MEDICAL POLICY STATEMENT
OHIO MEDICAID

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<th>Policy Name</th>
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<td>Drug Testing</td>
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| Policy Type | MEDICAL       | Administrative | Pharmacy | Reimbursement |

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A. Subject
Drug Testing

B. Background
Drug testing is a part of medical care during the initial assessment, ongoing monitoring, and recovery phase for members with substance use disorder (SUD); for members who are at risk for abuse/misuse or diversion of drugs; and/or for other medical conditions. The drug test guides a provider in diagnosing and planning the member’s care when prescription medications or illegal drugs are of concern.

Urine is the most common specimen to monitor drug use. There are two main types of urine drug testing (UDT): presumptive and confirmatory. Drug testing is sometimes also referred to as toxicology testing.

C. Definitions
- **Presumptive/Qualitative test** - The testing of a substance or mixture to determine its chemical constituents, also known as qualitative testing.
- **Confirmatory/Quantitative test** - A test that determines the amount of a substance per unit volume or unit weight, also known as quantitative or definitive testing.
- **Random drug test** - A laboratory drug test administered at an irregular interval that is not known in advance by the member.
- **Relapse** - When a person with addiction returns to use after a period of sobriety.
- **Early and Periodic Screening, Diagnostic and Treatment (EPSDT)** - This benefit provides comprehensive and preventive health care services for children under age 21 who are enrolled in Medicaid.
- **Aberrant behavior** - Member’s behaviors that may indicate medication/drug abuse or misuse such as losing prescriptions, early refill requests, or multiple prescribers for controlled substances in the Prescription Drug Monitoring Program.
- **Independent laboratory** - A laboratory certified to perform diagnostic and/or clinical tests independent of an institution or a provider’s office.
- **Participating/non-participating** - Participating means in-network and contracted with CareSource. “Non-participating,” means out-of-network, not contracted with CareSource.
- **Qualified Laboratories**: When an out-of-network qualified laboratory provides toxicology test results to the referring health care provider within two business days of receipt of the test specimen, the MCP shall pay that laboratory at least sixty percent of the Medicaid laboratory services fee schedule. For the purposes of this requirement, a qualified laboratory is a laboratory that is enrolled with Medicaid as an independent laboratory, and that **meets all of the following conditions**:
  1. Is accredited by the College of American Pathologists; and
  2. Is approved by the New York Clinical Laboratory Evaluation Program; and
  3. Indicates to the MCP that it is providing services and billing as a qualified laboratory.
- **Opioid treatment program (OTP)** - Program or qualified provider delivering opioid treatment to members with an opioid agonist treatment medication.
- **Residential services** for substance use –
Ohio Administrative code defines residential services as “These services are co-occurring capable, co-occurring enhanced, and complexity capable in nature and provided by addiction treatment, mental health and general medical personnel in a twenty four hour treatment setting. Services are provided in Ohio department of mental health and addiction services certified permanent facilities which are staffed twenty four hours a day.”

- **Clinical Laboratory Improvement Amendments (CLIA)** - The Centers for Medicare & Medicaid Services (CMS) regulates programs that test human specimens to ensure accurate, reliable and timely patient test results regardless of where a test is performed and includes physician offices.
- **Chronic opioid therapy** - Refers to the use of opioids to treat chronic pain more than three months or past the time of normal tissue healing.
- **Diversion** - Unlawful channeling to regulated pharmaceuticals from legal sources to the illicit marketplace and includes transferring drugs to people they were not prescribed for.

D. Policy

Drug testing is one component of a comprehensive clinical approach during the initial assessment, stabilization, maintenance and recovery phase for members with a substance use disorder (SUD). It is also used to screen members periodically that are prescribed chronic opioid therapy (COT) for pain based on a risk score.

For substance-related disorders, drug testing may help the provider compare a member’s reported drug(s) of choice with the test results to verify subjective information. The assessment process including initial drug testing will aid the treatment provider to individualize the plan for drug testing for a member.

Drug testing may help determine if a member is adhering to prescription medication, reveal nonprescribed drugs or illicit drugs, or provide evidence to suggest diversion. Providers requesting drug testing should have proficiency in drug test interpretation and understand what they are ordering.

