2018-2019 Annual Physician Notice of Laboratory Compliance

To our Valued Healthcare Partners:

AIT Laboratories, a HealthTrackRx company, maintains an active compliance program that reflects our commitment to conduct business in compliance with all federal, state and local laws. As a participant in federally funded healthcare programs, AIT Laboratories delivers annual provider information and education regarding laboratory compliance, billing and coding guidelines, and information to our provider clients on the responsibilities we share.

This physician annual notice specifies current Medicare/Medicaid program requirements and AIT Laboratories policies. Please carefully review the information and contact Melissa Stokes, AIT Laboratories Compliance Manager, at (972) 833-4642 or melissa@healthtrackrx.com if you have any questions or concerns. AIT Laboratories also offers an anonymous hotline for reporting any compliance concerns and can be accessed using the following methods:

Toll Free Number: 844-990-0002
Website: www.lighthouse-services.com/healthtrackrx
Email: reports@lighthouse-services.com
Fax: 215-689-3885

AIT Laboratories must rely on you, our provider clients, for the following key compliance elements:

Disclosure of Exclusions from Federal Healthcare Programs

Under federal law, no payment will be made by any federal healthcare program for any items or services furnished, ordered, or prescribed by an excluded individual or entity. Under the Centers for Medicare & Medicaid Services' (CMS) rules, providers must not employ or contract with individuals or entities excluded from participation in any health care program or debarred by the GSA. CMS does not permit payments furnished under the plan by an individual or entity while being excluded from participation. CMS has further advised states that they should require providers to search the HHS OIG website monthly to capture exclusions and reinstatements. Professionals who are required to be licensed shall notify AIT Laboratories in writing within (5) days of receiving any written or oral notice of any adverse action, including, without limitation, exclusion from participation in any federal or state health care or procurement programs, any filed and served malpractice suit or arbitration action; any adverse action by an applicable state licensing board taken or pending; any adverse action which has resulted in the filing of a report with the applicable state licensing board any revocation of DEA license; or a conviction of any felony or a misdemeanor of moral turpitude; any action against any certification under the Medicare or Medicaid programs.

List of Excluded Individuals/Entities (LEIE): The OIG established a program to exclude individuals and entities who have been found to have violated federal law and/or regulations. The effect of an OIG exclusion from Federal healthcare programs is that no Federal healthcare program payment may be made for any items or services (1) furnished by an excluded individual or entity, or (2) directed or prescribed by an excluded physician (42 CFR 1001.1901). This payment ban applies to all methods of Federal program reimbursement, whether payment results from itemized claims, cost reports, fee schedules or a prospective payment system (PPS). Any items and services furnished by an excluded individual or entity are not reimbursable under Federal health care programs. In addition, any items and services furnished at the medical direction or prescription of an excluded physician are not reimbursable when the individual or entity furnishing the services either knows or should know of the exclusion. This prohibition applies even when the Federal payment itself is made to another provider, practitioner or supplier that is not excluded.

System for Award Management (SAM) is the Official U.S. Government system that consolidated the capabilities of CCR/FedReg, ORCA, and the List of Parties Excluded from Federal Procurement and Non-procurement Programs (EPLS). The GSA maintains the a single comprehensive list of individuals and firms excluded by Federal government agencies from receiving federal contracts or federally approved subcontracts and from certain types of federal financial and nonfinancial assistance and benefits. The EPLS was originally created for information of and use by Federal agencies.

Medicaid State Sanction Data**:** Many states maintain their own database of individuals and entities they sanction. Several call for or require health care entities to screen against this list. This is in addition to not in lieu of screening against the Federal sanction information.

