Medicare Medical Policy

Drug Testing in Pain Management and Substance Use Disorder Treatment

MEDICARE MEDICAL POLICY NUMBER: 6

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Note: This policy addresses prescription drug monitoring. Therapeutic drug monitoring is out of scope.

Service	Medicare Guidelines
Urine *Drug Testing (UDT)*	• Testing performed in CA, NV, WA, OR, AK, MT, ID, AZ, ND, SD, UT, or WY: LCD for Urine Drug Testing (L36668) • Testing performed in TX/CO: LCD for Controlled Substance Monitoring and Drugs of Abuse Testing (L35006) • Testing performed in MA/IL: LCD for Urine Drug Testing (L39611) • Testing performed in GA: LCD for Urine Drug Testing (L35724)

Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below)*

- **Medicare Coverage Manuals:** Medicare does not have criteria for drug testing in a coverage manual.
- **National Coverage Determination (NCD):** There is a national coverage determination (NCD) for *Hair Analysis* (190.6), which provides non-covered indications for hair analysis; however, it does not address hair analysis for drug testing. In addition, Medicare does not have an NCD for drug testing using other specimen samples, such as blood or oral fluid (saliva).
- **Local Coverage Determination (LCD)/Local Coverage Article (LCA):** According to Medicare guidelines, "Jurisdiction of payment requests for laboratory services furnished by an independent laboratory… lies with the A/B MAC (B) serving the area in which the laboratory test is performed."[3] While most Medicare contractors (MACs) have a coverage policy for *urine* drug testing, the tests identified below which use *other* types of specimens (e.g., blood, saliva, hair, etc.) do **not** have an available LCD or LCA for their respective service areas.
- Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(B) as the available Medicare coverage policies provide flexibility for coverage decisions beyond the above NCD and LCD.

• ***NOTE:*** *The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*	
Oral Fluid *or* ***Hair*** *Drug Testing (e.g., PLA codes 0011U and 0116U)*	Company medical policy for Drug Testing in Pain Management and Substance Use Disorder Treatment I. These services are considered **not medically necessary** for Medicare based on the Company medical policy. *See Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to review for medical necessity under *Social Security Act, §1862(a)(1)(A),* the following documentation **must** be provided. If any of these items are not submitted, the review may be delayed and the decision outcome could be affected. The following list is based on the Noridian web page for *Drug Testing Documentation Requirements:*[4]

- Notes to support an appropriate testing frequency based on the stage of screening, treatment, or recovery;
- The rationale for the drugs/drug classes ordered;
- The test results must be documented within the medical record and must be used to direct patient care;
- Any additional documentation to support the reasonable necessity of the service(s) performed as needed to support applicable local coverage determination (LCD) criteria.

BACKGROUND

This policy addresses prescription drug monitoring, but therapeutic drug monitoring is out of scope.

A prescription drug monitoring program (PDMP) is "an electronic database that tracks controlled substance prescriptions. Information from PDMPs can help clinicians identify patients who may be at

risk for overdose and provide potentially lifesaving information and interventions. PDMP data also can be helpful when patient medication history is unavailable and when care transitions to a new clinician."[5]

In contrast, therapeutic drug monitoring (TDM) is "the clinical practice of measuring specific drugs at designated intervals to maintain a constant concentration in a patient's bloodstream, thereby optimizing individual dosage regimens. It is unnecessary to employ TDM for the majority of medications, and it is used mainly for monitoring drugs with narrow therapeutic ranges, drugs with marked pharmacokinetic variability, medications for which target concentrations are difficult to monitor, and drugs known to cause therapeutic and adverse effects."[6]

MEDICARE AND MEDICAL NECESSITY

Urine Drug Testing

The Noridian LCD L36707 provides a section entitled "**Covered Indications for UDT**." Please review this section in full when reviewing for medical necessity. Please also review all testing frequency guidelines, non-covered services and indications within the LCD.

Hair Drug Testing

While there is a national coverage determination (NCD) for *Hair Analysis* (190.6), and it provides non-covered indications for hair analysis, it does not address the use of hair samples for drug testing. Therefore, the Company medical policy will be applied for this type of testing (see below).

Oral Fluid (Saliva) and Hair Drug Testing

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Plan's Medicare policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Since there are not fully established coverage criteria for drug testing using oral fluid (saliva) or hair specimens available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. See the Medicare Coverage Criteria table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

Separate payment of urine drug testing is not covered when performed at an inpatient facility or as part of an independent program service as testing is considered an integral part of the program or in-facility stay and is not separately reimbursable.

See associated local coverage articles (LCAs) for additional coding and billing guidance:

- LCA: Billing and Coding: Urine Drug Testing (A55001)
- LCA: Billing and Coding: Controlled Substance Monitoring and Drugs of Abuse Testing (A56645)
- LCA: Billing and Coding: Urine Drug Testing (A59416)
- LCA: Billing and Coding: Urine Drug Testing (A54799)

Medicare provides additional coding guidance in MLN Matters® Number SE1105.[7]

Specimen Validity Testing

"Providers performing validity testing on urine specimens utilized for drug testing shall *not* separately bill the validity testing. For example, if a laboratory performs a urinary pH, specific gravity, creatinine, nitrates, oxidants, or other tests to confirm that a urine specimen is not adulterated, this testing is not separately billed."[8] If these services are billed, they will be denied as not medically necessary under the terms of LCD L36707 (see the *Non-Covered Services* section, #10).

