

MEDICAL POLICY STATEMENT OHIO MARKETPLACE PLANS

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Drug Testing			MM-0066		
Policy Type					
MEDICAL	Administrative	Pharmacy	Reimbursement		

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

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B. BACKGROUND

Monitoring for controlled substances is performed to detect the use of prescription medications and illegal substances of concern for the purpose of medical treatment. Monitoring for controlled substances plays a key role particularly in the care of persons undergoing medical treatment with chronic pain therapy and substance-related disorder. Drug testing that is medically necessary for the management of members being treated with drugs that are potentially abusive or addictive such as opioids and related medications, or for members suspected of using illicit drugs solely or in combination with prescribed controlled substances is billable to CareSource. Qualitative/presumptive drug testing performed as part of routine, prenatal care for pregnant members is also billable to CareSource.

Providers should have a working knowledge of analytic detection including primary agents, metabolites, lab threshold concentrations, and time periods involved in detection. The combination of a patient's self-report and drug testing results serve as important tools in controlled substance monitoring, as well as a point of patient engagement.

Qualitative/presumptive testing is a routine part of care, used when immediate results are needed, knowing results may be less accurate than quantitative/confirmatory tests. Quantitative/confirmatory testing is used when results may affect changes in medication, when patients dispute qualitative/presumptive results, or in treatment transitions.

Anecdotal evidence to support testing for individual patients should be balanced with the limited population evidence for added value of multiple tests for chronic pain patients or substance related disorders patients. For example, in a 2015 evaluation of 2,551,611 de-identified patients' urine drug test results over four years in the U.S., Quest Diagnostics identified that the best achieved yearly inconsistency rate in all urine drug tests was (when the results of a drug test are not consistent with the patient's history and prescribed medicines) 53% (in 2014 vs 63% in 2011).

C. DEFINITIONS

- Intensive Outpatient Services (IOP) generally provide increased weekly services consisting primarily of counseling and education for Substance Abuse Disorder (SUD).
- Partial Hospital Program (PH or PHP), sometimes known as "Day Treatment" is characterized by:
 - o Individual has a moderate risk of severe withdrawal
 - Generally features 20 or more hours per week of clinically-intensive programming
 - Adolescents receive services often during school hours and typically have access to educational services (or are coordinated with school)
 - Psychiatric and medical consultation usually within 8 hours by phone or 48 in person
 - Highly structured, distinct clinical services required

• Clinically-managed, low-intensity residential services

- o No withdrawal risk, or minimal or stable withdrawal
- Typically in a halfway house, group or other supportive living environment with 24-hour staff
- Individuals who because of specific functional limitations need safe and stable living environment and 24-hour Care
- Services are community based, not hospital based
- Clinical services usually no less than 5 hours per week
- Community and house meetings, emphasis on community recovery



- Qualitative analysis The testing of a substance or mixture to determine its chemical constituents, also known as presumptive testing.
- Quantitative test A test that determines the amount of a substance per unit volume or unit weight, also known as confirmatory testing.
- Random alcohol and drug test a lab test administered at an irregular interval which is not announced in advance to the person being tested, and which detects the presence of alcohol, drugs or substances in the individual.
- Outpatient Treatment Programs (OTP) drug testing requirements for substance-related disorder treatment, in the US Federal Code, "OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient."
- **Medication Assisted Treatment (MAT)** treatment of opioid substance-related disorder with buprenorphine, methadone, or Vivitrol.
- **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 by CareSource.

NOTE: CareSource may request documentation to support medical necessity. Appropriate and complete documentation must be presented at the time of review to validate medical necessity.

D. POLICY

l. Clinical Situation

- A. The member's clinical situation warrants additional testing and is medically necessary as indicated by **ONE or more of the following.**
 - 1. The member is receiving Intensive Outpatient Services (IOP) or Partial Hospital Services (PH or PHP sometimes known as "Day Treatment") for Substance-Related Disorder **ALL of the following:**
 - 1.1 Member meets criteria for Substance-Related Disorder
 - 1.2 Testing frequency as indicated by **ONE of the following:**
 - a. Testing is ordered no more frequently than weekly.
 - b. Testing required above minimum guideline thresholds as indicated by the **TWO or more of the following:**
 - (1) Poor participation in services.
 - (2) Collateral information from member's support network reporting recent use.
 - (3) Evidence of intoxication or behavior suggesting renewed use
 - (4) Recent deterioration in functioning (loss of job, school, active BH symptoms).
 - (5) State Prescription Monitoring Program shows DEA drug prescriptions that member did not disclose.
 - 1.3 Provider has documented current or planned action to support member if drug test result shows unexpected result or medication not disclosed by member and includes TWO or more of the following:
 - a. MAT dose adjustment.
 - b. Second opinion or consultation with another prescriber.
 - c. Level of Care increased to **ONE of the following:**
 - (1) Partial Hospital Services (PHP).
 - (2) Residential.
 - (3) Inpatient.







