Medical Policy Manual Laboratory, Policy No. 68

Drug Testing for Substance Use and Pain Management

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Presumptive and definitive urine drug testing are often used in coordination with a multifaceted intervention approach to monitor patients in pain management and substance use treatment programs. This policy is not intended to interfere with appropriate monitoring of opioid use.

MEDICAL POLICY CRITERIA

Notes:

- This policy does not address the use of urine drug testing in the following circumstances:
  - Emergency department testing, including for the detection of potential overdose or poisoning.
  - Screening for commercial drivers licensing, or any other job-related testing.
  - State/legally mandated drug testing.
- Presumptive immunoassay (qualitative) and/or definitive confirmatory (quantitative) urine drug testing will not be covered as required for, or in conjunction with, participation in care at a facility. Urine drug testing is considered included in the facility reimbursement.

I. Presumptive immunoassay (qualitative) urine drug testing with codes 0007U, 0227U, 80305, 80306, or 80307 may be considered **medically necessary** when all of the following are met:

   A. Only 1 of the 5 presumptive codes may be billed per date of service with one unit per code for pain management or substance use treatment; and

   B. Testing does not exceed 15 presumptive codes per year, meaning per rolling year, beginning on the first date a claim for the service is received.

II. Presumptive immunoassay (qualitative) urine drug testing for pain management or substance use treatment, is considered **not medically necessary** when Criteria I. are not met, including, but not limited to the following:

   A. Any use of codes not listed in Criteria I.; or

   B. When such testing exceeds 15 presumptive codes per year (as defined above).

III. Definitive confirmatory (quantitative) urine drug testing with codes G0480, G0481, or G0659 may be considered **medically necessary** when all of the following are met:

   A. Only 1 of the 3 definitive codes may be billed per date of service with one unit per code for pain management or substance use treatment; and

   B. Testing does not exceed 15 definitive codes per year, meaning per rolling year, beginning on the first date a claim for the service is received.

IV. Definitive confirmatory (quantitative) urine drug testing for pain management or substance use treatment is considered **not medically necessary** when Criteria III. Are not met, including, but not limited to the following:

   A. Any use of codes not listed in Criteria III. (e.g., 0082U, 0328U, G0482, G0483); or

   B. When such testing exceeds 15 definitive codes per year (as defined above).

V. Oral fluid and hair drug testing are considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

CHRONIC PAIN AND CLINICAL MANAGEMENT

Chronic pain is a major clinical management problem and prescribed opioids may be used to treat multiple nononcologic conditions. However, the dangers of prescription misuse, opioid use disorder, and overdose have been a growing problem throughout the United States.

Substance use, abuse, and addiction involving numerous prescription and illicit drugs is also a serious social and medical problem. Addiction is a primary, chronic disease of brain reward, motivation, memory, and related circuitry and is manifested by individual pathologic pursuit of reward and/or relief by substance use and other behaviors.

Confirming whether patients follow these behavioral guidelines can be a challenge. Risk-assessment screening instruments 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.

URINE DRUG TESTING

There are various approaches to incorporating urine drug screening into pain management and substance use 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.

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.

There are two primary categories of urine drug testing:

I. Presumptive Immunoassay (Qualitative) Testing

   These tests can be performed either in a laboratory or at point-of-service with Certification of Waiver or a Medical Test Site Accredited License. Presumptive 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. Amount of labeled antigen that binds with the antibody is inversely proportional to the amount of the drug or metabolite in the sample.

   Presumptive 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, i.e., an antibody's reactivity with a compound other than the target of the test, varies widely among immunoassays.

   Presumptive 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 one to four hours for laboratory-based tests.[1]

II. Definitive Confirmatory (Quantitative) Testing to Identify a Specific Drug

Confirmatory tests are performed in a laboratory or by a provider with Certificate of Registration, Compliance of Accreditation or Medical Test Site Categorized License or Accredited License. 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.[2]

Urine Drug Test Accuracy

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 (e.g., 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.

Urine Drug Testing Strategy

Existing protocols vary for use of qualitative versus quantitative tests. Some of these involve conducting 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 presumptive immunoassays.

