Urine Drug Screening
Clinical Coverage Criteria

Overview

Urine drug testing is performed to detect the use of prescription medications and illegal substances of concern for the purpose of medical treatment. Confirmatory testing is an additional test completed to verify the results of the urine drug test. Urine drug testing should not routinely include a panel of all drugs of abuse. The test should be focused on the detection of specific drugs. The frequency of testing should be at the lowest level to detect the presence of drugs.

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial

☒ Medicare Advantage

☒ MassHealth ACO

☒ NaviCare

☒ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have an NCD for urine drug testing. National Government Services, Inc. has an LCD for Urine Drug Testing (L36037) and an LCA: Billing and Coding: Urine Drug Testing (A56761) (MCD search 02/10/2022).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Fallon Health's Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health may cover urine drug testing when medically necessary. Prior authorization is not required. Adherence to the below documentation and criteria is required, this is subject to audit.

Documentation requirements:

1. All documentation must be maintained in the member's medical record and available to Fallon Health upon request.
2. Every page of the record must be legible and include appropriate member identification information [e.g., complete name, dates of service(s)]. The record must include the identity of the physician or non-physician practitioner responsible for and providing the care of the member.
3. If requested for review, the submitted medical record should support the use of the selected ICD-10 code(s). The submitted CPT/HCPCS code should describe the service performed. Documentation maintained by the ordering provider/treating provider must indicate the medical necessity for performing a qualitative drug test.
4. Medical record documentation (e.g., history and physical, progress notes) maintained by the ordering provider/treating provider must indicate the medical necessity for performing a qualitative drug test. All tests must be ordered in writing by the treating provider and all drugs/drug classes to be tested must be indicated in the order.
5. If the provider of the service is other than the ordering/referring provider, that provider must maintain printed copy documentation of the lab results, along with printed copies of the ordering/referring provider's order for the qualitative drug test. The provider must include the clinical indication/medical necessity in the order for the qualitative drug test. Orders which include statements such as "conduct additional testing as needed or custom profile" will not be accepted.

Criteria:
Fallon Health will not reimburse for:

- Confirmatory drug screens when billed with any combination of more than twenty (20) units within a calendar year beginning January 1st of each year per Member, as it exceeds clinical guidelines.
- Presumptive drug screens when billed with any combination of more than twenty (20) units within a calendar year beginning January 1st of each year per member, as it exceeds clinical guidelines.
- Quantitative tests in lieu of drug screening services or as a routine supplement to drug screens.
- Saliva testing in conjunction with urine drug screening.

Fallon Health may cover urine drug testing for medical conditions, such as those listed below, when medical necessity is demonstrated and when treatment planning by the requesting provider is dependent upon the test results.

- Altered mental status
- Medical or psychiatric condition where drug toxicity may be a contributing factor
- Fetal withdrawal syndrome
- Possible exposure of the fetus to illicit drugs taken by the mother
- To assess and treat Members with substance use disorders
- To assess adherence to prescribed medications

All urine drug testing should be performed at an appropriate frequency based on clinical needs. Substance use disorder treatment adherence is often best measured through random testing rather than frequent scheduled testing.

A full panel screen should only be considered for initial testing when appropriate or when the Member's behavior suggests the use of drugs not identified on the original screening. Medical documentation must support the justification for conducting a full panel screening. Subsequent testing should only be conducted for those substances identified on the Member's initial profile.

- The preferred method of urine drug testing for a Member with a history of polysubstance use during the monitoring period is by utilization of a multi-drug screening kit (qualitative analysis by multiplex method for 2-15 drugs or drug classes).

The Plan will not reimburse for presumptive screening greater than 20 units within a calendar year beginning January 1st of each year per member, as this exceeds clinical guidelines. For coverage of confirmatory testing, the test results must be necessary for treatment planning and be requested by the ordering provider. Written orders are required.

Confirmatory Testing:
Drug confirmation (see table below) by a second method is indicated when either of the following has occurred:

- The result of the screen is positive and there is a need for definitive levels for specific medical management that would change the member's treatment plan.
- The result is negative and the negative finding is inconsistent with the patient's medical history.

