Claim Submission Cover Sheet:
Controlled Substance Monitoring and Drugs of Abuse Testing

A RRB-Contracted Specialty Medicare Administrative Contractor

Beneficiary Name	
Date of Service	
ICN Number	
HIC Number	
Billing Code	
Billing Modifier	

Ensure that the following are easily identifiable with the documentation submitted.

- **Beneficiary Name on all documentation**
- **Date of Service**
- **Appropriate CPT/HCPCS code(s) Billed**
- **Appropriate Modifier(s) Billed**

Covered Indications

Group A – Symptomatic patients, Multiple drug ingestion and/or Patients with unreliable history

A presumptive Urine Drug Testing (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:

- 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

Presenting signs or symptoms will be treated presumptively to stabilize the patient while awaiting rapid, then definitive testing to determine the cause(s) of the presentation.

The patient's medical record must include:

- ☐ **The presumptive findings, definitive drug tests ordered and reasons for the testing.**

Group B - Diagnosis and treatment for substance abuse or dependence

Ordered tests and testing methods (presumptive and/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 Substance Use Disorders (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. 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).

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Frequency of Presumptive UDT for SUD: The testing frequency must meet medical necessity and be documented in the clinician's medical record.

a. For patients with **0 to 30** consecutive days of abstinence:
   - o Presumptive UDT is expected at a frequency of 1 to 3 presumptive UDT per week.
   - o More than 3 presumptive panels 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:
   - o Presumptive UDT is expected at a frequency of 1 to 3 UDT per week.
   - o More than 3 presumptive UDT in one week is not reasonable and necessary and is not be covered by Medicare.

c. For patients with **> 90** consecutive days of abstinence:
   - o Presumptive UDT is expected at a frequency of 1 to 3 UDT in one month.
   - o More than 3 physician-directed UDT in one month is not reasonable and necessary and is not covered by Medicare.

Frequency of Definitive UDT for SUD: 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:
   - o Definitive UDT is expected at a frequency not to exceed 1 physician-directed testing profile in one week.
   - o 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:
   - o Definitive UDT is expected at a frequency of 1-3 physician-directed testing profiles in one month.
   - o 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:
   - o Definitive UDT is expected at a frequency of 1-3 physician-directed testing profiles in three months.
   - o More than 3 definitive UDT in 3 months is not reasonable and necessary and is not covered by Medicare.

The patient's medical record must include:

- □ **Appropriate testing frequency based on the stage of screening, treatment, or recovery**
- □ **Rationale for the drugs/drug classes ordered**
- □ **Results must be documented in the medical record and used to direct care**

<u>Group C - Treatment for patients on chronic opioid therapy (COT).</u>

COT UDT Testing Objectives:

- 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;
- 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.

Patients with specific symptoms of medication aberrant behavior or misuse may be tested for monitoring patient adherence and compliance during active treatment (<90 days) for substance use or dependence.
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. Frequency of testing beyond the baseline presumptive UDT must be based on individual patient needs substantiated by documentation in the patient's medical record.

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Recommendations for the ordering of presumptive and definitive UDT for patients on COT are as follows:

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.

COT Monitoring Testing:

Ongoing testing may be medically reasonable and necessary based on:
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.

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.

Patient's medical record should minimally include the following elements:

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

<u>Other Covered Services</u>

Reflex Testing by Reference Laboratories

a. Reflex testing under the following circumstances is reasonable and necessary:
   - o 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
   - o 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.

b. Direct to definitive UDT without a presumptive UDT is reasonable and necessary, when individualized for a particular patient.

c. Definitive testing to confirm a negative presumptive UDT result, upon the order of the clinician, is reasonable and necessary in the following circumstances:
   - o The result is inconsistent with a patient's self-report, presentation, medical history, or current prescribed medication plan (should be present in the sample);
   - o 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
   - o To rule out an error as the cause of a negative presumptive UDT result.

d. 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.

<u>Important Notes:</u>

Medical Necessity is evidenced not only by utilization of the appropriate billing CPT code and applicable modifier, but also by clinical documentation in the patient's medical record supporting the diagnosis and necessity of the services.

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This check list is provided as a reminder of what to include when responding to a request for records. The documentation should include, but is not limited to:

- ☐ **Beneficiary name and date of service on all documentation.**
- ☐ **Documentation legible and complete including signature(s)**
- ☐ **Signature attestation (if applicable).**
- ☐ **Abbreviation key (if applicable).**

This checklist is not intended to be all-inclusive; each Medicare claim is given individual consideration for coverage.

Always remember when sending records all entries should be dated and have legible signature. If you notice a signature is illegible please provide either a signature log or attestation to support the provider of the services. Failure to provide a legible signature will result in claim delays and possibly service denials. (CMS Internet Only Manual: Publication 100-08, Chapter 3, Section 3.4.1.1)

Please ensure that all documentation is legible and complete.