I. UDT order

A. An order for UDT must include at a minimum **ALL** of the following:
   1. List the type of test to be performed (presumptive or confirmatory).
   2. Include all medications currently prescribed to the member.
   3. Drug and drug class to be tested.
   5. Be signed and dated by a qualified provider.
   6. UDT order must specifically match the number, level and complexity of the testing components performed.

B. Copies of test results alone without the proper provider’s order for the test are not sufficient documentation of medical necessity to support a claim.

II. Provider Documentation

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*CareSource*
A. Provider must maintain a complete legible medical record for the member and include the following:
   1. Complete member name and identification on each page of record.
   2. Identification of the provider responsible for providing member care.
   3. Appropriate indication for UDT.
   4. How the UDT result will guide the plan of treatment.
   5. CPT code that accurately describes the service performed.

B. Provider documentation must support medical necessity of UDT.
   1. All components of a UDT panel must be supported by medical necessity.
   2. A panel of drugs may be performed as part of an initial assessment to develop a monitoring plan as long as it is supported with medical necessity. A panel of drugs should only be conducted based on an individualized treatment plan noting the need for confirmatory test with greater than 14 drug tests. These tests are rarely indicated for routine UDT.

III. Prior Authorization (PA)
   A. CareSource will consider all prior authorization requests when they are medically necessary to the member’s treatment and care OR if they fall within the standards of care under EPDST guidelines. Presumptive testing should be the initial test considered, as often a positive result of a drug class is enough to inform the provider about a need to change the treatment plan.
      1. The Ohio Department of Health Standard UDT PA Form must be provided along with the appropriate supporting documentation when requesting a PA.
      2. CareSource will require a PA for UDT tests >30 presumptive and/or > 12 confirmatory UDT per member per calendar year.
      3. PA is required for any non-participating provider with CareSource for non-emergency room setting.
      4. PA is required for any non-participating, non-qualified lab/facility with CareSource for non-emergency room setting.
      5. PA is required for any non-participating, qualified lab/facility with CareSource for non-emergency room setting.
      6. PA is NOT required in an emergency room setting. Confirmatory testing is rarely needed in this setting. UDT utilization will be monitored by CareSource.
      7. PA needs to make a clear case for medical necessity for the level of testing being requested, it may include but is not limited to:
         a. Phase of treatment (e.g. assessment, early recovery, induction, stabilization, maintenance).
         b. Current level of care (e.g. use of ASAM levels).
         c. Member drug(s) of choice.
         d. Days since last drug test with unexpected results.
         e. Current prescribed drugs including over-the-counter drugs and illicit drugs that have had unexpected results in recent tests.
         f. Member current active symptoms that led to the request.
         g. Provider actions taken on recent unexpected test results and member response to that action.
         h. The clinical documentation shows that the member is contesting the result of an unexpected presumptive test.
i. The test is not being requested for third party reasons, or as a condition to stay in sober housing or residential facility (see additional information below).

j. Results of any pill counts performed by treatment team.

B. Providers and laboratories will need to ensure specimen integrity appropriate for the stability of the drug being tested until the PA process is complete i.e. freezing specimen. Diluted, substituted or adulterated urine samples will alter a test result. Checking for color, specific gravity, temperature and creatinine can help determine the specimen integrity. If tampering is suspected, the sample should be discarded and when possible the member should remain at provider facility until a new specimen obtained can be tested.

C. Must submit appropriate clinical documentation with PA request to determine appropriate medical necessity.

D. If needed, the licensed practitioner that is operating in his/her scope of practice must obtain the prior authorization.

IV. Quantity Limitations

A. CareSource will cover up to 30 presumptive and 12 definitive UDT per member per calendar year.
   1. CareSource will cover up to 30 presumptive UDT per member per calendar year.
   2. CareSource will cover up to 12 definitive UDT per member per calendar year.

B. For presumptive tests, each CPT code is counted as one test.

C. For confirmatory tests, all CPT tests performed on the same date of service count as one test.

D. In determining medical necessity for additional tests, current clinical information will be considered as well as review of prior medical records will be performed to determine the medical appropriateness of the initial 30 presumptive and 12 definitive drug tests ordered within a calendar year.

V. Laboratory

A. CareSource may require documentation of FDA-approved complexity level for instrumented equipment, and/or Clinical Laboratory Improvement Amendments (CLIA) Certificate of Registration, Compliance, or Accreditation as a high complexity lab.

