Medicare Medical Policy

Drug Testing for Therapeutic or Substance Use Monitoring

MEDICARE MEDICAL POLICY NUMBER: 6

Effective Date: 12/1/2023

Last Review Date: 11/2023

Next Annual Review: 11/2024

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.

Service	Medicare Guidelines
Urine *Drug Testing (UDT)*	• Testing performed in WA/OR: Local Coverage Determination (LCD) for Urine Drug Testing (L36707) • Testing performed in CA/NV: 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: LCD for Urine Drug Testing (L36037) • Testing performed in GA: LCD for Urine Drug Testing (L35724)
Oral Fluid *or* ***Hair*** *Drug Testing (e.g., PLA codes 0011U and 0116U)*	Company medical policy for Drug Testing for Therapeutic or Substance Use Monitoring 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:*[1]

- 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

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).

MEDICARE AND MEDICAL NECESSITY

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)*.

The Company 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. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations.

During the MAO review, an evidence-based process must be used. This includes using authoritative evidence, such as studies performed by government agencies (i.e., the FDA), well-designed clinical

studies that appeared in peer reviewed journals, and evaluations performed by independent technology assessment groups. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

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: Lab: Controlled Substance Monitoring and Drugs of Abuse Testing (A55030)

Medicare provides additional coding guidance in MLN Matters® Number SE1105.[3]

SPECIMEN VALIDITY TESTING

"Providers performing validity testing on urine specimens utilized for drug testing shall not separately bill the validity testing."[4]

HCPCS CODE H0003

The *National Physician Fee Schedule Relative Value File (NPFSRVF)*, which is published by the Centers for Medicare and Medicaid Services (CMS)[2], 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.

CPT CODES 80320-80377

CPT codes 80320-80377 have also been assigned a Status Indicator of "I" codes and are also 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])*
	~~0143U~~	**Termed 6/30/2023** ~~Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments~~

		~~including sample validation, per date of service *(Used to report CareViewRx, by Newstar Medical Laboratories, LLC [Georgia])*~~
	~~0144U~~	**Termed 6/30/2023** ~~Drug assay, definitive, 160 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service *(Used to report CareViewRx Plus, by Newstar Medical Laboratories, LLC [Georgia])*~~
	~~0145U~~	**Termed 6/30/2023** ~~Drug assay, definitive, 65 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service *(Used to report PainViewRx, by Newstar Medical Laboratories, LLC [Georgia])*~~
	~~0146U~~	**Termed 6/30/2023** ~~Drug assay, definitive, 80 or more drugs or metabolites, urine, by quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service *(Used to report PainViewRx Plus, by Newstar Medical Laboratories, LLC [Georgia])*~~
	~~0147U~~	**Termed 6/30/2023** ~~Drug assay, definitive, 85 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service *(Used to report RiskViewRx, by Newstar Medical Laboratories, LLC [Georgia])*~~
	~~0148U~~	**Termed 6/30/2023** ~~Drug assay, definitive, 100 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service *(Used to report RiskViewRx Plus, by Newstar Medical Laboratories, LLC [Georgia])*~~
	~~0149U~~	**Termed 6/30/2023** ~~Drug assay, definitive, 60 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service *(Used to report PsychViewRx, by Newstar Medical Laboratories, LLC [Georgia])*~~
	~~0150U~~	**Termed 6/30/2023** ~~Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service *(Used to report PsychViewRx Plus, by Newstar Medical Laboratories, LLC [Georgia])*~~
	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])*
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

1. Noridian web page for *Drug Testing Documentation Requirements*; Last Updated 3/2/2022; Available at: https://med.noridianmedicare.com/web/jfb/topics/documentation-requirements/drug-testing [Last cited 10/24/2022]
2. Medicare Physician Fee Schedule (PFS) Relative Value Files; Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files
3. Centers for Medicare and Medicaid Services (CMS). MLN Matters® Number: SE1105. Medicare Drug Screen Testing. https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/se1105.pdf. Accessed 10/09/2023.
4. Centers for Medicare and Medicaid Services (CMS). MLN Matters Number: SE18001. Proper Coding for Specimen Validity Testing Billed in Combination with Drug Testing. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE18001.pdf. Accessed 10/09/2023.

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