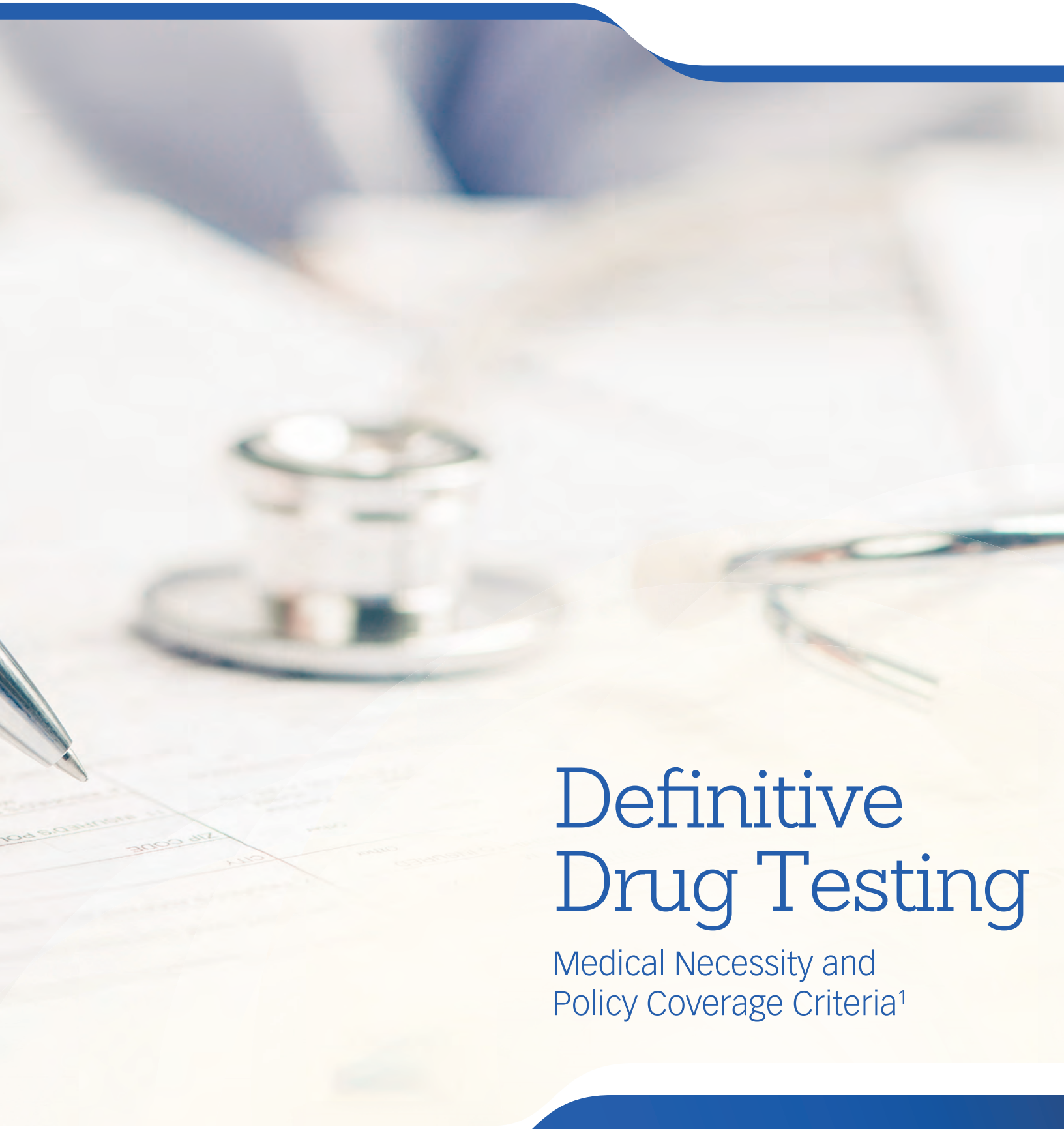

Definitive Drug Testing

Medical Necessity and Policy Coverage Criteria[1]

[1]*See generally applicable Local Coverage Determinations, including Palmetto GBA, Local Coverage Determination, "Controlled Substance Monitoring and Drugs of Abuse Testing," L35724; and/or applicable commercial payer coverage policies.*

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"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 critiera. 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.

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 ("Controlled Substance Monitoring and Drugs of Abuse Testing," L35724), the details of which are discussed in this document.

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

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.

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."

Chronic Opioid Therapy Patients

For patients on **Chronic Opioid 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., SOAPP score—low, medium, or high risk)

Testing Objectives for **Chronic Opioid Therapy** include:

- Identifying absence of prescribed medication and potential for abuse, misuse, and diversion
- Identifying undisclosed substances, such as alcohol, 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 Therapy**, include:

- Initial presumptive and/or definitive baseline testing.
- 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 clinician documented 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., SOAPP score).

Frequency limits based on validated risk assessment and stratification:

RISK GROUP	BASELINE	FREQUENCY OF TESTING
Low Risk	Prior to Initiation of COT	Random testing 1 - 2 times, every 12 months
Moderate Risk	Prior to Initiation of COT	Random testing 1 - 2 times, every 6 months
High Risk	Prior to Initiation of COT	Random testing 1 - 3 times, every 3 months

Source: Palmetto GBA, Local Coverage Determination, "Controlled Substance Monitoring and Drugs of Abuse Testing," L35724

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
- Patient admits to use of illicit or non-prescribed controlled substance

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.

Substance Use Disorder Patients

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.

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 physician directed test per week
31 - 90 consecutive days	Not to exceed 1 - 3 physician directed test(s) per month
> 90 consecutive days	Not to exceed 1 - 3 physician directed test(s) per 3 months

Source: Palmetto GBA, Local Coverage Determination, "Controlled Substance Monitoring and Drugs of Abuse Testing," L35724

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.

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 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, 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 frequency based upon the stage of screening, treatment, or recovery;
- the rationale for the drugs/drug classes ordered; and
- document test results w/in 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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