Medical Necessity

Medicare will only pay for tests that meet the Medicare coverage criteria and are medically necessary for the diagnosis or treatment of the individual patient. Criteria to establish medical necessity for testing must be based on patient-specific elements identified during the clinical assessment and documented by the clinician in the patient's medical record. Tests used for routine screening of patients without regard to their

individual need are not usually covered by the Medicare Program, and therefore are not reimbursed. As a participating provider in the Medicare Program, AIT Laboratories, has a responsibility to make a good faith effort to ensure all tests requested are performed and billed in a manner consistent with all federal and state law regulations. As the physician, you are responsible for documenting medical necessity in the patient's medical record (including physician signature) and for providing appropriate diagnostic information in the form of ICD-10 codes to the highest level of specificity or a narrative to AIT Laboratories. *The Office of Inspector General takes the position that a physician who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act.* Refer to Exhibit 1B under "Documentation Requirements" for further details.

Recent policy changes and Health Plan actions, including increased use of post-payment audits, has encouraged AIT Laboratories to more aggressively enforce long-standing policies that patients' medical records must include documentation of medical necessity for ordering tests. Though this is specified in each AIT Laboratories *Practitioner Acknowledgement Form* that is signed by the provider and filed with AIT Laboratories we are also educating any laboratory that is currently using AIT Laboratories as the Reference Laboratory.

Test Order Requisition

To ensure accurate processing and testing, efficient patient identification, timely reporting of laboratory results, valid laboratory orders must include the following:

Patient's full legal name, date of birth, reason for each test ordered, date and time of collection, source (when applicable), and the licensed ordering practitioner's name and address. Handwritten orders must be signed and dated by the provider. Custom Profiles may be used if patient specific medical necessity is recorded in the patient's medical records and clearly marked on the Test Order Requisition. Signature stamps are NOT acceptable.

Although the provider signature is not required on laboratory requisitions, if signed, the requisition will serve as acceptable documentation of a physician order for the testing. In the absence of a signed requisition, documentation of your intent to order each laboratory test must be included in the patient's medical record and available to AIT Laboratories upon request, as needed. Documentation must accurately describe the individual tests ordered; it is not sufficient to state 'labs ordered'.

The pre-printed test order requisition is the tool used to communicate the physician order to the laboratory, but is NOT considered the valid 'order' as defined by Medicare. Upon request by AIT Laboratories or its payers/auditors, ordering providers are required to provide any/all chart documentation (including physician signature) that reflect the actual lab order and supports the authenticity and medical necessity of the lab order(s) submitted.

Test Ordering

A standard AIT Laboratories test requisition form should be used when ordering tests. This requisition is designed to emphasize physician choice and encourage physicians to order only those tests which the physician believes are appropriate and medically necessary for the treatment and diagnosis of each patient. If AIT Laboratories receives a non-AIT Laboratories requisition form or an incomplete AIT Laboratories requisitions form, processing of your test order may be delayed. As necessary, AIT Laboratories will contact physicians to have them resubmit the test order on a AIT Laboratories test requisition form or otherwise clarify each specific test being ordered.

Physician Custom Profiles

Laboratories that continue to offer clients the opportunity to request customized profiles must provide annual written notices that: (1) explain the Medicare reimbursement paid for each component of each such profile; (2) inform physicians that using a customized profile may result in the ordering of tests which are not covered, reasonable or necessary and that tests will not be billed; and (3) inform physicians that the OIG takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal and administrative law. Recent policy changes from Medicare Administrative Contractors support a growing movement away from physician's use of non-patient specific custom profiles when ordering laboratory drug testing. We support these efforts to help better ensure that only medically necessary tests are ordered for each patient and we have taken steps to ensure compliance.

AIT Laboratories does not accept "Standing Orders" or the default to a standing order if no order is on the Test Requisition Form. AIT Laboratories has provided all existing and new clients with a Custom Order Form that promotes physician choice for each test offered by AIT Laboratories. Along with the custom order form replacing standing orders, AIT Laboratories has enforced requirements on the Test Order Requisition that is submitted with each specimen for testing. The physician has the choice to order individual tests based on patient-specific medical necessity and if

the custom profile is desired, the physician must indicate the order to use the "custom profile" for the specific patient. Test requisitions without a clearly marked test order will result in delay of test results.

Custom Profiles must contain the physician signature and date in addition to the ordering provider's printed name and NPI Number. Custom Profiles should only be used in connection with extended treatment by the same ordering physician, and with the same diagnosis code(s). The ordering provider should record the frequency and duration for the order, not to exceed 365 days from the original order date, in the patient's medical record and treatment plan.

