

Urine Drug Testing 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:

- Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)
- ⊠ MassHealth ACO
- ⊠ NaviCare HMO SNP
- ⊠ NaviCare SCO
- ☑ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- ⊠ Community Care

Prior authorization is not required for urine drug testing. Adherence to documentation requirements and coverage criteria is expected and claims are subject to audit.

Documentation requirements:

- 1. All documentation must be maintained in the member's medical record and available to Fallon Health upon request.
- 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.
- 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.

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria for urine drug testing apply to MassHealth ACO and Community Care members.

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 conditions 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 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 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.

For confirmatory testing, the test results must be necessary for treatment planning and be requested by the ordering provider. Written orders are required. Note: For MassHealth ACO members, confirmatory (definitive) drug testing is not reimbursed when performed on the same date of service as presumptive drug testing.

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.

Fallon Health will not reimburse for:

- Confirmatory drug testing, also known as definitive drug testing, 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 testing, also known as drug screening, 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 testing in lieu of drug screening services or as a routine supplement to drug screens.

• Saliva testing in conjunction with urine drug screening.

Medicare Variation

Medicare statutes and regulations do not have coverage criteria for urine drug testing. Medicare does not have an NCD for urine drug testing. National Government Services, Inc., the Part A and B Medicare Administrative Contractor (MAC) with jurisdiction in the Plan's service area has an LCD for urine drug testing (L39611) (Medicare Coverage Database search 04/15/2025). Coverage criteria for urine drug testing is fully established by Medicare, therefore the Plan's coverage criteria are not applicable.

MassHealth Variation

MassHealth does not have Guidelines for Medical Necessity Determination for urine drug testing (MassHealth website search 04/15/2025), therefore, the Plan's coverage criteria are applicable.

<u>Claim Edit for Definitive Drug Testing Billed on the Same Date of Service as Presumptive Drug</u> Testing

MassHealth does not pay for definitive and presumptive testing/screening on the same date of service (DOS), as noted in MassHealth Transmittal Letter LAB-50 (Updated) March 2020 and MassHealth Transmittal Letter PHY-152 (July 2017). Consistent with MassHealth, Fallon Health implemented a claim edit that will deny definitive drug testing (G0480, G0481, G0482 and G0483) billed on the same date of service as presumptive drug testing (CPT 80305, 80306 and 80307) effective for dates of service on or after July 1, 2023.

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 not specific to the member's clinical condition.
- Saliva testing 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
G0400	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-
00404	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-
0.0 / 0.0	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,
0.0 / 0.0	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
00050	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,
1	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.
	Retirement Date 12/23/2023. Available at:
	https://localcoverage.cms.gov/mcd_archive/view/lcd.aspx?lcdInfo=36037:47&bc=0. Accessed
	04/15/2025. L36037 Urine Drug Testing has been replaced by L39611 Urine Drug Testing.
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- National Government Services, Inc. Local Coverage Determination (LCD). Urine Drug Testing (L39611). Original Effective Date 12/24/2023. Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39611. Accessed 04/15/2025.
- National Government Services, Inc. LCD Reference Article: Billing and Coding: Urine Drug Testing (A56761). Original Effective Date 08/01/2019. Revision Effective Date 10/01/2021. Retirement Date 12/23/2023. Available at: https://localcoverage.cms.gov/mcd_archive/view/article.aspx?articleInfo=56761:33. Accessed 04/15/2025. A56761 Urine Drug Testing has been replaced by A59416 Urine Drug Testing.
- National Government Services, Inc. LCD Reference Article. Billing and Coding: Urine Drug Testing (A59416). Original Effective Date 12/24/2023. Revision Effective Date 10/01/2024. Available at: https://www.cms.gov/medicare-coveragedatabase/view/article.aspx?articleId=59416&ver=6. Accessed 04/15/2025.
- 5. Commonwealth of Massachusetts. MassHealth Independent Clinical Laboratory Bulletin 9. February 2013.
- 6. 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: Review/Approval(s):	05/01/2014 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). Utilization Management Committee: 04/15/2025 (annual review; approved with no changes to coverage criteria: added new sections for
	Utilization Management Committee: 04/15/2025 (annual review; approved with no changes to coverage criteria; added new sections for Medicare and MassHealth Variation).

Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service

area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follows CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

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.

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.