JF CONTROLLED SUBSTANCE MONITORING AND DRUGS OF ABUSE TESTING

This checklist is intended to provide healthcare providers with a reference for use when responding to documentation requests for this service. It is not intended to replace the published guidelines or policy.

Policy References

- Local Coverage Determination (LCD) L36707
- Local Coverage Article (LCA) A55030

Documentation References

- Controlled Substances Act
- Certification of Opioid Treatment Programs, 42 Code of Federal Regulations (CFR) 8
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Internet Only Manual (IOM) Publications: 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 50; 100-03, Medicare National Coverage Determination (NCD) Manual, Chapter 1, Part 4, Section 280.14; 100-04, Medicare Claims Processing Manual, Chapter 17, Section 20.1.3 and Section 70

Documentation Requirements

- Overall Medical Necessity Documentation requirements
- Definitive Medical Necessity
- Group A Covered Indications - Symptomatic patients, Multiple drug ingestion, Patients with unreliable history
- Group B Covered Indications - Diagnosis and treatment for substance abuse or dependence
- Group C Covered Indications - Treatment for patients on chronic opioid therapy (COT)
- NON-Covered Services
- Other Covered Services

Overall Medical Necessity Documentation requirements

First make sure that the documentation supports the overall Medical Necessity requirements, then check the different groups (Group A, B, or C) in the LCD. If your patient does not fit within

one of those groups, then look at the Other Covered Services. If the clinical service does not fit in that category, then it may be under the Non-Covered Services.

The purpose of a UDT is to provide information to clinicians by identifying the presence or absence of drugs.

- [ ] Timely information
- [ ] Objective information
- [ ] **Actionable information**

Overall, the documentation must support:

- [ ] Why the UDT is being ordered
  - Ordering a Definitive over a Presumptive or dip stick - The documentation must support why you are doing a definitive test.
- [ ] How it is going to be used in the treatment of the patient
- [ ] Opioid Risk Assessment tool

Definitive Medical Necessity

Reminder: 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.

- [ ] **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. Verify the following:**
  - [ ] Identify a specific substance or metabolite that is inadequately detected by a presumptive UDT screen;
  - [ ] 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.

Group A Covered Indications

Symptomatic Patients, Multiple Drug Ingestion, and/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 presumptive, then definitive testing to determine the cause(s) of the presentation. The need for definitive UDT is based upon presumptive 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 emergency room or 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.

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

Group B Covered Indications

Diagnosis and Treatment for Substance Abuse or Dependence

UDT is a medically necessary and useful component of chemical dependency diagnosis and treatment.

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 number of UDTs billed over time 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.

Maximum Number of Allowed Presumptive UDTs for SUD

Consecutive Days of Abstinence	Allowed Amount of Testing	Not Medically Necessary
0 – 30 consecutive days of abstinence	Not to exceed 3 presumptive UDTs in a rolling 7 days	More than 3 presumptive UDTs in a rolling 7 days
31 – 90 consecutive days of abstinence	Not to exceed 3 presumptive UDTs in a rolling 7 days	More than 3 presumptive UDTs in a rolling 7 days
>90 consecutive days of abstinence	Not to exceed 3 presumptive UDTs in a rolling 30 days	More than 3 presumptive UDTs in a rolling 30 days is not reasonable and necessary and is not covered by Medicare.

Maximum Number of Allowed Definitive UDTs for SUDs

Consecutive Days of Abstinence	Allowed Amount of Testing	Not Medically Necessary
0 – 30 consecutive days of abstinence	Not to exceed 1 definitive UDT in a rolling 7 days	More than 1 definitive test in a rolling 7 days
31 – 90 consecutive days of abstinence	Not to exceed 3 definitive UDTs in a rolling 30 days	More than 3 definitive tests in a rolling 30 days
>90 consecutive days of abstinence	Not to exceed 3 definitive UDTs in a rolling 90 days	More than 3 definitive tests in a rolling 90 days

Group C Covered Indications

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.

Medical Necessity Guidance:

Criteria to establish medical necessity for UDT 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 laboratory findings;
- ☐ Current treatment plan;
- ☐ Prescribed medication(s);
- ☐ Risk assessment plan

The number of UDTs billed overt time beyond the baseline presumptive UDT must be based on individual patient needs substantiated by documentation in the patient's medical record.

ONGOING testing maybe Medically Reasonable and Necessary based on:

- ☐ Patient history
- ☐ Clinical assessment of:
  - ☐ Medication side effects or inefficacy
  - ☐ Suspicious behaviors
  - ☐ Self-escalation of dose
  - ☐ Doctor-shopping
  - ☐ Indications or symptoms of illegal drug use
  - ☐ Evidence of diversion
  - ☐ Other clinician documented change in affect or behavioral pattern
  - ☐ Prescription compliance
  - ☐ Potential issues of abuse or diversion (lost prescriptions, early refills, etc.)

UDT Frequency Based on Risk Assessment and Stratification

Risk Group	Baseline	Frequency of Testing
Low Risk	Prior to Initiation of COT	Presumptive and definitive UDT not to exceed 2 times each in a rolling 365 days 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.

Risk Group	Baseline	Frequency of Testing
Moderate Risk	Prior to Initiation of COT	Presumptive and definitive UDT not to exceed 2 times each in a rolling 180 days 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	Presumptive and definitive UDT not to exceed 3 times each in a rolling 90 days 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 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
- ☐ Change in patient's medical condition or behavior
- ☐ Patient admits to use of illicit or non-prescribed controlled substances

NON-Covered Services

- ☐ Blanket Orders-same orders for all patients in a health care provider's practice.
- ☐ 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).
- ☐ Routine standing orders for all patients in a physician's practice are not reasonable and necessary.
- ☐ 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.
- ☐ It is not reasonable and necessary for a physician to perform presumptive IA testing and order presumptive IA testing from a reference laboratory. Medicare will only pay for one

presumptive test result per patient per date of service regardless of the number of billing providers.

- ☐ 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.
- ☐ 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 and/or quantification typically by GC-MS or LC-MS/MS. Semi-Quantitative is defined as a numerical estimation of the approximate concentrations.
- ☐ 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 and/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.

If any of the above are checked an ABN maybe issued.

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 methods that include but are not limited to GC-MS or LC-MS/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. When medical record documentation that is individualized for a particular patient satisfies medical necessity requirements found elsewhere in this LCD (e.g., risk assessment, frequency), direct to definitive UDT without a presumptive UDT may be reasonable and necessary.
- ☐ 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
- [ ] When there is an unexpected negative presumptive UDT result, and it is clinically imperative to know if it is truly positive or negative; the medical record should state such.

- [ ] 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.