Custom Profiles are to be reviewed on an annual basis and AIT Laboratories require you to submit a new custom [profile, noting your changes or renewing the custom profile in its current state. Also, you may amend your custom profile at any time. We suggest that the physician keep a copy of their custom profile readily available and in the patient's medical record when ordering laboratory test services as a reference to help ensure that only medically necessary tests are ordered.

Verbal Test Orders

Medicare regulations require that all orders for laboratory tests be in writing. If a physician or his/her authorized representative orders a test by telephone or wishes to add a test to an existing order, a written order is required to support the verbal order. In these cases, AIT Laboratories will send a confirmation of the verbal order request to the ordering physician, requesting it to be signed and sent back to the laboratory for its records. Testing will not be performed until the signed confirmation or a properly completed AIT Laboratories requisition form is returned to the laboratory.

ABN

If a 'non-covered' diagnosis is used, the patient must be notified prior to specimen collection and given the opportunity to sign the Advance Beneficiary Notice (ABN). The ABN must be completed for any Medicare patient where claim denial is suspected based on medical necessity or frequency limitations. Medicare does not cover routine test screens. The signed, original ABN must be attached to the original lab order prior to submission. Per Medicare rules, requesting the ABN on all Medicare beneficiaries is considered an unacceptable practice.

Medicare National and Local Coverage Determinations

The Medicare Program publishes National Coverage Determination (NCDs) and local Medicare contractors publish Local Coverage Determinations (LCDs) for certain tests. These policies identify the conditions for which the included tests are or are not covered or reimbursed by Medicare with reference to specific diagnostic information. LCDs that apply to qualitative drug screens (presumptive tests), and confirmatory or quantitative drug tests (definitive testing) can be found through the Medicare website at https://www.cms.gov/medicare/coverage/determinationprocess/LCDs.html

AIT Laboratories will also make these LCDs available to any interested physician upon request.

The LCD issued by Novitas Solutions entitled "Controlled Substance Monitoring and Drugs of Abuse Testing (L35006)" provides guidance regarding appropriate indications and expected frequency for Urine Drug Testing (UDT). This policy is applicable to laboratories located in Novitas Jurisdiction, which encompasses Texas. AIT Laboratories adopted a Compliance Program that reflects the OIG Clinical Laboratory Compliance Program Guidelines and encourage all Healthcare Partners to do the same.

Patient Privacy (HIPAA)

Under the Health Insurance Portability and Accountability Act (HIPAA), AIT Laboratories is a health care provider and a covered entity. It is our policy to comply with the letter and intent of the HIPAA privacy and security standards. Our privacy policy is available at http://www.healthtrackrx.com.

Prohibited Referrals & Inducements

It is the policy of AIT Laboratories to comply with all aspects of the laws and regulations governing physician self-referral, most noticeably the Stark Law. The Stark Law's self-referral ban states that if a financial relationship exists between a physician (or an immediate family member) and a laboratory (or certain other kinds of healthcare providers), and the relationship does not fit into one of the law's exceptions, then (a) the physician may not refer Medicare patients to the laboratory and (b) the laboratory may not bill Medicare for services referred by the physician. The kinds of relationships between laboratories and physicians that may be affected by these laws include the lease or rental of space or equipment and the purchase of medical or other services by a laboratory from a referring physician.

Federal Law prohibits offering or paying remuneration-meaning anything of value- to induce the referral of tests that are covered by Medicaid, Medicare or other federal health care programs. Any form of kickback, payment or other remuneration that is intended to secure the referral of federal health care program testing business is strictly prohibited and should be reported to the AIT Laboratories Compliance Hotline by calling 844-990-0002.

Clinical Consultants

Physicians and other clinicians authorized to order tests have the services of clinical consultants and toxicologists available to ensure proper test ordering and answer questions. They may be reached at 940-435-0242.

