G0480-G0483

DEFINITIVE URINARY DRUG TESTING

FACT SHEET

Description

CPT Codes G0480-G0483, Definitive Urinary Drug Testing

Definitive/Quantitative/Confirmation (hereafter called "definitive" UDT) is used when medically necessary to identify specific medications, illicit substances and metabolites; reports the results of analytes absent or present typically in concentrations such as ng/mL.

Medical Necessity

Physician-directed definitive testing is reasonable and necessary when ordered for a particular patient based upon historical use and community trends. However, the same physician-defined profile is not reasonable and necessary for every patient in a physician's practice. Definitive UDT orders should be individualized based on clinical history and risk assessment and must be documented in the medical record.

Criteria to establish medical necessity for drug testing must be based on patient-specific elements identified during the clinical assessment, and documented by the clinician in the patient's medical record and minimally include the following elements:

a. Patient history, physical examination, and previous laboratory findings.
b. Signed and dated order or intent to order noted in medical record
c. Current treatment plan.
d. Prescribed medication(s)
e. Risk assessment

Frequency of testing beyond the baseline presumptive UDT must be based on individual patient needs substantiated by documentation in the patient's medical record.

Frequency of Definitive UDT for Substance Use History (SUD)

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 decisions and clinical assessment. The frequency and the rational for definitive UDT must be documented in the patient's medical record.

a. For patients with 0 to 30 consecutive days of abstinence, definitive UDT is expected at a frequency not to exceed 1 physician-directed testing profile in one week. More than 1 physician-directed testing profile in one week is not reasonable and necessary and is not covered by Medicare.
b. For patients with 31 to 90 consecutive days of abstinence, definitive UDT is expected at a frequency of 1-3 physician-directed testing profiles in one month. More than 3 UDT in one month is not reasonable and necessary and is not covered by Medicare.
c. For patients with > 90 day of consecutive abstinence, definitive UDT is expected at a frequency of 1-3 physician-directed testing profiles in three months. More than 3 definitive UDT in 3 months is not reasonable and necessary and is not covered by Medicare.

Documentation Requirements for Substance Use History (SUD)

The patient's medical record should include but is not limited to:

1. The assessment of the patient by the ordering provider as it relates to the complaint of the patient for that visit,
2. Relevant medical history
3. Results of pertinent tests/procedures
4. Signed and dated office visit record/ operative report (Please note that all services ordered or rendered to Medicare beneficiaries must be signed.)

This Fact Sheet is for informational purposes only and is not intended to guarantee payment for services, all services submitted to Medicare must meet Medical Necessity guidelines. The definition of "medically necessary" for Medicare purposes can be found in Section 1862(a)(1)(A) of the Social Security Act – Medical Necessity (http://www.ssa.gov/OP_Home/ssact/title18/1862.htm).

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Chronic Opioid Therapy (COT)

A physician who is writing prescriptions for medications to treat chronic pain can manage a patient better if the physician knows whether the patient is consuming another medication or substance, which could lead to drug-drug interactions. Additionally, UDT may help the physician monitor for medication adherence, diversion, efficacy, side effects, and patient safety in general.

Medical Necessity Guidance

Criteria to establish medical necessity for drug testing must be based on patient-specific elements identified during the clinical assessment, and documented by the clinician in the patient's medical record and minimally include the following elements:

a. Patient history, physical examination and previous laboratory findings;
b. Current treatment plan;
c. Prescribed medication(s)
d. Risk assessment

Frequency of testing beyond the baseline presumptive UDT must be based on individual patient needs substantiated by documentation in the patient's medical record. Recommendations for the ordering of presumptive and definitive UDT for patients on COT are as follows:

Chronic Opioid Therapy (COT) Baseline Testing

Initial presumptive and/or definitive COT patient testing may include amphetamine/methamphetamine, barbiturates, benzodiazepines, cocaine, methadone, oxycodone, tricyclic antidepressants, tetrahydrocannabinol, opioids, opiates, heroin, and synthetic/analog or "designer" drugs.

Chronic Opioid Therapy (COT) Monitoring Testing

Ongoing testing may be medically reasonable and necessary based on 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. As part of the clinical evaluation of the patient the provider should inquire about prescription compliance and potential issues of abuse or diversion such as lost prescriptions, early refill requests, or requests for escalating dose of medication. The frequency of testing must be based on the individual's risk potential. Sample frequency based on risk is listed in table below.

The clinician should perform random UDT at random intervals, in order to properly monitor a patient. UDT testing does not have to be associated with an office visit.

Patients with specific symptoms of aberrant behavior or misuse associated with medication use may be tested more frequently. However, the rationale for more frequent testing must be supported in the medical record.

UDT Frequency Based on Risk Assessment and Stratification*

Testing must be based on clinician's documented medical necessity and reviewed by the clinician in the management of prescribing/renewing a controlled substance for every risk group outlined on the next page.

Testing Objectives

a. Identifies absence of prescribed medication and potential for abuse, misuse, and diversion.
b. Identifies undisclosed substances, such as alcohol, unsanctioned prescription medication, or illicit substances.
c. Identifies substances that contribute to adverse events or drug-drug interactions.
d. Provides objectivity to the treatment plan.
e. Reinforces therapeutic compliance with the patient.
f. Provides additional documentation demonstrating compliance with patient evaluation and monitoring.
g. Provide diagnostic information to help assess individual patient response to medications (e.g., metabolism, side effects, drug-drug interaction, etc.) over time for ongoing management of prescribed medications.

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Risk Group	Baseline	Frequency of Testing
Low Risk	Prior to Initiation of COT	Random testing 1-2 times every 12 months for 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.
Moderate Risk	Prior to Initiation of COT	Random testing 1-2 times every 6 months for prescription medications, non-prescribed medication that may pose a safety risk if taken with prescribed medications, and illicit substances, based on patient history, clinical presentation, and/or community usage.
High Risk	Prior to Initiation of COT	Random testing performed 1-3 times every 3 months for prescribed medications, non-prescribed medications that may pose a safety risk if mixed with prescribed and illicit substances based on patient history, clinical presentation and/or community usage.

***Note:** Any additional definitive UDT beyond 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 change in patient's medical condition
- Patient admits to use of illicit or non-prescribed controlled substance.

Resources

For more information regarding Definitive Drug Testing, please view the following resources:

CMS National Coverage Policy

- Title XVIII of the Social Security Act, §1862(a)(1)(A). Allows coverage and payment for only those services that are considered to be reasonable and necessary.
- 42 CFR 410.32(a). Order diagnostic tests.
- 42 CFR 411.15(k)(1). Particular Services excluded from coverage.
- CMS On-Line Manual, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, §§80.0, 80.1.1, 80.1.2. Clinical Laboratory services.
- CMS Internet Only Manuals, Pub 100-02 Medicare Beneficiary Policy Manual chapter 15, §80 Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests, §80.1.1 Certification Changes
- Section 80.6-Requirements for Ordering and Following Orders for Diagnostic Tests: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf#page=111
- https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf

LCD

- Controlled Substance Monitoring and Drugs of Abuse Testing: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=36029&ver=38&contractorName=9&contractorNumber=239%7c1&lcdStatus=all&sortBy=title&bc=AAAAgAAAAAAA
- Billing and Coding: Controlled Substance Monitoring and Drugs of Abuse Testing (A56818) (https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=56818&ver=34)

CMS Publication: MLN

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ProviderComplianceLabServices-Fact-Sheet-ICN909221.pdf

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