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Subject: Drug Testing in Pain Management and Substance Use Disorder Treatment

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Patients in pain management programs and substance use disorder treatment may misuse prescribed opioids and/or may use nonprescribed drugs. Consequently, these patients are often assessed before treatment and monitored while receiving treatment. Various strategies are available to monitor the patients, and multicomponent interventions are often used.

One strategy for monitoring patients is testing of biologic specimens for the presence or absence of drugs. Urine, blood, exhaled breath, oral fluid, sweat, and hair are matrices used in drug testing. All matrices have advantages and disadvantages with respect to sensitivity and specificity over different time windows, time to obtain results, different susceptibility to sample tampering and ease of collection. Currently, urine is the preferred matrix. Advantages of urine drug testing (UDT) are that it is readily available and standardized techniques for detecting drugs in urine exist.

There are 2 primary categories of urine drug testing:

- Presumptive (i.e. immunoassay, qualitative) Testing: This testing can be performed either in a laboratory or at point of service. 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. 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. Immunoassay findings are generally reported qualitatively as either positive (drug level above a prespecified threshold) or negative (drug level below a prespecified threshold).

- Definitive (i.e. confirmatory, specific drug identification, quantitative) Testing: Confirmatory tests are always performed in a laboratory. Gas chromatography/mass spectrometry (GC/MS) and liquid chromatography/mass spectrometry (LC/MS) are considered to be the criterion standard for confirmatory testing. The tests are able to quantify the amount of drug or metabolite present in the urine sample. Defintive 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.

Urine, blood, exhaled breath, oral fluid, sweat, and hair are matrices that can be used in drug testing. Currently, urine is the most commonly used biologic substance. Advantages of UDT are that it is readily available and standardized techniques for detecting drugs in urine exist. All matrices have advantages and disadvantages with respect to sensitivity and specificity over different time windows, time to obtain results, different susceptibility to sample tampering, and ease of collection.

POSITION STATEMENT:

In outpatient pain management, presumptive (i.e. immunoassay) drug testing **meets the definition of medical necessity** for:

- Baseline screening before initiating treatment or at the time treatment is initiated, when the following conditions are met:
    - A clinical assessment of member history and risk of substance use disorder is performed;
    - Clinicians have knowledge of test interpretation
    - There is a plan in place regarding how to use test findings clinically and;
    - Drug testing is ordered by a clinician during an office visit.
- Subsequent monitoring of treatment at a frequency appropriate for the risk-level of the member.

In outpatient substance use disorder treatment, point-of-care, laboratory, or in-office presumptive (i.e., immunoassay) drug testing **meets the definition of medical necessity** under the following conditions:

- Baseline screening before initiating treatment or at the time treatment is initiated (i.e. induction phase), one (1) time per program entry, when the following conditions are met:
    - A clinical assessment of member history and risk of substance use disorder is performed;
    - Clinicians have knowledge of test interpretation
    - There is a plan in place regarding how to use test findings clinically and;
    - Drug testing is ordered by a clinician during an office visit.
- Stabilization and Maintenance phase:
    - Using an appropriate test, matrix and frequency of testing for the risk level of the member and the substance being used
    - Documentation in the medical record explains the following:

- Rationale for the specific test(s) ordered;
- Member's history of substance use;
- How drug testing results will guide medical decision-making.

Note: Presumptive drug testing is limited to twenty-four (24) tests within a 12-month period. There is insufficient clinical evidence to support the use of daily or multiple testing per day in clinical practice. **Refer to section entitled Reimbursement Information.**

Definitive (i.e., confirmatory) drug testing, in outpatient pain management or substance use disorder treatment, **meets the definition of medical necessity** under the following circumstances:

- When immunoassays for the relevant drug(s) are not commercially available or
- In specific situations for which definitive drug levels are required for clinical decision making (i.e. unexpected positive test inadequately explained by the member; unexpected negative test (suspected medication diversion); need for definitive levels to compare with established benchmarks for clinical decision making).

Note: Definitive drug testing is limited to twenty-four (24) tests within a 12-month period. There is insufficient clinical evidence to support the use of daily or multiple testing per day in clinical practice. Refer to section entitled **Reimbursement Information**.

In outpatient pain management and outpatient substance use disorder treatment, drug testing is considered **experimental or investigational** when the above criteria are not met including but not limited to routine presumptive or definitive drug testing or standing orders (eg, testing at every visit, without consideration for specific member risk factors or without consideration for whether definitive testing is required for clinical decision making). The evidence is insufficient to determine the effects of the technology on health outcomes.

All other drug testing **does not meet the definition of medical necessity** including, but not limited to:

- Definitive testing instead of drug screening or as a routine supplement to drug screens
- Routine tests for confirmation/verification of specimen integrity/validity (e.g., urinalysis, creatinine, specific gravity, nitrates, chromates, pH, temperature)
- Simultaneous specimen screening (i.e., blood and urine)
- Testing ordered by third parties (such as courts, schools, or employers) or ordered for the sole purpose of meeting the requirements of a third party
- Testing for residential monitoring.

