

Definitive Drug Testing

Medical Necessity and Policy Coverage Criteria[1]

[1]See generally applicable Local Coverage Determinations, including Palmetto GBA, Local Coverage Determination, "Urine Drug Testing," L35724; and/or applicable commercial payer coverage policies.

AEGIS® Sciences Corporation

Dear Ordering Provider,

Urine and oral fluid drug testing play an important role in patient care across pain management, substance use disorder treatment, psychiatry, and primary care. When ordered appropriately and supported by clear clinical documentation, presumptive and definitive drug testing provide objective information that can guide treatment decisions, improve patient safety, and support continuity of care.

Payers consistently evaluate drug testing claims based on whether the medical record clearly supports medical necessity for the test ordered. To support you in your process of documenting medically necessary test orders, we are pleased to provide the enclosed Definitive Drug Testing Guide, which summarizes key principles reflected across major commercial and government medical policies. This guide is intended as an educational resource to help align test selection and documentation with common payer expectations.

Key Documentation Principles to Support Medical Necessity

When ordering presumptive or definitive drug testing, the medical record should clearly reflect:

- The clinical indication for testing, such as monitoring adherence to prescribed therapy, evaluating unexpected findings, assessing risk for misuse or diversion, or guiding treatment decisions in substance use disorder or chronic pain management.
- Patient specific rationale, including relevant history, symptoms, risk factors, diagnosis, stage of treatment or recovery, or changes in clinical status.
- Test selection aligned to clinical need, with definitive testing targeted to specific drugs or drug classes that are relevant or frequently encountered within the population being treated.
- How results will be used to inform care, such as medication adjustments, counseling, safety planning, escalation or de escalation of therapy, or referral decisions.

Across payers, definitive testing is expected to be individualized, clinically justified, and adequately documented rather than reflexive or standing.

Our laboratory is committed to supporting ordering providers with accurate testing, clear reporting, and education around responsible test utilization. If you have questions regarding test selection, documentation best practices, or interpretation of results, our clinical support team is available to assist.

Thank you for your continued commitment to patient centered, evidence based care.

- Aegis Medical Policy, Regulatory and Clinical Sciences Teams

Palmetto GBA is the Medicare Administrative Contractor (MAC) with jurisdiction over Aegis.

While there is no National Coverage Determination concerning definitive drug testing, the majority of the MACs across the country have adopted Local Coverage Determinations (LCD) modeled after Palmetto's LCD ("Urine Drug Testing," L35724), the details of which are discussed in this document. Information and educational components within this document is extracted primarily from Palmetto's LCD. While the title of the LCD is Urine Drug Testing, both urine and oral fluid are noted as preferred biologic specimens for testing because of the ease of collection, storage, and cost-effectiveness. Multiple factors may influence a clinician's selection of specimen type, including but not limited to, the period of detection, any collection-related barriers such as access to restroom facilities, or substances to be included in testing.

Some commercial payers may have coverage policies with similar, different, or conflicting criteria as compared to the CMS contractors and should be considered when applicable for a particular patient.

"Medical necessity" means providing health care services that are reasonable and necessary for the diagnosis or treatment of illness or to improve the functioning of a malformed body member. Providers may order testing they determine to be medically necessary, giving due consideration to applicable medical policy coverage criteria. Providers must make their ordering decisions based upon their professional judgment as to what level of care is medically necessary and appropriate with the understanding that some testing may lack coverage and may result in higher or lower patient costs.

CMS contractors and, in particular, the Palmetto LCD generally recognize the following **Indications Supporting Medical Necessity** for definitive drug testing, based upon individualized assessments of each patient:

- Identifying a specific substance or metabolite that is inadequately detected by a presumptive drug test
- Definitively identifying specific drugs in a large family of drugs
- Identifying a specific substance or metabolite that is not detected by presumptive tests such as fentanyl, meperidine, synthetic cannabinoids and other synthetic/analog drugs
- Identifying drugs when a definitive concentration of a drug is needed to guide management (e.g., discontinuation of THC use according to a treatment plan) Identifying a negative, or confirming a positive, presumptive test result that is inconsistent with a patient's self-report, presentation, medical history, or current prescribed pain medication plan
- Ruling out an error as the cause of an unexpected presumptive test result
- Identifying non-prescribed medication or illicit use for ongoing safe prescribing of controlled substances
- Using results in a differential assessment of medication efficacy, side effects, or drug-drug interactions

The Palmetto LCD also states: definitive testing may be medically necessary based upon "patient specific indications, including historical use, medication response, and clinical assessment, when accurate results are necessary to make clinical decisions."

