URINE DRUG TESTING
IN PAIN MANAGEMENT AND SUBSTANCE ABUSE TREATMENT

Policy Number: 2015M0092A  Effective Date: November 01, 2015

INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee's specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member's EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:
Patients in pain management programs and substance abuse treatments may misuse prescribed opioids and/or may use non-prescribed drugs. Patients in these settings are often assessed before treatment and monitored while they are receiving treatment. Urine drug screening is one monitoring strategy and is often part of a multifaceted intervention. This policy describes the use of urine drug testing (UDT) to detect or monitor the use of these medications and/or illegal substances of concern that can be misused or diverted, such as marijuana, cocaine, amphetamines, PCP, barbiturates and opioids.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

I. Qualitative Urine Drug Testing (UDT)

Qualitative UDT (e.g., Immunoassay testing) may be considered MEDICALLY NECESSARY to detect or screen the use of prescription medications and illegal substances of concern under ANY of the following circumstances:

A. Substance abuse treatment

1. Baseline screening on initial entrance into a substance abuse treatment program when ALL of the following criteria are met:
   • An adequate clinical assessment of patient history and risk of substance abuse is performed, including obtaining information from the *Minnesota Prescription Drug Monitoring program; AND
   • Clinicians have knowledge of test interpretation; AND
   • Clinical documentation specifies how the test result will be used to guide clinical decision making.
   2. During the stabilization phase of treatment no more frequently than once a week for a maximum of 4 weeks.
   3. During the maintenance phase of treatment no more frequently than once a month.
   Note: Qualitative urine drug testing is limited to fifteen (15) tests within a 12-month period. There is insufficient clinical evidence to support the use of daily or multiple testing per day in clinical practice.

B. Chronic pain management

1. Baseline screening on initial entrance into a chronic pain management program when ALL of the following criteria are met:
   • An adequate clinical assessment of patient history and risk of substance abuse is performed, including obtaining information from the state prescription drug monitoring program; AND
   • Clinicians have knowledge of test interpretation; AND
   • Clinical documentation specifies how the test result will be used to guide clinical decision making.
   2. During subsequent monitoring of treatment, no more frequently than the following times according to the risk level of the individual, as determined by a validated screening tool for
assessing the risk of aberrant drug-related behaviors (e.g., the Opioid Risk Tool [ORT] of the Screener and Opioid Assessment for Patients with Pain [SOAPP®]):

- Twice a year for patients who are low to moderate risk;
- Four times a year for patients who are high risk OR receiving an opioid dose >120 mg MED/d;
- At the time of the office visit for patients demonstrating aberrant behavior defined by one or more of the following:
  - Lost prescriptions
  - Request for early refills
  - Obtained opioids from multiple providers
  - Unauthorized dose escalation
  - Apparent intoxication

*Note*: Qualitative urine drug testing is limited to fifteen (15) tests within a 12-month period. There is insufficient clinical evidence to support the use of daily or multiple testing per day in clinical practice.

II. **Quantitative Urine Drug Testing (UDT)**

Qualitative UDT (e.g., specific drug identification or confirmatory testing) for substance abuse treatment or chronic pain management may be considered **MEDICALLY NECESSARY** under **ANY** of the following conditions:

A. **ALL** of the following criteria are met:
   1. Qualitative UDT was performed according to the medically necessary criteria described in [Section I](#), and the result was one or more of the following:
      - Positive for a non-prescribed drug with abuse potential, OR
      - Positive for an illicit drug (e.g., methamphetamine or cocaine), OR
      - Negative for prescribed medications, AND
   2. Clinical documentation specifies supporting rationale for each quantitative test ordered, AND
   3. Clinical documentation specifies how the test result will be used to guide clinical decision making.

B. **BOTH** of the following criteria are met:
   1. A qualitative test for the relevant drug(s) is not commercially available, AND
   2. The testing is performed according to the medically necessary criteria described in [Section I](#) with the exception that it is quantitative rather than qualitative testing.