The Plan will not reimburse for drug confirmation greater than 20 units within a calendar year beginning January 1st of each year per member, as this exceeds clinical guidelines.

For coverage of confirmatory testing, the test results must be necessary for treatment planning and be requested by the ordering provider. Written orders are required.

Note: Use of non-contracted labs may have the unintended consequence of subjecting the member to unnecessary services not ordered by you as the treating provider or other unreasonable financial exposure. In such circumstances, Fallon Health may hold the treating or ordering provider financially liable for services not medically necessary or non-reimbursable on the part of the non-participating lab.

Medicare

Fallon Health follows coverage criteria in National Government Services, Inc. Local Coverage Determination (LCD) for Urine Drug Testing (L36037) and billing and coding guidelines in LCA: Billing and Coding: Urine Drug Testing (A56761) for Medicare members, including Medicare Advantage, NaviCare and PACE plan members,.

LCD Link: **Urine Drug Testing (L36037)**
LCA Link: **Billing and Coding: Urine Drug Testing (A56761)**

The following terminology relates to urine drug testing (UDT)

- Presumptive/Qualitative Drug Testing (hereafter called "presumptive" UDT) - Used when medically necessary to determine the presence or absence of drugs or drug classes in a urine sample; results expressed as negative or positive or as a numerical result; includes competitive immunoassays (IA) and thin layer chromatography.
- Definitive/Quantitative/Confirmation (hereafter called "definitive" UDT) - Used when medically necessary to identify specific medications, illicit substances and metabolites; reports the results of analytes absent or present typically in concentrations such as ng/ml; definitive methods include, but are not limited to GC-MS and LC-MS/MS testing methods only.

Covered Indications for UDT and Expected Frequency of Testing
Group A – Symptomatic patients, multiple drug ingestion and/or patients with unreliable history
A patient who presents in a variety of medical settings with signs or symptoms of substance use toxicity will be treated presumptively to stabilize the patient while awaiting rapid, then definitive testing to determine the cause(s) of the presentation. The need for definitive UDT is based upon rapid test findings, responses to medical interventions, and treatment plan. A presumptive UDT should be performed as part of the evaluation and management of a patient who presents in an urgent care setting with any one of the following:

- Coma
- Altered mental status in the absence of a clinically defined toxic syndrome or toxidrome

- Severe or unexplained cardiovascular instability (cardiotoxicity) Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome
- Seizures with an undetermined history
- To provide antagonist to specific drug

The presumptive findings, definitive drug tests ordered and reasons for the testing must be documented in the patient's medical record.

Group B - Diagnosis and treatment for substance abuse or dependence
A patient in active treatment for substance use disorder (SUD) or monitoring across different phases of recovery may undergo medical management for a variety of medical conditions. A physician who is writing prescriptions for medications to treat either the SUD or other conditions may need to know if the patient is taking substances which can interact with prescribed medications or taking prescribed medications as expected. The risk of drug-drug interactions is inherent to the patient, and may be compounded by prescribed medications.

UDT is a medically necessary and useful component of chemical dependency diagnosis and treatment. The UDT result influences treatment and level of care decisions. Ordered tests and testing methods (presumptive and/or definitive) must match the stage of screening, treatment, or recovery; the documented history; and Diagnostic and Statistical Manual of Mental Disorders (DSM V) diagnosis. For patients with no known indicators of risk for SUDs, the clinician may screen for a broad range of commonly abused drugs using presumptive UDT.

For patients with known indicators of risk for SUDs, the clinician may screen for a broad range of commonly abused drugs using definitive UDT.

For patients with a diagnosed SUD, the clinician should perform random UDT, at random intervals in order to properly monitor the patient. Testing profiles must be determined by the clinician based on the following medical necessity guidance criteria:
- Patient history, physical examination, and previous laboratory findings
- Stage of treatment or recovery;
- Suspected abused substance; Substances that may present high risk for additive or synergistic interactions with prescribed medication (e.g., benzodiazepines, alcohol).

The patient’s medical record must include an appropriate testing frequency based on the stage of screening, treatment, or recovery; the rationale for the drugs/drug classes ordered; and the results must be documented in the medical record and used to direct care.

