URINE DRUG TESTING IN THE OUTPATIENT SETTING

Policy # 87

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Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for SelectHealth Commercial, SelectHealth Advantage (Medicare), and SelectHealth Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Patients in pain management programs may misuse prescribed controlled substances and/or may use non-prescribed drugs. Patients in these settings are often assessed clinically for abuse potential before treatment and are monitored while they are receiving treatment. Urine drug testing (UDT) is one monitoring strategy; it is most often used as part of a multifaceted intervention that includes other components such as patient contracts.

Commercial Plan Policy

SelectHealth **covers urine drug testing in the outpatient setting in *limited circumstances*.**

Coverage Criteria:

1. **For Management of the Chronic Non-Cancer Pain Patient (any ONE of the following tests will be allowed):**

Presumptive Drug Testing

- **80305 -** *Drug tests, presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges), including sample validation when performed, per date of service*
- **80306 -** *Drug tests, presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) read by instrument-assisted direct optical observation (e.g., dipstick, cups, cards, cartridges), including sample validation when performed, per date of service*

Definitive Drug Testing

- **G0480 -** *Drug tests, definitive, using 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); qualitative or quantitative, all sources, including specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed*
- **G0481 -** *Drug tests, definitive, using 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); qualitative or quantitative, all sources, including specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed

- **G0482 -** *Drug tests, definitive, using 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); qualitative or quantitative, all sources, including specimen validity testing, per day, 15-21 drug class(es), including metabolite(s) if performed*
- **G0483 -** *Drug tests, definitive, using 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); qualitative or quantitative, all sources, including specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed*
- **G0659 -** *Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes*

2. For Management of Substance Abuse Disorder and Drug Rehabilitation (any ONE of the following):

Presumptive Drug Testing

- **80305 -** *Drug tests, presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g. dipsticks, cups, cards, cartridges), including sample validation when performed, per date of service*
- **80306 -** *Drug tests, presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) read by instrument-assisted direct optical observation (e.g. dipstick, cups, cards, cartridges), including sample validation when performed, per date of service*

Definitive Drug Testing

- **G0480 -** *Drug tests, definitive, using 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); qualitative or quantitative, all sources, including specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed*

- **G0481 -** *Drug tests, definitive, using 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); qualitative or quantitative, all sources, including specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed*
- **G0482 -** *Drug tests, definitive, using 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); qualitative or quantitative, all sources, including specimen validity testing, per day, 15-21 drug class(es), including metabolite(s) if performed*
- **G0483 -** *Drug tests, definitive, using 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); qualitative or quantitative, all sources, including specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed*
- **G0659 -** *Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes*

SelectHealth does not cover urine drug testing using immunoassay methodology, 80307, excluding the emergency room visit. (Drug tests, presumptive, any number of devices or procedures by instrumented chemistry analyzers [e.g., immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry], including sample validation when performed, per date of service) **are not covered for any indication** as current evidence demonstrates this testing lacks adequate sensitivity and specificity for its intended purpose and alternative methods are available; this methodology is believed to be not medically necessary.

SelectHealth Advantage (Medicare/CMS)

SelectHealth Advantage **will follow the commercial plan policy**.

SelectHealth Community Care (Medicaid)

SelectHealth Community Care **will follow the commercial plan policy**.

Summary of Medical Information

According to an evidence assessment by the American Society of Interventional Pain Physicians (ASIPP), approximately one third of chronic pain patients do not use controlled substances as prescribed or may abuse them. Moreover, studies report that a substantial proportion of chronic pain patients inaccurately report non-adherence to prescribed medications and use of illicit drugs.

The dramatic increase of opioid use leading to the alarming rate of addiction and mortality through misuse and drug diversion has led to the need for intense monitoring by UDT.

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. The Intermountain CPM, Management of Chronic Non-Cancer Pain was created to assist the primary care physician in chronic pain management. This tool highlights the presence of "aberrant behaviors" which 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 asking for early refills.

Urine drug testing is recommended by numerous societies to evaluate compliance and determine misuse, diversion, or suspected substance abuse disorder. Despite the relative lack of medical evidence through randomized control studies that UDT alters clinical outcomes, this test has become the standard of care to assess for compliance or evaluate for deviant behavior. The premise that UDT discourages nonmedical drug use and diversion of controlled substances is unclear.