III. Both qualitative and quantitative urine drug testing are considered **NOT MEDICALLY NECESSARY** in all other situations including, but not limited to:

A. Routine testing (e.g., testing at every visit, without considering member risk factors or whether the testing is required for clinical decision making).

B. Quantitative testing instead of drug screening or as a routine supplement to drug screens.
C. Simultaneous blood and urine specimen screening.
D. Testing for non-medical purposes such as the following:
   • Legal purpose, such as court-ordered drug screening or forensic examinations
   • Employment
   • Sports participation or recreational purpose
   • Enrollment in school or the military
   • Social service agency investigations
   • Testing for parents related to divorce or child custody cases

Clinical Considerations:
Qualitative urine drug testing (e.g., Immunoassay testing) is performed to detect or screen the use of prescription medications and illegal substances of concern for the purpose of medical treatment.

Quantitative urine drug testing (e.g., specific drug identification or confirmatory testing) is an additional test completed to verify the results of the urine drug test (UDT). UDT should not routinely include a panel of all drugs of abuse. The test should be focused on the detection of specific drugs. The frequency of testing should be at the lowest level to detect the presence of drugs.

The interpretation of urine drug tests requires consideration of many factors, such as the patient’s history and personal risk factors; the type, frequency and magnitude of the test findings and the practitioner’s ability to address the findings with the patient. Therefore, 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. Furthermore, continuing to prescribe controlled substances if illicit drug use is suspected poses ethical, regulatory and legal risk for the prescriber.

*The Minnesota Prescription Drug Monitoring Program is administered by the MN Board of Pharmacy (BOP), and collects prescription data on all schedule II-V controlled substances, as well as butalbital, regardless of how the prescription was paid for (cash, insurance, etc.). The MN BOP was given authority under Minnesota Statute M.S. § 152.126 to establish a program with the purpose of promoting public health and welfare by detecting diversion, abuse, and misuse for the prescription medications classified as controlled substances under the Minnesota statutes.

BACKGROUND:
In 2010, an estimated 22.6 million Americans aged 12 or older (approximately 8.9 percent of the population) were current illicit drug users, meaning they had used an illicit drug during the month prior to the survey. Of that same population, those who needed specialized treatment for a drug or alcohol problem, almost 21 million, did not receive it.

Screening, brief intervention, and referral to treatment (SBIRT) for illicit drug use is a public health intervention aimed at first identifying and recruiting illicit drug users who may be considering treatment, and then providing a brief face-to-face intervention to advise and motivate them to enter treatment, and
to provide appropriate treatment. The purpose is to promote changes in the client’s substance use behavior, i.e., reduction or quitting, with the assumption that this may prevent future drug-related medical, social, psychological, or legal problems. Screening may include questions about frequency and quantity of drug use and tests for biological markers in urine, breath, saliva, sweat, blood or hair. Urine drug testing, the most widely used test for the longest time, has established cutoffs for detecting many commonly abused drugs, however it only detects recent use and needs confirmation to be accurate.

Opioids have been used increasingly over the last decade for treating chronic pain of noncancerous origin. This has been accompanied by an increase in abuse or diversion of these controlled substances (Peppin 2012). Urine drug testing (UDT) can be used by clinicians to monitor patients for abuse, misuse and diversion of prescribed opioids (Peppin et al. 2012).

In 2009, the American Pain Society (APS) and the American Academy of Pain Medicine (AAPM) issued joint Opioid Treatment Guidelines stating that high-risk individuals on chronic opioid therapy (COT) should periodically undergo a UDT or other test confirming adherence to the COT plan of care. Also, the APS-AAPM guidelines recommend that patient compliance with a COT plan of care should be evaluated in all patients, even those who are not considered high risk (Chou et al. 2009). In 2005, Gourley, Heit, and Almahrezi also advocated for UDT as a component when treating all chronic pain patients with opioids, as all patients are at risk for misuse of opioids.

Currently, urine is the most commonly used biological substance in drug testing. Advantages of urine sampling are that it is readily available, and standardized techniques for detecting drugs in urine exist. Other biological specimens e.g., blood, oral fluids, hair and sweat, can also be tested and may gain in popularity over time as techniques for collecting and analyzing these specimens become more standardized.