To avoid false claim submission, please be sure to:

1. Order only those tests necessary for diagnosis or treatment. Each component of a panel must be necessary for the panel to qualify Medicare reimbursement.
2. Provide a diagnosis, sign or symptom for each test ordered
3. Document this information in the patient's medical record followed by the ordering physician's signature
4. Obtain an ABN from the Medicare patient when the tests do not meet the medical necessity criteria.

CMS National Coverage Policy

AIT Laboratories has included statements from the CMS National Coverage Policy and is attached hereto in Exhibit 1A.

Local Coverage Determination

AIT Laboratories has included statements from the Novitas Solutions, Inc. *Controlled Substance Monitoring and Drugs of Abuse Testing* (L35006) and is attached hereto as Exhibit 1B.

Medicare Rates

AIT Laboratories's test list with CPT and HCPS G-Codes and Medicare maximum reimbursement rates for each test is attached hereto as Exhibit 2.

1A. CMS National Coverage Policy

Title XVIII of the Social Security Act, Section 1862(a) (1) (A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Code of Federal Regulations (CFR) Title 42, Part 410.32 indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements) who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician (or other qualified non-physician provider) who is treating the beneficiary are not reasonable and necessary (see section 411.15 (k)(1) of this chapter).

Medicare regulations at 42 CFR 410.32(a) state in part, that "…diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements) who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." Thus, except where other uses have been authorized by statute, Medicare does not cover diagnostic testing used for routine screening or surveillance.

1B. Local Coverage Determination (LCD): Controlled Substance Monitoring and Drugs of Abuse Testing (L35006)

LCD ID: L35006 Jurisdiction: Texas Contractor: Novitas Solutions, Inc. Contract #: 04412

Coverage Indications, Limitations, and/or Medical Necessity

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier. Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

Introduction and Overview

For purposes of clarification the term physician or clinician refers to a Physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements). 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. A presumptive drug screen is used to detect the presence of a drug in the body. A blood or urine sample may be used. However, urine is the best specimen for presumptive screening, as blood is relatively insensitive for many common drugs, including psychotropic agents, opioids, and stimulants. 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, as described below. Typically, the "spot" chemical tests (referred to above) are urine dipsticks or multiple drug cup devices.

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.

This policy provides:

- The appropriate indications and expected frequency of testing for safe medication management of prescribed substances in risk stratified pain management patients or in identifying and treating substance use disorders.
- Documentation requirements, by the clinician in the patient's medical record, to support the medical necessity for drug testing on an individual patient basis.
- An overview of presumptive urine drug testing (UDT) and definitive UDT testing by various methodologies.

Limitations of Presumptive UDT

Primarily screens for drug classes rather than specific drugs, and therefore, the 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;

Given that not all prescription medications or synthetic/analog drugs are detectable or have assays available, it is unclear as to whether other drugs are present when some tests are reported as positive;

Cut-off may be too high to detect presence of a drug. This information could cause a practitioner to make a wrong assumption or clinical decision.

Definitive UDT:

Gas Chromatography coupled with Mass Spectrometry (GC-MS) and High Performance Liquid Chromatography coupled with Tandem Mass Spectrometry (LC-MS/MS) are complex technologies that use the separation capabilities of gaseous or liquid chromatography with the analytical capabilities of mass spectrometry.

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 a specific substance or metabolite that is not detected by presumptive UDT such as fentanyl, meperidine, synthetic cannabinoids and other synthetic/analog drugs;
• Identify drugs when a definitive concentration of a drug is needed to guide management (e.g., discontinuation of THC use according to a treatment plan);

• 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 medication or illicit use for ongoing safe prescribing of controlled substances; and
• Use in a differential assessment of medication efficacy, side effects, or drug-drug interactions.
• 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 of results. While these tests require different sample preparation and analytical runs, they are 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.

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.
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 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.

Covered Indications for UDT

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.

A presumptive UDT should be performed as part of the evaluation and management of a patient who presents in an urgent care setting with any one of the following:

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

Group B - Diagnosis and treatment for substance abuse or dependence.

A patient in active treatment for substance use disorder (SUD) or monitoring across different phases of recovery may undergo medical management for a variety of medical conditions.

