and not known to have engaged in aberrant drug-related behaviors, clinicians should consider periodically obtaining urine drug screens or other information to confirm adherence to the COT plan of care (weak recommendation, low-quality evidence).<sup>25</sup>

The guideline gives no recommendation for drug testing using oral fluid or hair samples.

American Society of Interventional Pain Physicians (ASIPP)

The 2006 (revised 2012) ASIPP evidence-based guideline for responsible opioid prescribing in chronic non-cancer pain gave the following recommendations:

Regarding the initial steps of opioid therapy, ASIPP states:

“Urine drug testing (UDT) must be implemented from initiation along with subsequent adherence monitoring, in an in office setting with immunoassay and confirmation for accuracy with chromatography in select cases, to identify patients who are non-compliant or abusing prescription drugs or illicit drugs, and urine drug testing may decrease prescription drug use or illicit drug use when patients are in chronic pain management therapy. (Evidence: good)”<sup>26</sup>

Regarding adherence monitoring, ASIPP states:

“In order to reduce prescription drug use and doctor shopping, adherence monitoring by urine drug testing and PMDPs (prescription drug monitoring programs) provide evidence that is essential to the identification of those patients who are non-compliant or abusing prescription drugs or illicit drugs. (Evidence: fair)”<sup>26</sup>

The guideline gives no recommendation for drug testing using oral fluid or hair samples.

American Society of Addiction Medicine (ASAM)

In 2013, ASAM published a white paper which, “describes the uses of drug testing as a primary

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prevention, diagnostic, and monitoring tool to identify the presence or absence of drugs of use or therapeutic agents related to addiction management in multiple settings.”<sup>27</sup> The guidelines note the following regarding presumptive and definitive testing:

“POC (point-of-care) testing, relying on IA (automated Immunoassay) technology, is currently limited to a relatively narrow range of drug classes and a few specific drugs (usually 15 or less) and to urine and oral fluid samples. IA drug tests are incapable of distinguishing among specific drugs within a class (e.g. amphetamines, barbiturates, benzodiazepines, opioids), are variably reactive with drugs within a class, and are vulnerable to cross-reactivity with other, sometimes unrelated, molecules. Laboratory-based immunoassays are available for scores of drugs, but because the technology requires an antibody and not all drugs elicit an antibody response (i.e. small molecules such as alcohol or ethyl sulfate), immunoassays are not available for all drugs.

Confirmation of presumptive positive results (and at times presumptive negative results) from laboratory or POC immunoassay tests is sometimes performed, potentially by GC-MS. Gas chromatography separates the different drugs or metabolites in a specimen, and mass spectrometry definitively identifies specific drugs or metabolites. GC-MS analysis typically focuses on a select group of related compounds and to achieve this selectivity may involve cumbersome and time-consuming extraction and chemical derivatization processes.”

The ASAM guidelines cautioned against over-testing:

“Today, it is important not to let the best in drug testing become the enemy of the good, and to not embrace technologies merely because they are available and before their potential for improving patient care has been fully assessed. ***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 decisions.*** Choices of technology should be based on the clinical situation and patient risk. Cost must be considered in the choice of drug testing in balance with the clinical goals for each patient. The major need today is the wider and smarter use of the currently available drug testing technologies and practices.”

In 2017, ASAM published consensus guidelines which focused on when, where, and how often it is appropriate to perform drug testing to identify risk in patients with addiction.<sup>28</sup> The guideline indicated the following:

- “Before choosing the type of test and matrix, providers should determine the questions they are seeking to answer and familiarize themselves with the benefits and limitations of each test and matrix.
- Drug testing panels should be based on the patient’s drug(s) of choice and prescribed medications, and drugs commonly used in the patient’s geographic location and peer group.

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- Definitive testing techniques should be used whenever a provider wants to detect specific substances not identified by presumptive methods, quantify levels of the substance present, and refine the accuracy of the results.
- Definitive testing should be used when the results inform clinical decisions with major clinical or non-clinical implications for the patient (eg, treatment transition, changes in medication therapies, changes in legal status).
- When ordering a definitive test, providers should advise the testing laboratory if the presence of any particular substance or group of substances is suspected or expected.”

The guideline gives no recommendation for drug testing using oral fluid or hair samples.

**POLICY SUMMARY**

The evidence is insufficient to establish the clinical utility of urine drug testing for monitoring patients in pain management and substance use programs. However, several clinical practice guidelines agree that urine drug testing, both presumptive and definitive, is necessary to mitigate risk, monitor adherence to prescribed treatments, and prevent adverse effects in these patient populations. Therefore, presumptive and/or definitive urine drug testing may be considered medically necessary when criteria are met.

There is insufficient evidence to establish the analytic validity and clinical utility of other methodologies used for drug testing, including hair and oral fluid samples. Additionally, no clinical practice guidelines recommend the use of hair or oral fluid samples for drug testing. Therefore, these drug testing methodologies are considered investigational.

**INSTRUCTIONS FOR USE**

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

**REGULATORY STATUS**

Mental Health Parity Statement

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Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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