Targeted Probe and Educate

Laboratory Testing Services

Healthcare Common Procedure Coding System (HCPCS) Codes G0480 – G0483 and Current Procedural Terminology (CPT Code 80307

Disclaimer

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Objectives

- Identify Laboratory Testing Services
- Recognize eligibility and diagnosis requirements for these services
- Identify necessary documentation to be included in the medical record

Background

- Laboratory tests are covered under the Medicare program
- Some clinical laboratory procedures or tests require Food and Drug Administration (FDA) approval before coverage is provided.

Payment

Outpatient laboratory services can be paid in different ways:

- Physician Fee Schedule
- 101 percent of reasonable cost (critical access hospitals (CAH) only)
- Laboratory Fee Schedule
- Outpatient Prospective Payment System (OPPS), except for most hospitals in the State of Maryland that are subject to a waiver
- Reasonable Charge

Annually, Centers for Medicare & Medicaid Services (CMS) distributes a list of codes and indicates the payment method.

Payment

- Carriers, Fiscal Intermediaries (FI), and A/B Medicare Administrative Contractors (MACS) are responsible for applying the correct fee schedule for payment of clinical laboratory tests.
- Unless a laboratory, physician, or medical group accepts assignment, the A/B MAC makes no Part B payment for laboratory tests paid on the laboratory fee schedule. Laboratories, physicians, or medical groups that have entered into a participation agreement must accept assignment.

Payment for Review of Lab Test Results by Physician

- Reviewing results of laboratory test, phoning results to patients, filing such results, etc., are Medicare covered services
- Payment is included in the physician fee schedule payment for the evaluation and management (E and M) services to the patient
- The Current Procedure (CPT) lists different levels of E and M services and describes services that are included as E and M services.
- Such activities including obtaining, reviewing, and analyzing appropriate diagnostic tests

Order or Request

- A communication from the treating physician or practitioner requesting that a diagnostic test be performed for a beneficiary
- The order may conditionally request an additional diagnostic test if:
  - The result of the initial diagnostic test ordered yields to a certain value determined by the treating physician or practitioner
- The intent that the test be performed must be documented and support medical necessity

Documentation for the Order

- Signed and dated order or visit/progress note supporting intent to order
- Documentation must support medical necessity

Date of Service (DOS) Policy

- General rule: DOS of the test or service must be the date the specimen was collected
- Variation: If a specimen is collected over a period that spans two calendar days:
  - DOS must be the date the collection ended
- Exceptions to the DOS policy:
  - Stored specimens
  - Chemotherapy sensitivity tests/services performed on live tissue

Stored Specimens 30 Days or Less

- DOS of the test/service must be the date the test or service was performed if:
  - Test/service is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital
  - Specimen was collected while the patient was undergoing a hospital surgical procedure
  - It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted
  - Results of the test/service do not guide treatment provided during the hospital stay; and
  - Test/service was reasonable and medically necessary for treatment of an illness

Stored Specimens More Than 30 Days

- DOS of the test/service must be the date the specimen was obtained from storage
- If the specimen was stored for more than 30 calendar days before testing, the specimen is considered to have been archived and the DOS of the test must be the date the specimen was obtained from storage.

Clinical Laboratory Improvement Amendments (CLIA) Requirements

- In 1988 CLIA amended the Public Health Service Act to extend jurisdiction of the Department of Health and Human Services to regulate all laboratories that examine human specimens
- Purpose of CLIA program is to assure that lab testing specimens in interstate commerce consistently provide accurate procedures and services
- The CLIA mandates that virtually all laboratories, including physician office laboratories, meet applicable Federal requirements
- Laboratory must have a CLIA certificate in order to receive reimbursement from Federal programs

Local Coverage Determination

Local Coverage Determination L35006 – Controlled Substance Monitoring and Drugs of Abuse Testing

- Urine drug testing (UDT) provides objective information to assist clinicians in identifying the presence or absence of drugs or drug classes in the body and making treatment decisions.
- Presumptive drug screen is used to detect the presence of a drug in the body
- Blood or urine sample may be used
- Urine is the best specimen for presumptive screening

Drug Analysis Methodology

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- Common methods of drug analysis include chromatography, immunoassay, chemical ("spot") tests, and spectrometry. Analysis is comparative, matching the properties or behavior of a substance with that of a valid reference compound (a laboratory must possess a valid reference agent for every substance that it identifies).
- Drugs or classes of drugs are commonly assayed by presumptive testing. A presumptive test may be followed by definitive testing, when there is a positive inconsistent finding from the presumptive test in the setting of a symptomatic patient. Typically, the "spot" chemical tests (referred to above) are urine dipsticks or multiple drug cup devices.