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 three pairs of major salivary glands (parotid, sublingual, and submandibular), secretions from the minor salivary glands, oro-nasopharyngeal secretions, and cellular debris. The mixture of fluids obtained varies depending on the collection method used (e.g., spitting, suctioning, draining, or collection on some type of absorbent material). Drug concentrations can be affected by the collection method and by the use of saliva stimulation methods. Several collection devices are commercially available in the U.S., and they generally involve collection

on an absorbent material, such as foam pads; pads are then placed in a container with a stabilizing buffer solution. Drug concentrations may also depend on how the oral fluid is recovered from the collection device (e.g., by centrifugation or by applying pressure). Drug concentrations may not reflect blood levels because of residual amounts of a 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; they require a small sample volume (>25 µL). Immunoassays tend to be relatively sensitive techniques, but they have low specificity. Confirmation analysis is generally performed using MS-based methods. In recent years, advancements have been made in MS analysis techniques, including the development of multianalyte LC/MS methods.

A practical advantage of oral fluid collection compared with urine collection is that samples can be obtained under the direct supervision and without loss of privacy. It has been used in 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 use disorder treatment settings, particularly when substitution or tampering with urine drug samples is suspected.

HAIR TESTING

Hair is composed of protein that traps chemicals in the blood at the time the hair develops in the follicle. Hair on the human head grows at approximately 0.5 inches per month. Thus, a 1.5-inch hair sample could be used to detect drug use during the previous 90 days. Potential advantages of hair as a drug testing source include noninvasive collection; ease of collection, storage, and shipping; availability of samples for testing and retesting; and difficulty in tampering. Potential disadvantages include the inability to detect recent drug use (i.e., within the past seven days); difficulty in detecting very light drug use (e.g., a single episode); and drug levels can be affected by environmental exposure. In addition, variation in hair texture as well as cosmetic hair treatments can affect drug incorporation into 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 desired (e.g., pre-employment screening, post-drug-treatment verification of relapse).

REGULATORY STATUS

The Food and Drug Administration (FDA) has cleared assays for urine and oral fluid testing for drugs of abuse through the 510(k) regulatory pathway. Several collection devices are commercially available in the United States, and they generally involve collection on an absorbent material, such as foam pads; pads are then placed in a container with a stabilizing buffer solution.

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. Testing with GC/MS and some immunoassays are performed in laboratory settings. Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments for high-complexity testing.

EVIDENCE SUMMARY

Assessment of diagnostic testing typically focuses on three main principles:

1. The analytic validity of the test, which refers to the technical accuracy of the test in detecting a mutation that is present or in excluding a mutation that is absent;
2. The clinical validity of the test, which refers to the diagnostic performance of the test (sensitivity, specificity, positive and negative predictive values) in detecting clinical disease; and
3. The clinical utility of the test, i.e., how the results of the diagnostic test will be used to change management of the patient and whether these changes in management lead to clinically important improvements in health outcomes.

The focus of the following literature appraisal is on evidence related to the clinical utility of urine drug testing to:

- Provide clinically relevant information beyond other strategies for monitoring drug use in pain management and substance abuse treatment patients, and
- Alter treatment decisions and improve health outcomes as a result of confirmatory testing and/or presumptive immunoassay testing compared to clinical evaluation techniques.

MANAGING PATIENTS WITH ROUTINE URINE DRUG TESTING VERSUS CONFIRMATORY URINE DRUG TESTING

Confirmatory tests provide quantitative measurements of a wider range of medications and their metabolites compared to immunoassay testing and are considered effective for confirming an unexpected immunoassay result. Numerous studies were identified which evaluated the use of confirmatory urine drug testing to distinguish patients who are abusing prescription drugs from those who are complying with a prescribed dosing regimen.[3-9] However, no studies were identified that assessed how results from confirmatory testing improved patient management decisions or health outcomes compared to patients managed using routine immunoassay urine drug tests.

PRACTICE GUIDELINE SUMMARY

CENTERS FOR DISEASE CONTROL AND PREVENTION

In 2016, Centers for Disease Control and Prevention (CDC) guidelines on opioids for chronic pain was published.[10] These guidelines were updated and expanded to include management of pain of a shorter duration, and to clarify that they are not applicable to sickle cell disease- or cancer-related pain or patients receiving palliative or end-of-life care, in 2022.[11] The updated guidelines recommend the following regarding drug testing: "When prescribing opioids for subacute or chronic pain, clinicians should consider the benefits and risks of toxicology testing to assess for prescribed medications as well as other prescribed and nonprescribed controlled substances." The authors note that such testing should not be used punitively, including as a basis for dismissing patients from care, and that clinicians should consider the benefits and risks of toxicology testing prior to initiation and at least annually during opioid therapy. The guideline authors further note that restricting definitive confirmatory testing to situations and substances for which results are expected to affect management (e.g., results will influence decisions with major clinical or non-clinical implications, there is a need to detect specific agents or agents that cannot be identified in standard immunoassays, or to confirm unexpected screening test results) can reduce costs.