A physician who is writing prescriptions for medications to treat either the SUD or other conditions may need to know if the patient is taking substances which can interact with prescribed medications or taking prescribed medications as expected.

The risk of drug-drug interactions is inherent to the patient, and may be compounded by prescribed medications.

UDT is a medically necessary and useful component of chemical dependency diagnosis and treatment. The UDT result influences treatment and level of care decisions.

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.

For patients with a diagnosed SUD, the clinician should perform random UDT, at random intervals in order to properly monitor the patient. Testing profiles must be determined by the clinician based on the following medical necessity guidance criteria:

- 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 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 - Treatment for patients on 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 suggest the possibility of SUD or lead to drug-drug interactions. Additionally, UDT may help the physician monitor for medication adherence, efficacy, side effects, and patient safety in general. 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.

Drug Testing Panels

A. Presumptive UDT Panels

Presumptive UDT testing may be ordered as a panel because the Medicare billing codes are defined on a "per patient encounter" basis regardless of the number of analytes tested.

Presumptive UDT orders should be individualized based on clinical history and risk assessment, and must be documented in the medical record.

B. Definitive UDT Panels

At the current time, physician-directed definitive profile 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.

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.

Other Covered Services

1. Reflex Testing by Reference Laboratories – since reference laboratories do not have access to patient- specific data, reflex testing under the following circumstances is reasonable and necessary:

    ◦To verify a presumptive positive UDT using definitive UDT (GC-MS or LCMS/MS) before reporting the presumptive finding to the ordering clinician and without an additional order from the clinician;
    Or
    ◦ To confirm the absence of prescribed medications when a negative result is obtained by presumptive UDT in the laboratory for a prescribed medication listed by the ordering clinician.
2. Direct to definitive UDT without a presumptive UDT is reasonable and necessary, when individualized for a particular patient, in the following circumstances:

    ◦ To identify a specific substance or its metabolite that is in a large class of drugs, or that is inadequately detected or not detected by presumptive UDT, such as fentanyl, meperidine, synthetic cannabinoids, and other synthetic/analog drugs;

    ◦ For use in a differential assessment of medication efficacy, side effects, or drug-drug interactions;

    ◦ To identify non-prescribed medication or illicit substance use for ongoing safe prescribing of controlled substances, where clinician has documented concerns related to safety risks attendant to failure to identify specific substances suspected based upon clinical review and judgment; or

    ◦ To identify drugs when a definitive concentration of a drug is needed to guide management (e.g., discontinuation of THC use according to a treatment plan).

3. Definitive testing to confirm a negative presumptive UDT result, upon the order of the clinician, is reasonable and necessary in the following circumstances:

    ◦ The result is inconsistent with a patient's self-report, presentation, medical history, or current prescribed medication plan (should be present in the sample);

    ◦ Following a review of clinical findings, the clinician suspects use of a substance that is inadequately detected or not detected by a presumptive UDT; or

    ◦ To rule out an error as the cause of a negative presumptive UDT result.

4. Definitive testing to confirm a presumptive UDT positive result, upon the order of the clinician, is reasonable and necessary when the result is inconsistent with the expected result, a patient's self-report, presentation, medical history, or current prescribed medication plan.

Limitations

Non-Covered Services

1. Blanket Orders.

2. Reflex definitive UDT is not reasonable and necessary when presumptive testing is performed at point of care because the clinician may have sufficient information to manage the patient. If the clinician is not satisfied, he/she must determine the clinical appropriateness of and order specific subsequent definitive testing (e.g., the patient admits to using a particular drug, or the IA cut-off is set at such a point that is sufficiently low that the physician is satisfied with the presumptive test result).

3. Routine standing orders for all patients in a physician's practice are not reasonable and necessary.

4. It is not reasonable and necessary for a physician to perform presumptive POCT and order presumptive IA testing from a reference laboratory. In other words, Medicare will only pay for one presumptive test result per patient per date of service regardless of the number of billing providers.

5. 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.