There are 2 primary categories of urine drug testing:

1. Qualitative or screening testing (e.g., Immunoassay testing): These tests can be performed either in a laboratory or at point of service. A fixed amount of a labeled drug is added to the urine sample, and the drug or metabolite in the sample competes with the labeled drug for binding sites on the antibody. Immunoassay tests vary in the type of compounds they can detect. Some detect specific drugs and may fail to recognize similarly structured drugs within the same class. Other immunoassays identify only classes of drugs and thus results cannot be used to determine which drug a patient is taking. Immunoassay findings are generally reported qualitatively as either positive (drug level above a prespecified threshold) or negative (drug level below a prespecified threshold). These tests do not indicate specific levels.

2. Quantitative or confirmatory testing (e.g., Specific drug identification): Confirmatory tests are always performed in a laboratory. Gas chromatography/mass spectrometry (GC/MS) is considered to be the criterion standard for confirmatory testing. The tests are able to quantify the amount of drug or metabolite present in the urine sample. Quantitative tests can be used to confirm the presence of a specific drug identified by a screening test and can identify drugs that cannot be isolated by currently available immunoassays.
### REGULATORY STATUS:

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**
   Screening, brief intervention, and referral to treatment (SBIRT) is a procedure and, therefore, not subject to FDA regulation.

2. **CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):**
   Medicare has provided reimbursement for screening and behavioral counseling interventions in primary care to reduce alcohol misuse through a National Coverage Determination (NCD) (CMS, 2011). The reimbursement is effective for claims with dates of service on or after October 14, 2011, and will cover annual alcohol screening, and for those that screen positive, up to four brief, face-to-face, behavioral counseling interventions per year for Medicare beneficiaries, including pregnant women:
   - Who misuse alcohol, but whose levels or patterns of alcohol consumption do not meet criteria for alcohol dependence (defined as at least three of the following: tolerance, withdrawal symptoms, impaired control, preoccupation with acquisition and/or use, persistent desire or unsuccessful efforts to quit, sustains social, occupational, or recreational disability, use continues despite adverse consequences).
   - Who are competent and alert at the time that counseling is provided.
   - Whose counseling is furnished by qualified primary care physicians or other primary care practitioners in a primary care setting.

Nationally noncovered indications include:
   - Alcohol screening is noncovered when performed more than once in a 12-month period.
   - Brief face-to-face behavioral counseling interventions are noncovered when performed more than once a day; that is, two counseling interventions on the same day are noncovered.
   - Brief face-to-face behavioral counseling interventions are noncovered when performed more than 4 times in a 12-month period.

No National Coverage Determination (NCD) for SBIRT related to other drugs of abuse was identified on the CMS website (CMS, 2012). In the absence of an NCD, coverage is left to the discretion of local Medicare carriers.

National Coverage Determination (NCD) for Treatment of Drug Abuse (Chemical Dependency) (130.6): CMS recognizes that there are similarities between the approach to treatment of drug abuse and alcohol detoxification and rehabilitation. However, the intensity and duration of treatment for drug abuse may vary (depending on the particular substance of abuse, duration of use, and the patient's medical and emotional condition) from the duration of treatment or intensity needed to treat alcoholism. Accordingly, when it is medically necessary for a patient to receive detoxification and/or rehabilitation for drug substance abuse as a hospital inpatient, coverage for care in that setting is available. Coverage is also available for treatment services that are provided in the outpatient department of a hospital to patients who, for example, have been discharged from an inpatient stay for the treatment of drug substance abuse or who require treatment but do not require the availability and intensity of services found only in the inpatient hospital setting. The coverage available for these services is subject to the same rules generally applicable to the coverage of outpatient hospital services. The services must also be reasonable and necessary for the treatment of the individual’s condition. Decisions regarding reasonableness and necessity of treatment, the need for an inpatient hospital level of care, and length of treatment should be made by intermediaries based on accepted
medical practice with the advice of their medical consultant. (In hospitals under Quality Improvement Organization [QIO] review, QIO determinations of medical necessity of services and appropriateness of the level of care at which services are provided are binding on the title XVIII fiscal intermediaries for purposes of adjudicating claims for payment.)