Drug Tests

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- Gas Chromatography coupled with Mass Spectrometry is also known as GC-MS
- High Performance Liquid Chromatography couples with Tandem Mass Spectrometry is also known as LC-MS/MS
- These are complex technologies that use the separation capabilities of gaseous or liquid chromatography with the analytical capabilities of mass spectrometry

Definitions

Presumptive (Qualitative) Drug Testing

- Used when medically necessary to determine the presence or absence of drugs or drug classes in a urine sample
- Results expressed as negative or positive or as a numerical result
- Included competitive immunoassays (IA) and thin layer chromatography

Definitive (Quantitative) Confirmation

- Used when medically necessary to identify specific medications, illicit substances and metabolites
- Reports the results of drugs absent or present in concentrations of ng/ml
- Limited to GC-MS and LC-MS/MS testing methods only

Drugs and Drug Classes

- Examples of drugs or classes of drugs that are commonly assayed by presumptive tests, followed by definitive testing, are: alcohols, amphetamines, barbiturates/sedatives, benzodiazepines, cocaine and metabolites, methadone, antihistamines, stimulants, opioid analgesics, salicylates, cardiovascular drugs, antipsychotics, cyclic antidepressants, and others. Focused drug screens, most commonly for illicit drug use, may be more useful clinically.
- There should be a direct correlation between those positive findings generated from presumptive testing and those requested definitive tests to specifically confirm such findings.

Drug Testing HCPS and CPT Codes

- G0480 – definitive drug testing, 1-7 drug class(es)
- G0481 – definitive drug testing, 8 -14 drug class(es)
- G0482 – definitive drug testing, 15-21 drug class(es)
- G0483 – definitive drug testing, 22 or more drug class(es)

- 80307 – presumptive drug test, any number of drug classes, by instrument chemistry analyzers (eg, utilizing immunoassay)

Limitations of Presumptive UDT

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- Primarily screens for drug classes rather than specific drugs
- Practitioner may not be able to determine if a different drug within the same class is causing the positive result
- Produces erroneous results due to cross-reactivity with other compounds or does not detect all drugs within a drug class
- Not all prescription medications are detectable or have assays available, therefore, it is unclear whether other drugs are present when some tests are reported as positive
- Cut-off may be too high to detect presence of a drug
- Could cause a practitioner to make a wrong assumption or clinical decision

Definitive UDT

- Quantitative tests that identify all specific drugs, metabolites, and most illicit substances and report the results as absent or present in concentrations of ng/mL
- Definitive UDT is used in a differential assessment of medication efficacy, side effects, or drug-drug interactions

Definitive UDT (continued)

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Reasonable and necessary in order to:

- Identify a specific substance or metabolite that is inadequately detected by a presumptive UDT
- Definitively identify specific drugs in a large family of drugs
- Identify drugs when a definitive concentration of a drug is needed to guide management
- Identify a negative, or confirm a positive, presumptive UDT result that is inconsistent with a patient's self-report, presentation, medical history, or current prescribed pain medication plan
- Rule out an error as the cause of a presumptive UDT result
- Identify non-prescribed meds or illicit use for ongoing safe prescribing of controlled substances

Definitive UDT (continued)

- May be reasonable and necessary based on patient specific indications, including historical use, medication response, and clinical assessment, when accurate results are necessary to make clinical decisions
- The clinician's rationale for the definitive UDT and the tests ordered must be documented in the patient's medical record

Definitive UDT (continued)

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- Quantification should not be used to determine adherence with a specific dosage or time of dose of a pain medication or illicit drug for clinical purposes. Rather, the use of quantitative drug data may be important for many reasons such as in a differential patient assessment.
- For example, when several opioids are present in the urine of a patient prescribed a single opioid, quantification may help the clinician decide whether the presence of the other opioids is consistent with metabolism of the prescribed opioid, opioid contamination during manufacturing, or if more than one drug within a class is being used.