6. It is not reasonable and necessary for a reference laboratory to perform and bill IA presumptive UDT prior to definitive testing without a specific physician's order for the presumptive testing.

7. 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.

8. Drug testing of two different specimen types from the same patient on the same date of service for the same drugs/metabolites/analytes.

9. UDT for medico-legal or employment purposes or to protect a physician from drug diversion charges.

10. Specimen validity testing including, but not limited to, pH, specific gravity, oxidants, creatinine.

Notice: This LCD imposes frequency limitations as well as diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules. For frequency limitations please refer to the Utilization Guidelines section below.

As published in CMS IOM Pub. 100-08, Chapter 13, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under Section 1862(a)(1)(A).

Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective.

- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary).

- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:

    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member.

    - Furnished in a setting appropriate to the patient's medical needs and condition.

    - Ordered and furnished by qualified personnel.

    - One that meets, but does not exceed, the patient's medical needs.

    - At least as beneficial as an existing and available medically appropriate alternative.

The redetermination process may be utilized for consideration of services performed outside of the reasonable and necessary requirements in this LCD.

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

"A qualitative drug screen is used to detect the presence of a drug in the body. A blood or urine sample may be used. However, urine is the best specimen for broad qualitative screening…"

"Drugs or classes of drugs are commonly assayed by qualitative testing. A qualitative test may be followed by confirmation with a second method, when there is a positive inconsistent finding from the qualitative test in the setting of a symptomatic patient".

"Examples of drug or classes that are commonly assayed by qualitative tests, followed by confirmation with a second method, 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."

"Although there is not a specific companion LCD on quantitative drug testing, there should be typically a direct correlation between those positive findings generated from initial qualitative testing and those requested quantitative tests to specifically confirm such qualitative finding."

"Although comprehensive screening is unlikely to affect emergency management, the results may assist the admitting physician in evaluating the patient if the diagnosis remains unclear."

"Qualitative screening panels should be used when the results will alter patient management or disposition."

List of Indications

A qualitative drug test may be indicated for a symptomatic patient when the history is unreliable, when there has been a suspected multiple-drug ingestion, to determine the cause of a patient in delirium or coma, for the identification of specific drugs that may indicate when antagonists may be used.

Medicare will consider performance of a qualitative drug test reasonable and necessary when a patient presents with suspected drug overdose and one or more of the following conditions:

Unexplained coma;

Unexplained 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.

A qualitative drug test may be reasonable and necessary for patients with known substance abuse or dependence, when the results of such testing may impact their ongoing treatment.

A qualitative drug test may be reasonable and necessary for patients with symptoms of schizophrenia suspected to be secondary to drug or substance intoxication.

A qualitative drug test may be reasonable and necessary for chronic pain patients:

In whom other illicit drug use is suspected, when there has been an acute change in physical or mental status that meets the indications above.

To demonstrate abnormal findings, including the presence or absence of prescribed drugs, presence of nonprescribed substances, detection of illicit substances and adulterated urine samples.

Drugs or drug classes for which testing is performed should reflect only those likely to be present, based on the patient's medical history or current clinical presentation. Drugs for which specimens are being tested must be indicated by the referring provider in a written order.

Documentation Requirements

All documentation must be maintained in the patient's medical record and available to the contractor upon request.

Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The record must include the identity of the physician or non-physician practitioner responsible for and providing the care of the patient.

The submitted medical record should support the use of the selected ICD-10 code(s). The submitted CPT/HCPCS code should describe the service performed.

Medical record documentation (e.g., history and physical, progress notes) maintained by the ordering physician/treating physician must indicate the medical necessity for performing a qualitative drug test. All tests must be ordered in writing by the treating provider and all drugs/drug classes to be tested must be indicated in the order.

When a confirmatory test or a quantitative test is performed, the record must show that an inconsistent positive finding was noted on the qualitative testing or that there was no available, commercially or otherwise, qualitative test to evaluate the presence of a semi-synthetic or synthetic opioid in a patient who met the coverage criteria of this policy.

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 qualitative drug test. The physician must include the clinical indication/medical necessity in the order for the for the qualitative drug test.