B. Laboratories must maintain hard copy documentation of lab results with copies of the order for the drug test and any required PA.

VI. Clinical Indications

Testing should be individualized to the specific member. Analytes tested should be ordered based on the member’s drug(s) of choice. Periodically, drugs that are commonly used may be rotated into the random test schedule. Regionally prevalent drugs may be periodically rotated into the random test schedule. The rationale for which tests is not meant to include all drugs all of the time, rather the drugs most likely to be seen in the individual. This information helps the provider focus the testing to likelihood it would be used. Testing should be at the lowest level to inform
the provider that an intervention is needed based on the individual history of the member.

Drug testing is ideally performed on a random unannounced schedule with a specific time frame to produce a specimen. ASAM recommends a random-interval schedule to a fixed-interval schedule as it eliminates known non-testing periods. Testing every day, at every visits, on the same day of the week or at the same time is not random (ASAM reference). Providers should understand windows of detection time to determine frequency of testing. Too short of an interval may raise an issue of presumption of renewed when the same drug that was recently tested is still within its detection window. Drug testing does not have to be associated with an office visit when patients are called to do random tests.

Providers should be aware of the potential for cross-reactivity when using presumptive tests. Per SAMHSA, cross reactivity has a positive side. For example a confirmatory test for a specific opioid analyte will miss other opioids a member may be taking. Therefore an opioid screen is preferred over a specific test when looking for opiate type drugs.

When testing for alcohol, SAMHSA also states that a breathalyzer gives an estimate of blood alcohol level. This method is simple to use, inexpensive, gives instant results, and is noninvasive.

A. Drug Testing in Addiction Treatment
   1. UDT frequency is expected to be more frequent when medically necessary early in treatment or when tapering. UDT frequency is expected to decrease as member stabilizes. Prior to Initiation or in the Induction Phase (early recovery).
      a. Obtain history as well as a medical and psychological assessment.
      b. Review approximate time frame of drug detected in urine.
      c. Identify questions seeking to answer as well as treatment plan based on potential UDT results.
      d. Obtain an individualized baseline UDT based on member’s unique clinical presentation, prescribed medications, member’s self-reported drugs of choice, and regional drug trends.
      e. At least weekly (cite ASMA consensus guidelines).
      f. Discuss results with member.
      g. Agree on plan of care that includes treatment interventions and goals.
      h. This phase includes members that have relapsed.
      a. At least once per month.
   3. Intensive outpatient.
      a. At least weekly.
   4. Substance use disorder residential program.
      a. At least monthly.
   5. Stable recovery.
      a. Drug testing may be done less frequently if in stable recovery.
   6. For members taking long-action naltrexone.
      a. At least monthly.

B. Drug testing in an Opioid Treatment Program (OTP)
1. In maintenance treatment, federal regulations governing OTP require initial toxicology plus 8 random UDT screens per year per member.

2. In short-term detoxification treatment, one initial UDT per member.

3. In long-term detoxification treatment initial and monthly random UDT per member.

C. Drug testing by advanced practice registered nurse
   1. Prescribing naltrexone to treat opioid use disorder
      a. Complete UDT or serum medication levels at least every 3 months for the first year and then at least every 6 months thereafter
   2. Prescribing buprenorphine products
      a. Complete UDT or serum medication levels at least twice per quarter for the first year of treatment and once per quarter thereafter.

D. Chronic Pain Management
   1. Prior to or when initiating treatment
      a. Complete an assessment for risk of substance abuse using a validated risk assessment screening tool such as Screener and Opioid Assessment for Patient with Pain-Revisited (SOAPP-R) or the Opioid Risk Tool (ORT).
      b. Review the state prescription drug monitoring program data (PDMP)
      c. Obtain baseline UDT screening.
      d. Discuss results with member.
      e. Agree on plan of care that includes treatment goals, educating on risks and benefits, and strategies to mitigate risks.
      f. Combine evidence-based non-pharmacologic and non-opioid pharmacologic therapy as necessary.
   2. Ongoing monitoring of treatment is determined by level of risk for substance use
      a. Low risk – UDT once a year.
      b. Moderate risk – UDT twice a year.
      c. High risk – UDT up to 4 times a year.
      d. UDT when member shows aberrant drug-related behavior.
      e. Review PDMP data every 1-3 months.
      f. Evaluate benefits and harms of treatment at least every 3 months.