Use of hair as a specimen for drug testing is considered **experimental or investigational**. The evidence is insufficient to determine the effects of the technology on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding

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
80320	Alcohols
80321	Alcohol biomarkers; 1 to 2
80322	Alcohol biomarkers; 3 or more
80324	Amphetamines, 1 to 2
80325	Amphetamines, 3 to 4
80326	Amphetamines, 5 or more
80345	Barbiturates
80346	Benzodiazepines; 1-12
80347	Benzodiazepines; 13 or more
80348	Buprenorphine
80349	Cannabinoids, natural
80350	Cannabinoids, synthetic 1 to 3
80351	Cannabinoids, synthetic 4 to 6
80352	Cannabinoids, synthetic 7 or more
80353	Cocaine
80354	Fentanyl
80356	Heroin metabolite
80357	Ketamine and norketamine
80358	Methadone
80359	Methylenedioxyamphetamines (MDA, MDEA, MDMA)
80360	Methylphenidate
80361	Opiates, one or more
80362	Opioids and opiate analogs; 1 to 2
80363	Opioids and opiate analogs; 3 to 4
80364	Opioids and opiate analogs; 5 or more
80365	Oxycodone

80367	Propoxyphene
80371	Stimulants, synthetic
80375	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 1-3
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
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 (**Noncovered**)
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
0051U	Prescription drug monitoring, evaluation of drugs present by liquid chromatography tandem mass spectrommetry (LC-MS/MS), urine or blood, 31 drug panel, reported as quantitative results, detected or not detected, per date of service (**Noncovered**)
0054U	Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service (**Noncovered**)
0079U	Comparative DNA analysis using multiple selected single-nucleotide polymorphisms (SNPs), urine and buccal DNA, for specimen identity verification (**Noncovered**)
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 (**Noncovered**)
0093U	Prescription drug monitoring, evaluation of 65 common drugs by LC-MS/MS, urine, each drug reported detected or not detected **(Noncovered)**
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 (**Noncovered**)
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

HCPCS Coding

G0480	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem)

	and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (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 (eg, 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 (eg, 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 (eg, 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 (e.g., 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) (**Investigational**)

REIMBURSEMENT INFORMATION:

Codes 80305, 80306, 80307, & 0227U when billed in any combination, are limited to twenty-four (24) tests within a 12-month period regardless of the number of tests performed.

The following units of service will only be allowed per member date of service, regardless of the number of drug classes tested:

- One (1) unit of service for each of the following codes: 80305, 80306, 80307, 0227U, G0480, G0481, G0482, G0483, G0659.

Codes 80320, 80321, 80322, 80324, 80325, 80326, 80345, 80346, 80347, 80348, 80349, 80350, 80351, 80352, 80353, 80354, 80356, 80357, 80358, 80359, 80360, 80361, 80362, 80363, 80364, 80365, 80367, 80371, 80375, 80376, 80377, 0011U,G0480, G0481, G0482, G0483, and G0659 when billed in any combination, are limited to twenty-four (24) tests within a 12-month period regardless of the number of tests performed.

Specimen verification/validity testing is considered part of the quality control process for laboratory test management and is not separately reimbursable.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: The following were reviewed on the last guideline reviewed date: Local Coverage Determination (LCD) Controlled Substance Monitoring and Drugs of Abuse Testing (L36393); and LCD Reference Article- Billing and Coding: Controlled Substance Monitoring and Drugs of Abuse Testing (A57077) located at fcso.com.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

None applicable.

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 01/23/25.

GUIDELINE UPDATE INFORMATION:

11/15/13	New Medical Coverage Guideline.
08/15/14	Review; position statements, title, description, reimbursement section & references updated; formatting changes.
01/01/15	Annual HCPCS/CPT update. Added codes 80300-80377, G6030-G6058; removed codes 80100-80102 and 80104.
04/15/15	Review; position statements maintained, guideline title, reimbursement section and references updated.
09/15/15	Revision; position statement, coding, & reimbursement sections updated.
01/01/16	Annual HCPCS/CPT update; codes G0477-G0483 added; codes G0431, G0434, G6030-G6058 deleted; reimbursement section updated.
03/15/16	Annual review; update position statement section, title, and references; formatting changes.
01/01/17	Annual CPT/HCPCS update.Added 80305-80307, G0659; revised G0480-G0483; deleted 80300-80304, G0477-G0479; reimbursement section updated; formatting changes.
03/15/17	Revision; *qualitative* and *quantitative* replaced with *presumptive* and *definitive* in position statements; coding, description, and references updated.

01/01/18	Annual CPT/HCPCS update. Revised codes 80305-80307.
04/15/18	Review; Position maintained; policy title, description, position statements, coding, and references updated.
10/01/19	Quarterly CPT/HCPCS update. Added code 0116U.Added code 0011U.
2/15/20	Annual review; description, position statements, coding, and references updated.
04/01/20	Quarterly CPT/HCPCS update. Removed code 0006U.
01/01/21	Annual CPT/HCPCS update. Codes 82077 and 0227U added.
02/15/21	Annual review; Position statements, reimbursement information, coding, and references updated.
09/24/21	Revision: removed code 82077.
10/01/21	Quarterly CPT/HCPCS update. Code 0051U revised.
03/15/23	Review: Position statements maintained; references updated.
02/15/25	Review: Position statements maintained; program exception section and references updated.