Definitive UDT (continued)

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- Quantification may also provide information in the setting of illicit drug use. Serial creatinine-corrected quantitative values may assist in the differential assessment of ongoing drug use or cessation of drug use with continued drug excretion.

- Definitive UDT is used in a differential assessment of medication efficacy, side effects, or drug-drug interactions

Covered Indications

Group A – Symptomatic patients, multiple drug ingestion or patients with unreliable history

- A patient who presents in a variety of medical settings with signs or symptoms of substance use toxicity will be treated presumptively to stabilize the patient while awaiting rapid, then definitive testing to determine the cause(s) of the presentation
- The need for definitive UDT is based upon rapid test findings, responses to medical interventions, and treatment plan

The presumptive findings, definitive drug tests ordered and reasons for the testing must be documented in the patient's medical record.

Group A Indications

Patient who present to an urgent care setting with any one of the following:

- Coma
- Altered mental status in the absence of a clinically defined toxic syndrome or toxidrome
- Severe or unexplained cardiovascular instability (cardiotoxicity)
- Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome
- Seizures with an undetermined history
- To provide antagonist to specific drug

Group B

Group B – Diagnosis and treatment for substance abuse or dependence

- Patient in active treatment for substance use disorder (SUD) or monitoring across different phases of recovery
- Physician who is writing prescriptions for medications to treat either the SUD or other conditions may need to know if patient is taking substances which can interact with prescribed meds or taking prescribed meds as expected
- Risk of drug-drug interactions is inherent to the patient and may be compounded by prescribed medications

Group B

- Ordered tests and testing methods (presumptive or definitive) must match the stage of screening, treatment, or recovery; the documented history; and Diagnostic and Statistical Manual of Mental Disorders (DSM V) diagnosis.
- For patients with no known indicators of risk for SUDs, the clinician may screen for a broad range of commonly abused drugs using presumptive UDT.
- For patients with known indicators of risk for SUDs, the clinician may screen for a broad range of commonly abused drugs using definitive UDT.

Group B

For patients with a diagnosed SUD, clinician should perform random UDT, at random intervals.

Testing profiles must be determined by the clinician based on the following medical necessity guidance criteria:

- Patient history, physical examination, and previous lab 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)

Group B

- The patient's medical record must include an appropriate testing frequency 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.

Group C

Group C – Treatment for patients on chronic opioid therapy (COT)

- Physician who is writing prescriptions for medications to treat chronic pain can manage a patient better if they know whether patient is consuming another medication or substance
- UDT may help physician monitor for medication adherence, efficacy, side effects, and patient safety in general

Group C

- A broad cross section of the general population will develop either cancer pain syndrome or non-cancer pain which will require prolonged or chronic opioid therapy for management. The risk of addiction in this population is considered equivalent to the risk in the general population. In contrast to the population of individuals who have a history of SUD, in the cancer and non-cancer pain population the risk of SUD is inherent to the substance(s) to which the patient is exposed.

Chronic Opioid Therapy
UDT Testing Objectives

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- Identifies absence of prescribed medication and potential for abuse, misuse, and diversion
- Identifies undisclosed substances, such as alcohol, unsanctioned prescription medication, or illicit substances
- Identifies substances that contribute to adverse events or drug-drug interactions
- Provides objectivity to the treatment plan
- Reinforces therapeutic compliance with the patient
- Provides additional documentation demonstrating compliance with patient evaluation and monitoring

UDT Testing

UDT testing also provides 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

Medical Necessity

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:

- Patient history, physical examination and previous lab findings
- Current treatment plan
- Prescribed medication(s); and
- Risk assessment plan

National pain organizations, physician societies, and the Federation of State Medical Boards recommend a practical approach to definitive UDT for COT.

Frequency of Testing

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:

- COT Baseline Testing - Initial presumptive or definitive COT patient testing may include testing of multiple drug classes
- 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

Frequency of Testing

- The frequency of testing must be based on a complete clinical assessment of the individual's risk potential for abuse and diversion using a validated risk assessment interview or questionnaire and should include the patient's response to prescribed medications and the side effects of medications.
- 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.