- d. Planned changes in TWO or more of the following:
 - (1) Individual Counseling.
 - (2) Group counseling.
 - (3) Prescriber visits.
 - (4) Narcotic anonymous visits/AA visits.
 - (5) High-risk living environment.
- e. Other.
- 2. The member is in Induction Phase of Medication Assisted Treatment (MAT) for Substance-Related Disorder with buprenorphine/naloxone products, buprenorphine products, or methadone and the medical record includes documentation that supports **ALL of the following** criteria:
 - 2.1 Member meets criteria for Substance-Related Disorder
 - 2.2 Testing frequency as indicated by **ONE of the following:**
 - a. Testing is ordered no more frequently than weekly during the induction.
 - b. Testing required above minimum guideline thresholds as indicated by the **TWO** or more of the following.
 - (1) Poor participation in services.
 - (2) Collateral information from member's support network reporting recent use.
 - (3) Evidence of intoxication or behavior suggesting renewed use.
 - (4) Recent deterioration in functioning (loss of job, school, active BH symptoms).
 - (5) State Prescription Monitoring Program shows DEA drug prescriptions that member did not disclose.
 - 2.3 Provider has documented current or planned action to support member if drug test result shows unexpected result or medication not disclosed by member and includes **TWO or more of the following:**
 - a. MAT dose adjustment.
 - b. Second opinion or consultation with another prescriber.
 - c. Level of Care increased to ONE of the following:
 - (1) Opioid Treatment Program.
 - (2) Intensive Outpatient Program (IOP).
 - (3) Partial Hospital Services (PHP).
 - (4) Residential.
 - (5) Inpatient.
 - d. Planned changes in TWO or more of the following:
 - (1) Individual Counseling.
 - (2) Group counseling.
 - (3) Prescriber visits.
 - (4) Narcotic anonymous visits/AA visits.
 - (5) High-risk living environment.
 - e. Other.
 - 2.4 Member demonstrates **ALL** of the following:
 - a. Readiness for treatment.
 - b. Adheres to program rules and expectations.
 - c. No unsafe behaviors putting self or others at risk.
 - 2.5 Provider documents that member is in the appropriate level of care for the service being provided.
 - 2.6 Induction documentation shows member was in mild or higher withdrawal at the time of induction including **ONE** or more of the following:
 - a. Score from a validated opioid withdrawal scale [(e.g. Clinical Opioid Withdrawal Scale (COWS) or Clinical Institute Narcotic Assessment (CINA)].
 - Documentation demonstrates that member had the following withdrawal.
 symptoms after stopping or reducing an opioid by THREE or more of the following:

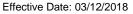




(1) Dysphoric mood.