Note, this non-coverage is **not** meant to imply that urine drug testing codes will automatically be denied because they include a specimen validation element.

HCPCS Code H0003

The *National Physician Fee Schedule Relative Value File (NPFSRVF)*, which is published by the Centers for Medicare and Medicaid Services (CMS)[9], indicates HCPCS code H0003 has been assigned a Status Indicator of "I." This is defined as "Not valid for Medicare purposes." In addition, HCPCS code H0003 is not recognized as a valid code for claim submission as indicated in the relevant Company Coding Policy *(HCPCS S-Codes and H-Codes,* 22.0*).* Providers need to use alternate available CPT or HCPCS codes to report for the service. If no specific CPT or HCPCS code is available, then an unlisted code may be used. Note that unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. Thus, if an unlisted code is billed related to a non-covered service addressed in this policy, it will be denied as not covered.

Presumptive and Definitive Drug Testing

According to CMS *National Correct Code Initiative* (NCCI) Manual, Chapter 10, E. Drug Testing:[10]

> "Presumptive drug testing may be reported with CPT codes 80305-80307. These codes differ based on the level of complexity of the testing methodology. **Only one code from this code range may be reported per date of service.**
>
> "Definitive drug testing may be reported with HCPCS codes G0480-G0483 and G0659. These codes differ based on the number of drug classes including metabolites tested. **Only one code from this group of codes may be reported per date of service.**"

Frequency Utilization

The Noridian LCD L36707 for urine drug testing services provides instructions regarding the maximum number of allowed presumptive and definitive urine drug tests (UDTs) for substance use disorders (SUD). This LCD states the medical record must include an appropriate number of UDTs billed over time. This should be 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.

Presumptive (Qualitative) Testing

As indicated by the NCCI guidelines above, only one presumptive test per patient per date of service will be allowed regardless of the number of billing providers.

In addition, presumptive testing is limited to **24** tests in a 12-month period. The LCD provides a maximum number of allowed definitive UDTs for substance use disorders, depending on the number of consecutive days of abstinence. However, not every patient is expected to require the maximum numbers of units, and therefore, the Plan will allow up to 24 tests over a 12-month period. More than 24 presumptive UDTs over a rolling 12-month period will be denied as not medically necessary, but can be appealed to determine if the member meets the LCD coverage criteria for both the testing and the frequency of the testing.

Definitive (Quantitative or Confirmation) Testing

As indicated by NCCI guidelines above, only one definitive test testing code may be reported per patient per date of service.

In addition, definitive testing is limited to **19** tests in a 12-month period. The LCD provides a maximum number of allowed definitive UDTs for substance use disorders, depending on the number of consecutive days of abstinence. Because not every patient will be expected to require the maximum numbers of units, the Plan will allow up to 19 tests over a 12-month period. More than 19 definitive UDTs over a rolling 12-month period will be denied as not medically necessary, but can be appealed to determine if the member meets the LCD coverage criteria for both the testing and the frequency of the testing.

CPT Codes 80320-80377

CPT codes 80320-80377 have been assigned a Status Indicator of "I" codes and are invalid for Medicare use. Therefore, consistent with Medicare, definitive drug testing CPT codes 80320-80377 should not be used and the appropriate HCPCS G0480-G0483, or G0659 should be reported instead.

CODES*		
CPT	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
	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 *(Used to report ToxProtect, by Genotox Laboratories LTD [Texas])*
	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 *(Used to report Cordant CORE™, by Cordant Health Solutions [Colorado])*
	0051U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service *(Used to report UCompliDx, by Elite Medical Laboratory Solutions, LLC [Texas])*
	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 *(Used to report NextGen Precision™ Testing, by Precision Diagnostics [Massachusetts])*
	0093U	Prescription drug monitoring, evaluation of 65 common drugs by LC-MS/MS, urine, each drug reported detected or not detected *(Used to report ComplyRX, by Claro Labs [Colorado])*
	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 *(Used to report Snapshot Oral Fluid Compliance, by Ethos Laboratories [Kentucky])*
	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 *(Used to report Comprehensive Screen, by Aspenti Health [Massachusetts])*
	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 *(Used to report CareView360, by Newstar Medical Laboratories, LLC [Georgia])*
	0603U	Drug assay, presumptive, 77 drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS), results reported as positive or negative *(Used to report SLL Comprehensive Drug Analysis, by Soft Landing Labs [Georgia])*
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 (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 (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; 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 (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 (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
	H0003	Alcohol and/or drug screening; laboratory analysis of specimens for presence of alcohol and/or drugs *(Medicare Status "I" code, invalid for Medicare use)*

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Annual review, no change (converted to new format 2/2023)
7/2023	Q3 2023 code updates
12/2023	Annual review, no change to criteria
12/2024	Annual review, no change to criteria
7/2025	Interim update, add information about quantity limits currently in place for Medicare members for definitive (quantitative) testing
8/4/2024	Interim update, add quantity limits for presumptive (qualitative) testing (8/15/2025: Replaced L36707 with L36668 due to Noridian JF consolidation with JE LCD policies)
12/2025	Annual review, no change to criteria
1/2026	Q1 2026 code updates