Keys to UDT are:

1. The test is underutilized
2. Random testing is essential
3. Require high sensitivity and specificity
4. Cost /Benefit ratio of different testing methods will determine the preferred UDT method
5. There are no strict criteria for UDT frequency
6. UDT provides information about recent drug use but does not identify substance use disorders or physical dependence.

There are two primary categories of urine drug testing:

1. **<u>Immunoassay testing (IA) (i.e., qualitative testing, screening):</u>**

   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 cross-reactivity, i.e., 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 pre-specified threshold) or negative (drug level below a pre-specified 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.

2. **<u>Specific drug identification (i.e., quantitative testing, confirmatory testing):</u>**

   Confirmatory tests are always performed in a CLIA certified laboratory. Gas chromatography/mass spectrometry (GC/MS) and liquid chromatography/tandem mass spectrometry (LC/MS/MS) are

common testing platforms for confirmatory testing. Analysis with these technologies may produce results either qualitatively or quantitatively, although quantitative results are more common. GC/MS is often associated with a targeted analysis for a specific drug or drug class. LC/MS/MS may be used for a targeted analysis, or for broad spectrum analysis covering many drug classes in a single analysis, including many drugs unavailable by immunoassay.

Still, the benefit of quantitative testing by LC/MS/MS compared with qualitative LC/MS testing is unknown. Many pain medicine specialists and addictionologists believe quantitative testing in certain drug classes offers advantages.

LC-MS/MS offers several advantages over IA, including greater sensitivity, greater specificity, and the ability to rapidly detect multiple drugs at one time, including opioids and adjunctive medications for treating people with chronic pain and other medical conditions. The ability of LC- MS/MS to detect low concentrations of drugs in small matrix volumes makes it ideally suited for the rapidly emerging field of oral fluid drug testing.

One examination of LC-MS/MS results following immunoassay POC testing in addiction treatment settings found high rates of clinically false negatives, that is, samples tested by POC were reported negative, but LC-MS/MS results were positive. Twenty-nine percent of opioids other than methadone identified by LC-MS/MS were missed by POC tests; 28% methadone, 43% amphetamines, 35% benzodiazepines, 40% cocaine, and 20% marijuana. Additionally, investigators found rates of office-based false positive results including 22% of opioids other than methadone identified as positive on POC but negative on LC-MS/MS, 46% methadone, 21% amphetamines, 61% benzodiazepines, 12% cocaine, and 21% marijuana. The “old” standard of testing only IA positive results may not accurately detect the patient with a substance abuse disorder.

Recent developments in drug testing technology and the emergence of widespread testing in medicine, especially in pain management, focused on a broader range of drugs and on the fact that tests with smaller drug panels and lower sensitivity and specificity fail to detect drugs that are present in many samples. This can lead to high rates of false negative results. The fact is that even the most sensitive tests with the broadest drug panels do not detect all drugs used, all the time. Many drug users “pass” drug tests because they have not used a drug in the few days before the test was administered or the particular drugs they were using were not present; even on an extended panel they have adulterated their urine sample to mask the presence of drugs or drank large quantities of fluids to reduce drug concentrations.

There is no universal standard today in clinical drug testing for medication monitoring or for drug testing in addiction treatment. This also is the case in chronic disease management where professional treatment visits occur in the outpatient setting over a span of months or even years.

Some laboratories offering clinical services analyze specimens by LC-MS/MS without an initial IA screen because of the larger number of drug classes and metabolites detected and the potential savings in not using and billing the IA step. LC-MS/MS specificity and sensitivity are improved when confirming individual drugs identified on an initial screen. The LC-MS/MS assay is less susceptible than IA testing to adulteration and dilution. LC-MS/MS can detect instances in which drug, but not metabolite, is present in urine, suggesting that an individual has feigned drug administration by adding a drug directly to the urine specimen or there may be a pharmacogenetic abnormality for an individual patient that will not allow them to metabolize that medication into its metabolites.

Overall, LC-MS/MS either qualitative or quantitative testing using large panels will increase the detection of substance abuse and diversion.