Specimen Type

Urine or oral fluid is the preferred biologic specimen for testing because of the ease of collection, storage, and cost-effectiveness. UDT cannot detect the dosage of drug ingested/used, the time of use, or the means of delivery (intravenous vs. oral vs. inhaled). Detection time of a substance in urine is typically 1-3 days depending on the drug, rate of metabolism, and rate of excretion. Lipid-soluble drugs, such as marijuana, may remain in body fat and be detected upwards of a week or more.

Documentation Requirements

- All documentation must be maintained in patient's medical record
- Every page of the record must be legible and include appropriate patient identification information and legible signature of provider
- Must support medical necessity of the services
- Must indicate the medical necessity for performing a qualitative drug test
- All tests must be ordered in writing by treating provider and all drugs/drug classes to be tested must be indicated in the order
- When definitive/quantitative test is performed, the record must show an inconsistent positive finding was noted on the presumptive testing or that there was no available presumptive test

Retention of Records

If the provider of the service is other than the ordering/referring physician, that provider must maintain hard copy documentation of the lab results, along with copies of the ordering/referring physician's order for the test. The physician must include the clinical indication/medical necessity in the order for the test.

Utilization Guidelines

- The contractor will consider presumptive UDT testing in excess of 12 per Calendar year not reasonable and necessary.
- The contractor will only pay for one presumptive UDT test per patient per date of service regardless of the number of billing providers.
- Utilization of these services should be consistent with locally acceptable standards of practice.

Substance Abuse Disorder – Utilization Guidelines

An exception to the utilization guidelines for presumptive UDT testing will be made for patients with documented diagnoses consistent with a substance abuse disorder (SUD), for which patients presumptive UDT shall not occur more than 3 times within a seven-day period, based upon the following guidelines for monitoring abstinence:

- Patients with 0 to 30 consecutive days of abstinence = 1 to 3 times per week. More than 3 presumptive panels in one week is not reasonable and necessary and is not covered.
- Patients with 31 to 90 consecutive days of abstinence = 1 to 3 times per week. More frequent testing is not covered.
- Patients with more than 90 consecutive days of abstinence = 1 to 3 times in one month. More frequent testing is not covered.

Chronic Opioid Therapy – Utilization Guidelines

The contractor will consider up to 12 definitive tests (i.e., definitive UDT) per Calendar year reasonable and necessary. This would correspond to 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 or community usage.

**The contractor will only pay for one presumptive UDT test per patient per date of service regardless of the number of billing providers.

Non-Covered Services

- Blanket Orders
- Routine standing orders for all patients in a physician's practice are not reasonable and necessary
- Drug testing of two different specimen types from the same patient on the same date of service for the same drugs/metabolites/analytes
- UDT for medico-legal or employment purposes or to protect a physician from drug diversion charges
- Specimen validity testing including, but not limited to, pH, specific gravity, oxidants, creatinine

Non-Covered Services

The following are considered NOT reasonable and necessary:

- Reflex definitive UDT when presumptive testing is performed at point of care – the clinician may have sufficient information to manage the patient
- Physician to perform presumptive POCT and order presumptive Immunoassay (IA) testing from a reference lab (Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers)
- Reference lab to perform and bill IA presumptive UDT prior to definitive testing without a specific physician's order for the presumptive testing

Non-Covered Services (continued)

- It is not reasonable and necessary for a physician to perform presumptive IA testing and order presumptive IA testing from a reference laboratory with or without reflex testing (Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers)
- IA testing, regardless of whether it is qualitative or semi-quantitative (numerical), may not be used to “confirm” or definitively identify a presumptive test result obtained by cups, dipsticks, cards, cassettes or other IA testing methods. Definitive UDT provides specific identification or quantification by GC-MS or LCMS/MS

Summary

- Discussed laboratory testing services documentation requirements
- Provided details about billing laboratory testing services

References

- Centers for Medicare & Medicaid Services Internet Only Manual, Publication 100-04, Medicare Claims Processing Manual, Chapter 16
- Local Coverage Determination (LCD) Controlled Substance Monitoring and Drugs of Abuse Testing – L35006
- Link to LCD L35006: https://LCD 35006 Controlled Substance Monitoring and Drugs of Abuse Testing
- www.novitas-solutions.com