Frequency of Presumptive UDT for SUD:
The testing frequency must meet medical necessity and be documented in the clinician’s medical record.
- For patients with 0 to 30 consecutive days of abstinence, presumptive UDT is expected at a frequency of 1 to 3 presumptive UDT per week. More than 3 presumptive panels in one week is not reasonable and necessary and is not covered by Medicare.
- For patients with 31 to 90 consecutive days of abstinence, presumptive UDT is expected at a frequency of 1 to 3 UDT per week. More than 3 presumptive UDT in one week is not reasonable and necessary and is not be covered by Medicare.
- For patients with > 90 consecutive days of abstinence, presumptive UDT is expected at a frequency of 1 to 3 UDT in one month. More than 3 physician-directed UDT in one month is not reasonable and necessary and is not covered by Medicare.

Frequency of Definitive UDT for SUD:
Depending on the patient’s specific substance use history, definitive UDT to accurately determine the specific drugs in the patient’s system may be necessary. Definitive testing may be ordered when accurate and reliable results are necessary to integrate treatment decisions and clinical

assessment. The frequency and the rational for definitive UDT must be documented in the patient's medical record.

- For patients with 0 to 30 consecutive days of abstinence, definitive UDT is expected at a frequency not to exceed 1 physician-directed testing profile in one week. More than 1 physician-directed testing profile in one week is not reasonable and necessary and is not covered by Medicare.
- For patients with 31 to 90 consecutive days of abstinence, definitive UDT is expected at a frequency of 1- 3 physician-directed testing profiles in one month. More than 3 UDT in one month is not reasonable and necessary and is not covered by Medicare.
- For patients with > 90 day of consecutive abstinence, definitive UDT is expected at a frequency of 1-3 physician-directed testing profiles in three months. More than 3 definitive UDT in 3 months is not reasonable and necessary and is not covered by Medicare.

Group C - Treatment for patients on chronic opioid therapy (COT)

A physician who is writing prescriptions for medications to treat chronic pain can manage a patient better if the physician knows whether the patient is consuming another medication or substance, which could suggest the possibility of SUD or lead to drug-drug interactions. Additionally, UDT may help the physician monitor for medication adherence, diversion, efficacy, side effects, and patient safety in general.

COT UDT Testing Objectives:

- Identifies absence of prescribed medication and potential for abuse, misuse, and diversion;
- Identifies undisclosed substances, such as alcohol, unsanctioned prescription medication, or illicit substances;
- Identifies substances that contribute to adverse events or drug-drug interactions;
- Provides objectivity to the treatment plan; e. Reinforces therapeutic compliance with the patient;
- Provides additional documentation demonstrating compliance with patient evaluation and monitoring;
- Provide diagnostic information to help assess individual patient response to medications (e.g., metabolism, side effects, drug-drug interaction, etc.) over time for ongoing management of prescribed medications.

Medical Necessity Guidance:

Criteria to establish medical necessity for drug testing must be based on patient-specific elements identified during the clinical assessment, and documented by the clinician in the patient's medical record and minimally include the following elements:

- Patient history, physical examination and previous laboratory findings;
- Current treatment plan;
- Prescribed medication(s)
- Risk assessment plan

National pain organizations, physician societies, and the Federation of State Medical Boards recommend a practical approach to definitive UDT for COT. Frequency of testing beyond the baseline presumptive UDT must be based on individual patient needs substantiated by documentation in the patient's medical record. Recommendations for the ordering of presumptive and definitive UDT for patients on COT are as follows:

COT Baseline Testing:

Initial presumptive and/or definitive COT patient testing may include amphetamine/ methamphetamine, barbiturates, benzodiazepines, cocaine, methadone, oxycodone, tricyclic antidepressants, tetrahydrocannabinol, opioids, opiates, heroin, and synthetic/analog or "designer" drugs.

COT Monitoring Testing:

Ongoing testing may be medically reasonable and necessary based on the patient history, clinical assessment, including medication side effects or inefficacy, suspicious behaviors, self-escalation of dose, doctor-shopping, indications/symptoms of illegal drug use, evidence of diversion, or other clinician documented change in affect or behavioral pattern. The frequency of testing must be based on a complete clinical assessment of the individual's risk potential for abuse and diversion using a validated risk assessment interview or questionnaire and should include the patient's response to prescribed medications and the side effects of medications.