Monitoring schedules and frequency of testing balance several considerations that constitute an individualized cost-benefit analysis for each patient. Risk and cost of failing to detect non-adherence and relapse is a consideration for the patient, the healthcare professional, and for society, overall.

Applicable Codes

CPT Codes	Descriptions
Covered Codes for	

Commercial Plans	
80305	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., 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, (e.g., immunoassay) read by instrument-assisted direct optical observation (e.g., dipsticks, cups, cards, 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 instrumented chemistry analyzers utilizing immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry), includes sample validation when performed, per date of service **[only covered when performed in an emergency room]**
Non-Covered Codes for Commercial Plans	
80320	Alcohols
80321	Alcohol biomarkers; 1 or 2
80322	Alcohol biomarkers; 3 or more
80323	Alkaloids, not otherwise specified
80324	Amphetamines; 1 or 2
80325	Amphetamines; 3 or 4
80326	Amphetamines; 5 or more
80327	Anabolic steroids; 1 or 2
80328	Anabolic steroids; 3 or more
80329	Analgesics, non-opioid; 1 or 2
80330	Analgesics, non-opioid; 3-5
80331	Analgesics, non-opioid; 6 or more
80332	Antidepressants, serotonergic class; 1 or 2
80333	Antidepressants, serotonergic class; 3-5
80334	Antidepressants, serotonergic class; 6 or more
80335	Antidepressants, tricyclic and other cyclicals; 1 or 2
80336	Antidepressants, tricyclic and other cyclicals; 3-5
80337	Antidepressants, tricyclic and other cyclicals; 6 or more
80338	Antidepressants, not otherwise specified
80339	Antiepileptics, not otherwise specified; 1-3
80340	Antiepileptics, not otherwise specified; 4-6
80341	Antiepileptics, not otherwise specified; 7 or more
80342	Antipsychotics, not otherwise specified; 1-3
80343	Antipsychotics, not otherwise specified; 4-6
80344	Antipsychotics, not otherwise specified; 7 or more

80345	Barbiturates
80346	Benzodiazepines; 1-12
80347	Benzodiazepines; 13 or more
80348	Buprenorphine
80349	Cannabinoids, natural
80350	Cannabinoids, synthetic; 1-3
80351	Cannabinoids, synthetic; 4-6
80352	Cannabinoids, synthetic; 7 or more
80353	Cocaine
80354	Fentanyl
80355	Gabapentin, non-blood
80356	Heroin metabolite
80357	Ketamine and norketamine
80358	Methadone
80359	Methylenedioxyamphetamines (MDA, MDEA, MDMA)
80360	Methylphenidate
80361	Opiates, 1 or more
80362	Opioids and opiate analogs; 1 or 2
80363	Opioids and opiate analogs; 3 or 4
80364	Opioids and opiate analogs; 5 or more
80365	Oxycodone
80366	Pregabalin
80367	Propoxyphene
80368	Sedative hypnotics (non-benzodiazepines)
80369	Skeletal muscle relaxants; 1 or 2
80370	Skeletal muscle relaxants; 3 or more
80371	Stimulants, synthetic
80372	Tapentadol
80373	Tramadol
80374	Stereoisomer (enantiomer) analysis, single drug class
80375	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise
80376	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 4-6
80377	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 7 or more
HCPCS Codes	
Covered for Commercial Plans	
G0480	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 and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed
G0481	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 and excluding

	immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed
G0482	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 and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), 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 or stereoisomers), including, but not limited to, GC/MS (any type, single tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 22 or more drug class(es), including metabolite(s) if performed
G0659	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes

Sources

1. ARUP Consult. Available at http://www.arupconsult.com/Topics/Opioids.html
2. Drug testing: A White paper of the American Society of Addiction Medicine (ASAM) October 26, 2013@www.asam.org (Retrieved March 25, 2015).
3. Drug Testing, Priority Health Coverage@http://www.priorityhealth.com/provider/manual/auths/medical-policies
4. Medicaid.utah.gov. (2018). *Laboratory Claim for Drug Analytes Related To Substance Use Disorder (SUD) Treatment*. [online] Available at https://medicaid.utah.gov/Documents/manuals/pdfs/Medicaid%20Information%20Bulletins/Traditional%20Medicaid%20Program/2018/April2018-MIB.pdf [Accessed 11 May 2018]

The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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