Individuals Receiving Chronic Opioid Therapy or Treatment with Other Controlled Substances

Purpose, Objectives, and Rationale for Testing

For patients on Chronic Opioid and other Controlled Medication Therapy, drug testing should be patient specific based on clinical assessment with documentation of the following minimal elements:

- Patient history, physical examination and previous laboratory findings
- Current treatment plan
- Prescribed medication(s)
- Risk assessment plan (e.g., Opioid Risk Tool score—low, moderate, or high risk)
- Providers are required to document within each patient medical record the test(s) ordered, as well as the medical necessity for each ordered test.

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 may be appropriate for testing. Testing Objectives for Chronic Opioid and other Controlled Medication Therapy include:

- Identifying absence of prescribed medication and potential for abuse, misuse, and diversion
- Identifying undisclosed substances, unsanctioned prescription medication, or illicit substances
- Identifying substances that contribute to adverse events or drug-drug interactions
- Providing objectivity to the treatment plan
- Reinforcing therapeutic compliance with the patient
- Providing additional documentation to demonstrate compliance with patient evaluation and management
- Providing diagnostic information to help assess patient response to medications over time for ongoing prescription management

Palmetto's coverage determinations regarding what to test for and the frequency of definitive testing for patients on **Chronic Opioid and other Controlled Medication Therapy**, include:

- Initial presumptive and/or definitive baseline testing. (Such testing may include amphetamine/methamphetamine, barbiturates, benzodiazepines, cocaine, methadone, oxycodone, tricyclic antidepressants, tetrahydrocannabinol, opioids, opiates, heroin, and synthetic/analog or "designer" drugs, depending on the patient's specific circumstances.)
- Beyond the initial baseline, additional Chronic Opioid Therapy monitoring testing may be reasonable and necessary based upon 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 cliniciandocumented change in affect or behavioral pattern.
- The frequency of testing must be based on the patient's risk potential for abuse and diversion using a validated risk assessment (e.g., Opioid Risk Tool score).

[1]See generally applicable Local Coverage Determinations, including Palmetto GBA, Local Coverage Determination, "Urine Drug Testing," L35724; and/or applicable commercial payer coverage policies.

Frequency limits based on validated risk assessment and stratification:

RISK GROUP	BASELINE	FREQUENCY OF TESTING
Low Risk	Prior to Initiation of COT	Up to 2 presumptive and 2 definitive tests in a rolling 365 days
Moderate Risk	Prior to Initiation of COT	Up to 2 presumptive and 2 definitive tests in a rolling 180 days
High Risk	Prior to Initiation of COT	Up to 3 presumptive and 3 definitive tests in a rolling 90 days

Source: Palmetto GBA, Local Coverage Determination, "Urine Drug Testing" L35724

Clinical scenarios may arise resulting in the necessity to test patients in excess of the frequency guidance provided within the coverage policy. Of note, rationale for testing must be clearly documented within patient records, and at times, may require additional authorization and approval prior to order placement. Any additional definitive drug testing beyond Palmetto's 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 changes in patient's medical condition or behavior
- Patient admits to use of illicit or non-prescribed controlled substance or displays symptoms of such use

Individuals Receiving Treatment for Substance Use Disorders

Purpose, Objectives, and Rationale for Testing

For diagnosis and treatment of Substance Use Disorders, drug testing should be patient specific, including evaluation and documentation of elements such as:

- 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 use of definitive testing should be based upon the patient's specific substance use history and when the provider needs to determine accurately specific drugs in the patient's system in order to integrate treatment decisions and clinical assessment.
- Providers are required to document within each patient medical record the test(s) ordered, as well as the medical necessity for each ordered test.

Frequency limits based on validated risk assessment, risk stratification, and duration of abstinence

Palmetto's coverage determinations regarding frequency of definitive testing for Substance Use Disorders include:

- 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 decision and clinical assessment.

PERIOD OF ABSTINENCE	FREQUENCY
0 - 30 consecutive days	Not to exceed 1 definitive test in a rolling 7 days
31 - 90 consecutive days	Not to exceed 3 definitive tests in a rolling 30 days
> 90 consecutive days	Not to exceed 3 definitive tests in a rolling 90 days

Source: Palmetto GBA, Local Coverage Determination, "Urine Drug Testing," L35724

Other Testing Frequency Considerations:

- Drug testing frequency should be guided by clinical assessment and evidence-based recommendations from organizations such as ADLM, AAPM, and ASAM.
- Palmetto's guidance as to the appropriate frequency of testing depends upon the type of treatment the patient is undergoing and the individualized patient needs, all of which must be supported within the medical record.
- Many managed care organizations impose annual utilization limits on drug testing. When specified, definitive testing is commonly limited to approximately 12-24 tests per year.
- Testing that exceeds payer frequency limits may require prior authorization or additional documentation supporting medical necessity.
- Providers should be familiar with payer-specific annual testing limits across their patient population to minimize coverage denials and support continuity of care.