2. Medicare 2018 Clinical Laboratory Fee Schedule (CLFS)

HCPCS	SHORTDESC	National Limit
80307	Drug test prsmv chem anlyzr	$ 79.81
G0480	Drug test def 1-7 classes	$ 117.65
G0481	Drug test def 8-14 classes	$ 160.99
G0482	Drug test def 15-21 classes	$ 204.34
G0483	Drug test def 22+ classes	$ 253.87
88300	Surgical path gross	$ 15.45
88302	Tissue exam by pathologist	$ 29.25
88304	Tissue exam by pathologist	$ 39.15
88305	Tissue exam by pathologist	$ 66.46
88311	Decalcify tissue	$ 21.53
88312	Special stains group 1	$ 93.98
88313	Special stains group 2	$ 66.21

Reference Information and Websites

ICD-10 Resources

http://www.cms.gov/Medicare/Coding/ICD10/index.html?redirect=/icd10

Signature Requirements: MLN Complying with Medicare Signature Requirements within the Internet-Only Manuals and Medicare Program Integrity Manual (Ch. 3: Verifying Potential Errors and Taking Corrective Action).

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/

Medical Necessity Policies for Laboratory Tests

National Coverage Determinations: https://www.cms.gov/medicare-coverage-database/indexes/lab-ncd-index.aspx?bc=BAAAAAAAAAAA&

Local Coverage Determination

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35006&ver=76&name=314*1&UpdatePeriod=749&bc=AAAAEAAAAAAAAA%3d%3d&

Advance Beneficiary Notices (ABN): ABN Form CMS-R-131

http://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html

Medicare's Clinical Laboratory Fee Schedule (CLFS)

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files.html

42 CFR 1001.1901
http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title42/42cfr1001_main_02.tpl

42 CFR 410.32
http://www.ecfr.gov/cgi-bin/text-idx?SID=45d58e853a7721326444d687746040f5&mc=true&node=pt42.2.410&rgn=div5#se42.2.410_132

Department of Health and Human Services Office of Inspector General. OIG Supplemental Compliance Guidance for Hospitals. 70 Fed. Reg. 4858, 4865 (Jan. 31, 2005). http://oig.hhs.gov/fraud/docs/complianceguidance/012705hospsupplementalguidance.pdf

Department of Health and Human Services Office of Inspector General. Compliance Program Guidance for Clinical Laboratories (63 Fed. Reg. 45076; August 24, 1998)
http://oig.hhs.gov/authorities/docs/cpglab.pdf

Centers for Medicare & Medicaid Services. State Medicaid Director Letter (SMDL #09-001). (Jan. 16, 2009).
http://www.cms.gov/SMDL/downloads/SMD011609.pdf

Department of Health and Human Services Office of Inspector General. "The Effect of Exclusion From Participation in Federal Health Care Programs." Special Advisory Bulletin. (Sept. 1999). http://oig.hhs.gov/exclusions/effects_of_exclusion.asp

"**National Practitioner Data Bank (NPDB).**" July 2011. United States Department of Health and Human Services. 14 Jul. 2011 <http://www.npdb-hipdb.hrsa.gov>

Oral Fluid and Urine Drug Testing

2017 CMS HCPCS Code	Code Description	2018 Medicare Allowable
80307	Presumptive drug test - any number of drug classes, any number of devices or procedures by instrumented chemistry analyzers, includes sample validation when performed, per date of service	$71.83
G0480	Definitive drug tests, 1-7 drug classes*	$114.43
G0481	Definitive drug tests, 8-14 drug classes*	$156.59
G0482	Definitive drug tests, 15-21 drug classes*	$198.74
G0483	Definitive drug tests, 22+ drug classes*	$246.92

*** Drug class includes any of the classes listed below. The list below matches the drugs included in those drug classes, for reference. Includes specimen validity testing, per day, including metabolites if tested.**

List of Drug Classes that may be included in Definitive Drug Testing Codes listed above