**LOCAL COVERAGE DETERMINATION (LCD) L28145**: Qualitative Drug Screening.

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, 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 qualitative screen, followed by confirmation with a second method.

Examples of drugs or classes of drugs that are commonly assayed by qualitative screens, 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. This local coverage determination documents National Government Services medical policy guidelines for the use of this laboratory test.

**INDICATIONS**: "Although technology has provided the ability to measure many toxins, most toxicological diagnoses and therapeutic decisions are made based on historical or clinical considerations: (1) laboratory turnaround time can often be longer than the critical intervention time course of an overdose; (2) the cost and support of maintaining the instruments, staff training, and specialized labor involved in some analyses are prohibitive; (3) for many toxins there are no established cutoff levels of toxicity, making interpretation of the results difficult." "Although comprehensive screening is unlikely to affect emergency management, the results may assist the admitting physicians in evaluating the patient if the diagnosis remains unclear." Qualitative screening panels should be used when the results will alter patient management or disposition (Richardson et al, 2007).

A qualitative drug screen may be indicated with a symptomatic patient when the history is unreliable, with multiple-drug ingestion, with a patient in delirium or coma, for the identification of specific drugs, and to indicate when antagonists may be used. The clinical utility of drug screens in the emergency setting may be limited because patient management decisions are unaffected, since most therapy for drug poisonings is symptom directed and supportive.

Medicare will consider performance of a qualitative drug screen medically 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;
• For monitoring patient compliance during active treatment for substance abuse or dependence.

A qualitative drug screen is considered medically reasonable and necessary in patients on chronic opioid therapy:
• In whom illicit drug use, non-compliance or a significant pre-test probability of non-adherence to the prescribed drug regimen is suspected and documented in the medical record; and/or
• In those who are at high risk for medication abuse due to psychiatric issues, who have engaged in aberrant drug-related behaviors, or who have a history of substance abuse.

Drugs or drug classes for which screening 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 screened must be indicated by the referring provider in a written order.

Confirmation of drug screens is only indicated when the result of the drug screen is different than that suggested by the patient’s medical history, clinical presentation or patient’s own statement.

Limitations: A qualitative drug screen is not medically reasonable or necessary to screen for the same drug with both a blood and a urine specimen simultaneously.

Medicare regards drug screening for medico-legal purposes (e.g., court-ordered drug screening) or for employment purposes (e.g., as a pre-requisite for employment or as a requirement for continuation of employment) as not medically necessary.

3. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA):
Laboratory tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA). Certain point-of-care immunoassays are commercially available as CLIA-waived tests for drugs such as cocaine, methadone, morphine, and oxycodone. For a list, see: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/waivetbl.pdf.

4. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):
Nothing was identified.

5. MINNESOTA Statute M.S. § 152.126 requires all dispensers (pharmacies or providers that dispense from their office) licensed by the State of Minnesota to report all controlled substance II-V and butalbital prescriptions dispensed on a daily basis. See subd 4 (c) for exception requirements.

CLINICAL EVIDENCE:
Urine drug testing (UDT) is the most commonly used monitoring technique in substance abuse treatment and chronic pain management programs. Peppin et al. (2012) recommend UDT be performed in conjunction with a complete history and physical, appropriate psychological screens and other evaluations.