WASHINGTON STATE AGENCY MEDICAL DIRECTORS' GROUP

The Agency Medical Directors' Group (AMDG) of Washington State updated guidelines on opioid dosing for chronic non-cancer pain were first published in 2010, and revised with the broadened scope of opioids for pain in 2015.[12, 13] Regarding the use of urine drug testing (UDT), the WA AMGD made the following statements:

> "The purpose of drug testing is to identify aberrant behavior, undisclosed drug use and/or abuse and verify compliance with treatment. If a decision has been made to prescribe opioids for chronic non-cancer pain, the prescriber should get a baseline UDT and screen all patients for risk level to develop an appropriate monitoring plan as well as a basis for consultation or referral. Although UDT and other screening tools are helpful in identifying aberrant behavior, it is also important for prescribers to use their clinical judgment in the development of a monitoring plan. The Prescriber should repeat random UDT based on the patient's risk category. There are several validated screening tools available to assess risk of aberrant behavior. The Opioid Risk Tool (ORT) provides a brief questionnaire that can easily be used in the primary care setting."

In addition, the WA AMDG noted that immunoassays are the most commonly used method of testing, although no standard UDT is suitable for all purposes and settings. The WA AMDG made the following recommendations regarding when confirmatory testing may be beneficial:

Natural Opioids (e.g., 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 (e.g., 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 (e.g., 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."

Opinions vary on the optimal frequency of urine drug screening to monitor patients on opioid therapy for chronic pain. The WA AMDG UDT algorithm for monitoring opioid treatment in chronic non-cancer pain includes test frequency recommendations, summarized as follows:

- Low risk by Opioid Risk Tool (ORT): one per year
- Moderate risk by ORT: two per year
- High risk or opioid dose >120 MED/d: three to four per year
- Aberrant: At time of visit

Note that the ORT is a copyrighted instrument.[14]

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS

In 2017, the American Society of Interventional Pain Physicians (ASIPP) issued guidelines on responsible, safe, and effective opioid prescribing for chronic noncancer pain.[15] The guidelines included the following recommendations on urine drug testing:

Table 1. 2017 ASIPP UDT Recommendations

Recommendation	LOE	SOE
"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."	I	Strong
"Screening for opioid abuse is recommended, as it will potentially identify opioid abusers and reduce opioid abuse."	II-III	Moderate
"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."	III	Moderate

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 (APS) and American Academy of Pain and Medicine (AAPM) issued joint clinical practice guidelines on the use of opioid therapy in chronic noncancer pain.[16] The clinical guidelines were based upon a high quality systematic review of the current evidence which included a comprehensive literature search and transparent appraisal of the quality of evidence. The APS/AAPM guideline indicated the following:

> "Patients with chronic pain may underreport or conceal illicit drug use. Regular or periodic urine drug screening has been proposed as a method for identifying patients using illicit drugs. Most urine drug screening tests utilize immunoassays, but cross-reactivity between various drugs and chemicals can cause false positive results. Urine tests based on gas chromatography-mass spectrometry assays are considered the most specific test for identifying individual drugs and metabolites and are often used to confirm positive results on immunoassays."

The APS/AAPM found the evidence regarding the diagnostic accuracy or urine drug screening to be limited to a single study with methodological shortcomings.

AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE

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.[17] An expert panel was convened to evaluate the current evidence, and develop recommendations. For urine drug testing, the panel recommended both presumptive and definitive testing at baseline and at random, “for patients prescribed opioids for the treatment of subacute [one to three months] or chronic pain [more than three months] to evaluate presence or absence of the drug, its metabolites and other substance(s) use. In certain situations, other screenings (e.g., hair particularly for information regarding remote use or blood) (for acute toxicity) may be appropriate.” The recommendation strength was graded: C (on a scale of A to C, where A is strongly recommended, B is moderately recommended, and C is recommended); and the confidence in the recommendation was labeled: High.

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

As a companion to the guidelines, ACOEM developed a combined Opioid Consent Form and Opioid Treatment Contract.[18] 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 four times a year, and at termination. Screening should also be performed if the provider suspects abuse of prescribed medication.