Drug	Drug Class	CPT/HCPCS
Ethylglucuronide	Alcohol Biomarkers	80321
Ethylsulfate		
Cotinine	Alkaloids, NOS	80323
Kava Metabolite		
Kratom Metabolite		
LSD Metabolite		
Amphetamine	Amphetamines	80324
Ephedrine/Pseudoephedrine		
Lisdexamphetamine		
Methamphetamine		
Phentermine		
Bupropion Metabolite	Antidepressants, NOS	80338
Trazodone Metabolite		
Venlafaxine Metabolite		
Citalopram Metabolite	Antidepressants, serotonergic	80332
Duloxetine		
Fluoxetine Metabolite		
Fluvoxamine		
Mirtazapine Metabolite		
Paroxetine		

Sertraline Metabolite		
Amitriptyline	Antidepressants, tricyclic	80335
Clomipramine Metabolite		
Desipramine		
Doxepin		
Doxepin Metabolite		
Imipramine		
Nortriptyline		
Carbamazepine	Antiepileptics	80339
Lamotrigine		
Levetiracetam		
Phenytoin		
Primidone		
Topiramate		
Valproic Acid		
Aripiprazole Metabolite	Antipsychotics	80342
Clozapine Metabolite		
Haloperidol		
Olanzapine		
Quetiapine Metabolite		
Risperidone Metabolite		
Ziprasidone		
Amo-Pentobarbital	Barbiturates	80345
Butabarbital		
Butalbital		
Phenobarbital		
Secobarbital		
Alprazolam	Benzodiazepines	80346
Alprazolam Metabolite		
Chlordiazepoxide		
Clobazam		
Clonazepam		
Clonazepam Metabolite		
Diazepam		
Estazolam		
Flunitrazepam		
Flunitrazepam Metabolite		
Flurazepam		
Flurazepam Metabolite		
Lorazepam		
Midazolam		
Midazolam Metabolite		
Nordiazepam		
Oxazepam		
Temazepam		
Triazolam		
Triazolam Metabolite		

Buprenorphine	Buprenorphine	80348
Norbuprenorphine		
Cocaine Metabolite	Cocaine	80353
DMT	Drug or substance definitive, NOS	80375
MeO-Dmt		
PCP		
Acetyl Norfentanyl	Fentanyl	80354
Fentanyl		
Norfentanyl		
Gabapentin	Gabapentine	80355
Heroin Metabolite	Heroin	80356
Ketamine Metabolite	Ketamine and norketamine	80357
Methadone	Methadone	80358
Methadone Metabolite		
MDA	Methylenedioxyamphetamines	80359
MDEA		
MDMA		
Methylphenidate Metabolite	Methylphenidate	80360
Carboxy-THC	Natural Cannabinoids	80349
Acetaminophen	Non-Opioid Analgesics	80329
Aspirin Metabolite		
Ibuprofen		
Naproxen		
Codeine	Opiates	80361
Hydrocodone		
Hydromorphone		
Morphine		
Norcodeine		
Norhydrocodone		
Butorphanol	Opioids	80362
Dextromethorphan		
Dextrorphan		
Meperidine		
Naloxone		
Naltrexone		
Normeperidine		
Pentazocine		
Noroxycodone	Oxycodone	80365
Noroxymorphone		
Oxycodone		
Oxymorphone		
Pregabalin	Pregabalin	80366
Norpropoxyphene	Propoxyphene	80367
Zaleplon	Sedative hypnotics	80368
Zolpidem		
Zopiclone		
Baclofen	Skeletal muscle relaxants	80369

Carisoprodol		
Cyclobenzaprine		
Meprobamate		
Isomer testing	Stereoisomer	80374
MDPV Metabolite	Stimulants, synthetic	80371
Methylone		
Normephedrone		
PVP Metabolite		
JWH073 Metabolite	Synthetic Cannabinoids	80350
JWH122-MAM2201 Metabolite		
JWH18-AM2201 Metabolite		
JWH210 Metabolite		
PB22 Metabolite		
RCS4 Metabolite		
UR144-XLR11 Metabolite		
Tapentadol	Tapentadol	80372
Tramadol	Tramadol	80373
Tramadol Metabolite		