- (2) Nausea or vomiting.
- (3) Muscle aches.
- (4) Lacrimation or rhinorrhea.
- (5) Pupillary dilation, piloerection or sweating.
- (6) Diarrhea.
- (7) Yawning.
- (8) Fever.
- (9) Insomnia.
- 3. The member's behaviors demonstrate potential risk of diversion and the documentation supports **ALL of the following** criteria:
 - 3.1 State Prescription Monitoring Program results reveal **THREE or more of the following:**
 - a. Scheduled DEA drug appears that member did not disclose.
 - b. Member using more than 4 prescribers to obtain Scheduled DEA drug within past 90 days.
 - Member is using more than 4 pharmacies to obtain Scheduled DEA drug within past 90 days.
 - d. 12 or more Scheduled DEA drug prescriptions within last 90 days.
 - 3.2 Provider documented risk factors including **THREE or more of the following:**
 - a. Requests for early refills.
 - b. Recent drug screen does not show MAT drug or metabolite.
 - c. Member claims lost prescription, lost medication, or stolen medication.
 - d. Pill counts (or film counts) are not correct.
 - e. Collateral information from member's support network alleging diversion.
 - f. Multiple recent ED visits where DEA drugs are prescribed (e.g., pain complaints).
 - g. Involvement in criminal justice system during treatment.
 - 3.3 Provider documents planned consequence if diversion likely based on result of this drug test order result and other risk factor data.
- 4. The member is being treated for chronic pain and the medical record includes **ALL of the following**:
 - 4.1 Member has a chronic pain diagnosis.
 - 4.2 Testing frequency is indicated by **ONE of the following:**
 - a. Testing ordered no more frequently than 4 times per year using **ONE of the following** validated risk tools:
 - (1) Screener and Opioid Assessment for Patients with Pain (SOAPP-R).
 - (2) Opioid Risk Tool (ORT).
 - (3) Other (Please NOTE).
 - b. Testing required above minimum guideline thresholds as indicated by the **ONE or more of the following:**
 - (1) Documented use of drug/substances other than as prescribed (misuse), or substance-related disorder symptoms as indicated by TWO or more of the following:
 - i. Poor participation in services.
 - Collateral information from member's support network reports misuse or abuse of medication, use of medication not prescribed, or diverting medication.
 - iii. Evidence of intoxication or behaviors suggesting substance-related disorder.
 - iv. Recent deterioration in functioning (loss of job, school, important relationships, new BH symptoms).
 - v. State Prescription Monitoring Program shows DEA drug prescriptions that member did not disclose.







- (2) Current or planned action taken to support member at risk for addiction is documented includes **ONE** or more of the following:
 - i. Provide addiction assessment on site if behavioral health services are integrated.
 - ii. Refer for addiction assessment and treatment program.
 - iii. Introduction of alternative pain therapies without addictive properties.
 - iv. Use of motivational interviewing or other technique to motivate member to change.
- 5. The member is receiving Residential Level of Service for Substance-Related Disorder and **ALL of the following** criteria are met:
 - 5.1 Member meets criteria for substance-related disorder.
 - 5.2 Testing frequency is indicated by **ONE of the following:**
 - a. Testing ordered no more frequently than monthly.
 - b. Testing required above minimum guideline thresholds as indicated by the **TWO** or more of the following:
 - (1) Poor participation in services.
 - (2) Collateral information from member's support network reporting recent use.
 - (3) Evidence of intoxication or behavior suggesting renewed use.
 - (4) Recent deterioration in functioning (loss of job, school, active BH symptoms).
 - (5) State Prescription Monitoring Program shows DEA drug prescriptions that member did not disclose.
 - 5.3 Provider has documented current or planned action to be taken to support member at risk for dropping out of treatment if drug test result shows medication other than prescribed medications and includes **TWO or more of the following:**
 - a. MAT dose adjustment.
 - b. Second opinion or consultation with another prescriber.
 - c. Level of Care increased to **ONE of the following:**
 - (1) Higher Intensity Residential.
 - (2) Inpatient.
 - d. Planned changes in TWO or more of the following:
 - (1) Individual Counseling.
 - (2) Group counseling.
 - (3) Prescriber visits.
 - (4) Narcotic anonymous visits/AA visits.
 - (5) High-risk living environment.
 - e. Other.
 - 5.4 Drug/substance testing is NOT being ordered as a program requirement to remain in residential program.
 - 5.5 Drug/substance testing is NOT for pre-employment testing or to meet federal requirements in the transportation industry to retain employment.
- 6. The member is pregnant and provider documentation supports medical necessity of requested test.
- 7. The member is under the age of 21 and provider documentation supports medical necessity of requested test.

II. General Criteria

- A. The member's medical record includes documentation that supports **ALL of the following** General Criteria for coverage:
 - Order for drug testing specifies the type of test to be performed as indicated by ONE of the following:







- 1.1 A **QUALITATIVE** (presumptive) test is medically necessary for the Clinical Situation(s) applicable in Section I above.
- 1.2 A **QUANTITATIVE** (definitive/confirmatory) test is medically necessary necessity for the Clinical Situation(s) applicable in Section labove as indicated by **ONE of the following:**
 - a. A qualitative/presumptive test was performed and requires confirmation, and
 ALL of the following criteria are met:
 - (1) A quantitative is required if a qualitative test result shows an unexpected finding or is inconclusive.
 - (2) The member contests the result of the qualitative/presumptive drug test performed.
 - b. Testing is requested for a drug/substance that has no qualitative/presumptive test equivalent and **ALL of the following** criteria are met for coverage:
 - (1) Provider intends to change treatment plan based on a confirmation of a contested positive result and documents change in the clinical record
 - (2) Drug/substance to be tested meets ONE of the following:
 - i. A MAT drug or metabolite (e.g. buprenorphine or methadone)
 - ii. A synthetic or semi-synthetic opioid is documented as one of the member's drug/substance of choice, or the member periodically uses one of these opioids.
 - iii. Member has demonstrated ongoing use of another drug/substance to get high or alter the effects of a drug/substance including MAT, and the drug/substance can only be tested quantitatively.
- 2. The reason for the test is documented (rationale for the specific test ordered) and includes **TWO** or more of the following criteria:
 - 2.1 Member's history of drug/substance of choice.
 - 2.2 Drug/substances prevalent in the member's geographic region for testing occasionally as part of random testing.
- 3. A signed and dated physician's order is present with **ALL of the following** criteria:
 - 3.1 Drug testing orders are individualized without the use of the following: standing orders, routine multi-panel tests, and reflexive testing (i.e., automatically performing confirmatory testing on the specimen prior to reviewing qualitative results with the member).
 - 3.2 Order includes type of test (presumptive vs. confirmatory).
 - 3.3 Order includes list of all medications currently prescribed for the patient as of the test date (including over-the-counter medications).
 - 3.4 The treatment provider's name is included on all orders for testing.
 - 3.5 Member is provided results of drug testing in a timely manner.
- III. Individualized Testing: In all cases other than routine qualitative drug testing as part of prenatal care, medical necessity for submitted charges must be individualized and documented in the member's medical record and included in the treatment plan of care. CareSource does not provide coverage for drug testing for forensic, legal, employment, transportation, or school purposes.
- IV. Non-Urine Testing:

CareSource will reimburse blood testing without a prior authorization in emergency department settings only, to evaluate acute overdose. Drug testing with blood samples performed in any other setting outside of an ER requires the provider or lab to obtain prior authorization in order to be reimbursed. Hair, saliva, or other body fluid testing for controlled substance monitoring has limited support in medical evidence and is not covered without prior authorization. Additionally, when non-urine drug testing is prior authorized, that non-urine drug testing is reimbursed at the lesser of coverage amounts per CPT for urine testing and non-urine testing.



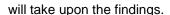
- V. **Urine Testing**: Urine for clinical drug testing is the specimen of choice because of its high drug concentrations and well-established testing procedures. Nevertheless, urine is one of the easiest specimens to adulterate.
 - A. If the provider suspects such an occurrence, the provider may choose to evaluate specimen validity using validity tests. Specimen validity testing is considered to be a quality control issue and is included in the CPT code payment. Additional codes for specimen validity testing should not be separately billed to CareSource. Tests for creatinine, specific gravity, temperature or nitrates are not billable to and will not be reimbursed by CareSource. Failure to document customized tests with medical necessity information for each individual member and for each of the drug tests ordered will result in the denial of the claim for reimbursement, audit, and/or overpayment requests, and any other program means for enforcing this policy.
 - B. Drug testing should be focused on the detection of specific drugs and not routinely include a panel of all drugs of abuse.
 - C. Orders for "custom profiles," "standing orders," "drug screen panel", "custom panel", "blanket orders," "reflex testing" or to "conduct additional testing as needed," are not billable to and will not be reimbursed by CareSource.
 - D. Testing on a routine basis is neither random nor individualized. Routine or reflex testing is not billable to and will not be reimbursed by CareSource. A random basis is defined as a basis which the patient cannot predict ahead of time. For example, testing performed at every clinical visit is not random.
 - E. CareSource does not provide coverage for drug testing as a requirement to stay in a facility, for example, in sober living or residential locations. Other than medically necessary indications for testing, drug testing required for a residential program is included in the cost of and payment for that program.
- VI. Provider Orders: CareSource requires that the ordering provider's name appear in the appropriate lines of the claims form;. A signed and dated provider order for the drug testing and/or testing is required. The provider's order must specifically match the number, level and complexity of the testing components performed.
- VII. **Non-participating providers**: Non-participating providers are not covered for drug testing laboratory services. Non-participating providers may use participating laboratories for drug testing services.