VETERANS AFFAIRS AND DEPARTMENT OF DEFENSE

In 2022, the Department of Veterans Affairs and Department of Defense updated clinical practice guidelines for managing opioid therapy for the treatment of chronic pain.[19] The recommendations on risk mitigation to prescribed opioids include obtaining a UDT (with patient consent) before initiating opioid therapy, and then randomly at a follow-up to confirm appropriate use. Other strategies recommended include clinical assessment such as random pill counts and use of prescription drug monitoring programs.

The guidelines included the following specific recommendations on UDT as part of risk mitigation:

"We recommend 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:

- 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"

The guideline states that gaining consent is required prior to a UDT; if a patient declines consent, "providers should factor that declination into their consideration about whether it is safe to continue opioids. Urine drug testing is required if long-term opioids are to be initiated or continued."

AMERICAN SOCIETY OF ADDICTION MEDICINE

The American Society of Addiction Medicine (ASAM) has published several documents on drug testing: a public policy statement (2010),[20] a white paper (2013), which provided background on the science and current practices of drug testing,[21] and guidelines (2017) on the effective use of drug testing.[22]

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."[20] 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."[21] 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.

The ASAM also published a focused update in 2020 focusing on the treatment of opioid use disorder.[23] The guideline states that "urine drug testing is a reasonably practical and reliable method to test for adherence to medication and illicit drug use. However, other reliable biological tests for the presence of drugs may be used. The frequency of drug testing should be determined by a number of factors, including the stability of the patient, the type of treatment, and the treatment setting. Drug testing is required a minimum of eight times per year for patients in OTP [opioid treatment programs]."

SUMMARY

In general, medical necessity means health care services that a physician, exercising prudent clinical judgement, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating illness, injury, disease or its symptoms meeting certain standards, appropriateness, and not primarily for convenience. Generally accepted standards of medical practice are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and the views of physicians practicing in relevant clinical areas, and any other relevant factors.

The research regarding the clinical utility of presumptive immunoassay (qualitative) or definitive (quantitative) confirmatory urine drug testing in pain management and substance abuse treatment is limited. However, there is consensus among clinical practice guidelines that presumptive and definitive urine drug testing may be warranted in specific cases. Therefore, presumptive immunoassay and definitive confirmatory urine drug testing may be considered medically necessary when specific policy criteria are met.

This policy is not intended to interfere with appropriate monitoring of opioid use. Current research does not show an improvement in health outcomes for additional testing beyond what is covered in the policy criteria, including but not limited to definitive drug testing for 15 or more drug classes. Because the purpose of definitive testing is to confirm an unexpected result on presumptive testing, definitive testing for numerous drugs or drug classes is generally not indicated. Clinical guidelines based on research recognize the limitations of the current literature, specifically a lack of rigorous prospective studies investigating the impact of screening on overall health outcomes. Practice recommendations based on provider consensus also state testing should be specific to the patient's situation. Therefore, all other presumptive or definitive confirmatory urine drug testing is considered not medically necessary when the policy criteria are not met.

Samples other than urine, such as oral fluid and hair, may also be tested for drugs. However, these methods have limitations and current guidelines recommend urine testing. Therefore, oral fluid and hair drug testing is considered investigational.

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CODES

Codes	Number	Description
CPT	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
	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
	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~~ (Deleted 7/1/2023)
	~~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~~ (Deleted 7/1/2023)
	~~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~~ (Deleted 7/1/2023)
	~~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~~ (Deleted 7/1/2023)
	~~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~~ (Deleted 7/1/2023)
	~~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~~ (Deleted 7/1/2023)
	~~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~~ (Deleted 7/1/2023)
	~~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~~ (Deleted 7/1/2023)

Codes	Number	Description
	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
	0328U	Drug assay, definitive, 120 or more drugs and metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), includes specimen validity and algorithmic analysis describing drug or metabolite and presence or absence of risks for a significant patient-adverse event, per date of service
	80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only (eg, utilizing immunoassay [eg, dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
	80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; read by instrument assisted direct optical observation (eg, utilizing immunoassay [eg, dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
	80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; by instrument chemistry analyzers (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
HCPCS	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.
	G0481	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), 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 (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol

Codes	Number	Description
		dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 15-21 drug class(es), including metabolite(s) if performed
	G0483	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)) , (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 22 or more drug class(es), including metabolite(s) if performed
	G0659	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (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
	P2031	Hair analysis (excluding arsenic)

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