Authorized Requests for Diagnostic Testing

- Per CMS 42 CFR §410.32, all diagnostic laboratory tests and other diagnostic tests must be ordered by the physician (or other qualified practitioner) who is treating the beneficiary.
- Though a provider signature on a test requisition isn't itself always an explicit requirement, it is highly encouraged as its inclusion may reduce the necessity to provide authenticated medical records to support necessity of requested testing.
- CMS required medical documentation to be:
  - Authenticated by the author
  - Hand-signed or properly electronically signed
  - Legible
  - Dated where required
  - Attributable to the practitioner responsible for the entry

Medical Documentation and Signatures

- Ordering should be individualized for each patient taking into account criteria discussed herein and in applicable medical policies.
- Providers are required to document within each patient medical record the test(s) ordered, as well as the medical necessity for each ordered test. Documentation may include, but is not limited to:

For Chronic Opioid and other Controlled Medication Therapy:

- the patient history, findings from physical exams, and previous laboratory findings;
- current treatment plan;
- prescribed medication(s);
- risk assessment plan; and
- any other reasoning in support of the ordered testing (e.g., aberrant behavior, patient admits to use of illicit or non-prescribed controlled substances, sudden changes in medical condition, side effect profile changes, patient response to prescribed medication changes, assessment for possible drug-drug interactions, evidence of diversion, etc.)

For Substance Use Disorders:

- the patient history, findings from physical exams, and previous laboratory findings;
- the stage of treatment or recovery;
- suspected abused substances;
- substances that may present high risk for additive or synergistic interactions with prescribed medication;
- the testing method and frequency based upon the stage of screening, treatment, or recovery;
- the rationale for the drugs/drug classes ordered; and
- document test results within the medical record

Aegis strongly encourages providers to sign the paper or electronic requisition for all ordered testing.

Aegis's Medical Policy, Regulatory, and Clinical Science Teams, which are comprised of an MD, PhDs, PharmDs, and Board Certified Toxicologists, are available to discuss questions related to coverage policies and Aegis's test offerings.

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Example Medical Necessity Checklist (check all that apply)

Attestation from Ordering Provider

☐ The testing ordered is reasonable and medically necessary for this patient and clinical encounter.

Patient Condition(s)

Chronic Opioid Therapy Risk Stratification*:

☐ Low
☐ Moderate
☐ High

Substance Use Disorder State of Treatment Risk Stratification*:

☐ Initiation/Induction
☐ Stabilization
☐ Maintenance

Other*:

☐ Other (e.g., long term use of non-opioid therapy such as benzodiazepines, stimulants, antidepressants, etc).

** Using a validated risk assessment tool (e.g., SOAPP-R, ORT, and PMQ) and based upon a complete clinical assessment of the individual's risk potential for abuse and diversion*

Clinical Purpose for Testing

☐ Baseline assessment prior to initiating or modifying therapy
☐ Ongoing monitoring of adherence or response to therapy
☐ Evaluation of unexpected or inconsistent prior test result
☐ Assessment of risk for misuse, diversion, or unsafe co-use
☐ Monitoring during treatment or recovery for substance use disorder

Patient Specific Risk or Indication

☐ Prescribed controlled substance(s)
☐ History of substance use disorder or misuse
☐ Psychiatric or behavioral health diagnosis
☐ Chronic pain or long term therapy requiring monitoring
☐ Aberrant behavior, change in clinical status, or reported concern
☐ Medication interaction or safety concern

Test Selection Rationale (Providers are required to document within each patient medical record the test(s) ordered, as well as the medical necessity for each ordered test)

☐ **Presumptive testing** sufficient for current clinical question

Definitive testing needed because (check one):
☐ Aberrant behavior, change in clinical status, or reported concern
☐ Specific drug or metabolite cannot be reliably identified by immunoassay
☐ Accurate identification needed to guide management or safety

Test Scope

☐ Tests ordered are patient specific (not blanket or routine)
☐ Panel size limited to substances relevant to this encounter
☐ Drugs/drug classes ordered reflect clinical history, risk, or treatment plan

Use of Results

☐ Results will inform care decisions (e.g., medication continuation, adjustment, counseling, test frequency)
☐ Results will be documented and reviewed in the medical record

Disclaimer: The information contained in this checklist is provided solely as an example of documentation practices that may support the medical necessity of laboratory testing. It is not intended to establish a standard of care, guarantee coverage or reimbursement, or serve as a comprehensive summary of all documentation requirements. Requirements may differ among managed care organizations, commercial insurers, Medicare, Medicaid programs, and other payers. Providers are solely responsible for determining the medical necessity of testing based on the patient's individual clinical circumstances and for maintaining documentation that satisfies applicable payer, regulatory, and legal requirements. Nothing in this resource should be construed as medical, legal, billing, or reimbursement advice, nor should it replace the provider's professional judgment.

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