VIII. Documentation Requirements:

All documentation must be accurate, complete, maintained in the member's medical record and available to CareSource upon request. The following documentation requirements apply:

- A. 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/presumptive drug test.
- B. Every page of the record must be legible and include appropriate member identification information (e.g., complete name, dates of service(s)).
- C. The record must include the identity of the physician or non-physician practitioner responsible for and providing the care of the member.
- D. The submitted medical record should support the use of the selected ICD-10-CM code(s) with appropriate indications for urine drug testing.
- E. The submitted CPT/HCPCS code should accurately describe the service performed.
- F. 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.
- G. Drug testing records and related entries in a member's medical record must be provided to CareSource upon request for auditing of medical necessity. Documentation must support medical necessity and specify why each test is ordered. Documentation must also support the number of analytes requested for testing, and what action the provider





IX. Confirmatory and Duplicative Testing

- A. Routine multi-drug quantitative/confirmatory testing is not billable to and will not be reimbursed by CareSource. Quantitative/confirmatory testing must be individualized for the member and medically necessary. Routine confirmations (quantitative) of drug tests with negative results are not covered by CareSource. Quantitative/confirmatory testing is covered for a negative drug/drug class test when the negative finding is inconsistent with the member's documented medical history and/or current documented chronic pain medication list, and indications substantiated in the medical record.
- B. Routine nonspecific or wholesale orders for drug testing (qualitative), confirmation or (quantitative) drugs of abuse testing are not billable.

X. Independent Laboratories

- A. Drug testing conducted for CareSource members by non-participating labs or facilities is not billable to and will not be reimbursed by CareSource, even if such tests were ordered by a participating provider.
- B. CareSource may require documentation of FDA-approved complexity level for instrumented equipment, and/or CLIA Certificate of Registration, Compliance, or Accreditation as a high complexity lab.
- C. Both participating providers and non-participating providers may potentially order laboratory tests for CareSource members
- D. Only participating independent laboratories can bill for quantitative/confirmatory drug tests.
- E. Laboratories must have the appropriate level of CLIA certification for the testing performed and be contracted (participating) with CareSource.
- F. Claims are not billable to CareSource if submitted by laboratories that are non-participating (not contracted) with CareSource.
- G. The ordering/referring provider must include the clinical indication/medical necessity in the order for the drug test as outlined above.
- H. The independent laboratory performing the drug testing must maintain hard copy documentation of the lab results, along with copies of the ordering/referring provider's order for the drug test.
- I. Participating laboratories performing drug testing services must bill CareSource directly. CareSource does not allow pass-through billing of services. Any claim submitted by a provider which includes services ordered by that provider, but are performed by a person or entity other than that provider or a direct employee of that provider, is not billable to CareSource.

XI. Other Non-billable Drug Testing

- A. Standing orders set up between a provider and a laboratory which are prewritten and/or result in the same drugs and drug classes to be tested on a routine, repeat basis, are not billable to and will not be reimbursed by CareSource.
- B. Drug testing is not billable to and will not be reimbursed by CareSource if required by a third party such as:
 - 1. For medico-legal purposes (e.g., court-ordered drug testing);
 - 2. For employment purposes (e.g., as a pre-requisite for employment or as a requirement for continuation of employment);
 - 3. As a condition of:
 - 3.1 Participation in school or community athletic activities or programs
 - 3.2 Participation in school or community extra circular activities or programs
 - 4. As a component of a routine physical/medical examination; e.g. (enrollment in school, enrollment in the military, etc.)
 - 5. As a component of medical examination for any other administrative purposes not listed above (e.g., for purposes of marriage licensure, insurance eligibility, etc.).



6. As a requirement to live in sober housing or residential services. Other than medically necessary indications for testing, drug testing required for a residential program is included in the cost of and payment for that program.

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

HCPCS CPT

F. RELATED POLICIES/RULES

Drug Testing Reimbursement Policy (PY-0089): https://www.caresource.com/providers/ohio/ohio-providers/payment-policies/

G. REVIEW/REVISION HISTORY

DATES		ACTION
Date Issued	08/23/2016	
Date Revised	03/22/2017	Updated definitions of testing; conditions of coverage clarified; testing limits redefined.
	12/13/2017	Revision of quantity limitations and prior authorization requirements; updated clinical criteria.
	02/16/2018	Removed quantity limits and prior authorization.
Date Effective	03/12/2018	

H. REFERENCES

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