E. Unexpected Results
   1. Discuss with member to understand any possible aberrant behavior.
   2. Potential reasons for unexpected results may include
      a. Nonadherence (either recently or not at all).
      b. Member utilizing drug amount below detection threshold.
      c. Substance cannot be identified in type of test performed.
      d. Lab Error.
      e. Member absorbs, excretes, and/or metabolizes at different rate.
      f. Not member’s urine sample.
      g. Diluted urine from water loading.
      h. Adulterated specimen.
      i. Diversion.
      j. Cross-reactivity with other medications or food.
   3. Potential interventions for unexpected results are dependent on assessment and may include
      a. Evaluate and discuss factors contributing to relapse.
      b. Minimize tampering opportunities during collection of sample.
c. Monitor pill counts.
d. Dose adjustment.
e. Review PDMP.
f. Collaborate or refer with specialist.
g. Change in level of care or intensity of treatment.
h. Change in lifestyle i.e. housing, support system.
i. Change in plan of treatment i.e. addition of behavioral therapy or community supports.
j. Attend to psychosocial barriers i.e. transportation, financial
k. Address co-occurring medical or behavioral needs.
l. Obtain confirmatory UDT (see Section VII of this policy).

VII. Confirmatory Testing
   A. Should not routinely be utilized as the first choice for UDT.
   B. Is medically necessary when ONE of the following is met:
      1. Presumptive testing was negative for prescription medications AND provider was expecting the test to be positive for prescribed medication AND member reports taking medication as prescribed OR
      2. Presumptive testing was positive for prescription drug with abuse potential that was not prescribed by provider AND the member disputes the presumptive testing results OR
      3. Presumptive testing was positive for illegal drug AND the member disputes the presumptive testing results OR
      4. A specific substance or metabolite is needed to be identified that cannot be identified by a presumptive testing. (e.g. semi-synthetic and synthetic opioids, certain benzodiazepines).

VIII. Blood Testing
   Blood drug testing is considered medically necessary when it is in the emergency room setting.

IX. Testing that is not medically necessary
   A. CareSource considers the following as NOT medically necessary for either presumptive or confirmatory testing
      1. Testing that is not individualized such as:
         a. Reflexive testing.
         b. Routine orders.
         c. Standard orders.
         d. Preprinted orders.
         e. Requesting all tests that a machine is capable of doing solely because a result may be positive.
         f. Large, arbitrary panels.
         g. Universal testing.
         h. Conduct additional testing as needed.
   B. Testing required by third parties such as
      1. Testing ordered by a court or other medico-legal purpose such as child custody.
      2. Testing for pre-employment or random testing that is a requirement of employment.
3. Physician’s health programs (recovery for physicians, dentists, veterinarians, pharmacists, etc.).
4. School entry or testing for athletics.
5. Testing required for military service.
6. Testing in residential facility, partial hospital, or sober living as a condition to remain in that community.
7. Testing with another pay source that is primary such as a county, state or federal agency.
8. Testing for marriage license.
10. Testing for other admin purposes.
11. Routine physical/medical examination.

C. Testing for validity of specimen
   It is included in the payment for the test and will not be reimbursed separately.

D. Blood drug testing when completed outside of the emergency room.

E. Hair, saliva, or other body fluid testing for controlled substance monitoring.

F. Any type of drug testing not addressed in this policy.

G. Routine nonspecific or wholesale orders including routine drug panels.

H. Routine use of confirmatory testing following a negative presumptive expected result.

I. Custom Profiles, standing orders, drug screen panel, custom panel, blanket orders, reflex testing or conduct additional testing as needed orders.

J. A confirmatory test prior to discussing results of presumptive test with member.

NOTE: Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis, subsequent medical review audits, recovery of overpayments identified, and provider prepay review.

E. Conditions of Coverage

F. Related Policies/Rules
   CareSource Drug Testing Reimbursement Policy PY-0020

G. Review/Revision History

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Updated clinical indications, quantity limits, and prior authorization requirements
Updated qualified laboratories per ODM guidance
Added ODM PA form
H. References


The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.