Patients should be assessed for risk of abusing or misusing opioids. Risk factors include the findings of the initial UDT, a positive smoking history, past and current medical history, past and current psychiatric history, prior opioid use and misuse, personal and family history of substance abuse, patient’s social environment. Risk should be reassessed if a patient requests refills ahead of schedule, requests higher doses of opioids or UDT detects no presence of the prescribed med. The patient’s pain should also be reevaluated, as disease processes can increase and change pain.
The Opioid Risk Tool (ORT) and the Screener and Opioid Assessment for Patients with Pain (SOAPP®) are validated tools developed for risk assessment. The Opioid Risk Tool is a brief, self-report screening tool designed by the National Institute on Drug Abuse for use with adult patients in primary care settings. It assesses risk for opioid abuse among individuals prescribed opioids for treatment of chronic pain. Patients categorized as high-risk are at increased likelihood of future, abusive drug-related behavior. The ORT can be administered and scored in less than 1 minute and has been validated in both male and female patients, but not in non-pain populations. The Screener and Opioid Assessment for Patients with Pain (SOAPP®) is a self-administered tool developed for use in chronic pain patients who are receiving, or under consideration for, long-term opioid therapy. It was developed to complement current risk assessment practices and to improve a clinician’s ability to assess a patient’s risk for opioid misuse (Inflexion, Inc., National Pain Centre at McMaster University).

Urine drug testing can be qualitative or quantitative. Qualitative tests are immunoassay tests that provide a positive or negative result for the presence of one or more drugs or drug classes but do not indicate specific levels of the substances. These tests can be performed either in a laboratory or at point-of-care and generally have rapid turnaround times. Quantitative tests are able to quantify the amount of drug or metabolite present and are used to confirm the presence of a specific drug identified by a screening test. These tests can also be used to identify drugs that cannot be measured by immunoassays, such as certain synthetic or semisynthetic opioids. Quantitative (i.e., confirmatory) tests are performed in a laboratory; gas chromatography/mass spectrometry is considered the criterion standard.

Urine specimens may be collected:
- As part of the intake process to confirm a newly admitted client’s substance use history
- As a routine part of therapy
- To identify an intoxicated client or confirm abstinence

An intensive outpatient treatment (IOT) program needs to establish a schedule for urine testing in compliance with Federal and State requirements (e.g., for methadone programs) in conjunction with the therapeutic needs of the client. Clients generally need more frequent monitoring during the initial stages of treatment while they may still be using substances. Routine specimen collection after admission should take place in conjunction with regular clinic visits.

**SUMMARY:**
Recommendations for UDT (Peppin et al. 2012) are based on expert opinion, as well as weak, but evolving evidence. Drugs or drug classes for which screening is performed should reflect only those drugs likely to be present, based on the patient’s medical history or current clinical presentation. Drugs for which specimens are being screened must be indicated by the referring provider in a written order.

**APPLICABLE CODES:**

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.
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<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>G0431</td>
<td>Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter</td>
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<td>G0434</td>
<td>Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter</td>
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<td>G6030-G6057</td>
<td>Definite Drug Testing Range</td>
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<td>G6058</td>
<td>Drug confirmation, each procedure</td>
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<th>ICD-9 Codes</th>
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<tr>
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<td>Antidepressant, unspecified</td>
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<td>969.01</td>
<td>Monoamine oxidase inhibitors</td>
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<td>Selective serotonin and norepinephrine reuptake inhibitors</td>
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<td>R78</td>
<td>Findings of drugs and other substances, not normally found in blood</td>
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<td>R78.5</td>
<td>Finding of other psychotropic drug in blood</td>
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<td>T43</td>
<td>Poisoning by, adverse effect of and underdosing of psychotropic drugs, not elsewhere classified</td>
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<td>T43.6</td>
<td>Poisoning by, adverse effect of and underdosing of psychostimulants</td>
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<td>Quantitative Drug Testing Therapeutic Drug Assay Code Range</td>
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<td>Drug screen, any number of drug classes from Drug Class List A; any number of non-TLC devices or procedures (e.g., immunoassay) capable of being read by direct optical observation, including instrumented-assisted when performed (e.g., dipsticks, cups, cards, cartridges), per date of service</td>
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<td>Drug screen, any number of drug classes from Drug Class List A; single drug class method, by instrumented test systems (e.g., discrete multichannel chemistry analyzers utilizing immunoassay or enzyme assay), per date of service</td>
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<td>80377</td>
<td>Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 7 or</td>
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<td>09/14/2015</td>
<td>New Policy 2015M0092A reviewed by Medical Policy Committee.</td>
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<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Council (QIACC).</td>
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