The clinician should perform random UDT at random intervals, in order to properly monitor a patient. UDT testing does not have to be associated with an office visit. Patients with specific symptoms of medication aberrant behavior or misuse may be tested in accordance with this document's guidance for monitoring patient adherence and compliance during active treatment (<90 days) for substance use or dependence.

UDT Frequency Based on Validated Risk Assessment and Stratification*:
Testing must be based on clinician's documented medical necessity and reviewed by the clinician in the management of prescribing/renewing a controlled substance for every risk group outlined below.

Risk Group	Baseline	Frequency of Testing
Low Risk	Prior to Initiation of COT	Random testing 1-2 times every 12 months for prescribed medications, non-prescribed medications that may pose a safety risk if taken with prescribed medications, and illicit substances based on patient history, clinical presentation, and/or community usage.
Moderate Risk	Prior to Initiation of COT	Random testing 1-2 times every 6 months for prescription medications, non-prescribed medication that may pose a safety risk if taken with prescribed medications, and illicit substances, based on patient history, clinical presentation, and/or community usage.
High Risk	Prior to Initiation of COT	Random testing performed 1-3 times every 3 months for prescribed medications, non-prescribed medications that may pose a safety risk if mixed with prescribed and illicit substances based on patient history, clinical presentation and/or community usage.

* Note: Any additional definitive UDT beyond recommendations above must be justified by the clinician in the medical record in situations in which changes in prescribed medications may be needed, such as:

- Patient response to prescribed medication suddenly changes
- Patient side effect profile changes
- To assess for possible drug-drug interactions
- Sudden change in patient's medical condition
- Patient admits to use of illicit or non-prescribed controlled substance

Exclusions

- Confirmatory drug screen when billed with any combination of more than twenty (20) units within a calendar year beginning January 1st of each year per member, as it exceeds clinical guidelines.
- Presumptive drug screen when billed with any combination of more than twenty (20) units within a calendar year beginning January 1st of each year per member, as it exceeds clinical guidelines.
- Quantitative tests in lieu of drug screening services or as a routine supplement to drug screens.
- Testing ordered by third parties, such as school, courts, or employers or requested by a provider for the sole purpose of meeting the requirements of a third party.

- Testing for residential monitoring.
- Routine urinalysis for confirmation of specimen integrity.
- Custom panels routinely requested that are unspecific to the member's clinical condition.
- Saliva testing done in conjunction with urine testing.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Code	Description
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
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
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 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, 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

The following codes are not covered:

Code	Description
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

References

1. National Government Services, Inc. Local Coverage Determination (LCD): Urine Drug Testing (L36037). Original Effective Date 12/01/2015. Revision Effective Date 10/01/2019. Available at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. Accessed 02/10/2022.
2. National Government Services, Inc. Local Coverage Article: Billing and Coding: Urine Drug Testing (A56761). Original Effective Date 08/01/2019. Revision Effective Date 10/01/2021. Available at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. Accessed 02/10/2022.
3. Commonwealth of Massachusetts. MassHealth Independent Clinical Laboratory Bulletin 9. February 2013.
4. American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. May 27, 2015.

Policy history

Origination date: 05/01/2014

Approval(s): Technology Assessment Committee: 03/26/2014, 04/23/2014 (approved new policy) 07/22/2015 (clarified policy language, updated confirmatory coding, exclusions, and references) 02/24/2016 (revised for 2016 coding, updated references), 12/07/2016 (non-covered codes 80300-80304 terminated, codes G0477-G0479 terminated and replaced with codes with codes 80305-80307) 02/01/2017 (added code G0659, policy not reviewed at committee), 10/25/2017 (added limit of 20 yearly presumptive screens, changed from 365 day methodology to calendar year starting in January, updated references), 05/15/2018 (clarified language regarding confirmatory testing criteria and added exclusion for saliva testing), 05/22/2019 (updated references)

02/10/2022 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.