REIMBURSEMENT POLICY STATEMENT
OHIO MARKETPLACE PLANS

Original Issue Date	Next Annual Review	Effective Date
03/08/2017	03/12/2019	03/12/2018
Policy Name		**Policy Number**
Drug Testing		PY-0089
Policy Type		
Medical	Administrative	Pharmacy	REIMBURSEMENT

Reimbursement Policies prepared by CSMG Co. and its affiliates (including CareSource) are intended to provide a general reference regarding billing, coding and documentation guidelines. Coding methodology, regulatory requirements, industry-standard claims editing logic, benefits design and other factors are considered in developing Reimbursement Policies.

In addition to this Policy, Reimbursement of services is subject to member benefits and eligibility on the date of service, medical necessity, adherence to plan policies and procedures, claims editing logic, provider contractual agreement, and applicable referral, authorization, notification and utilization management 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 federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

This Policy does not ensure an authorization or Reimbursement of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced herein. If there is a conflict between this Policy and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

CSMG Co. and its affiliates may use reasonable discretion in interpreting and applying this Policy to services provided in a particular case and may modify this Policy at any time.

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A. SUBJECT

Drug Testing

B. BACKGROUND

Reimbursement policies are designed to assist you when submitting claims to CareSource. They are routinely updated to promote accurate coding and policy clarification. These proprietary policies are not a guarantee of payment. Reimbursement for claims may be subject to limitations and/or qualifications. Reimbursement will be established based upon a review of the actual services provided to a member and will be determined when the claim is received for processing. Health care providers and their office staff are encouraged to use self-service channels to verify member's eligibility.

It is the responsibility of the submitting provider to submit the most accurate and appropriate CPT/HCPCS code(s) for the product or service that is being provided. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Claims submitted to CareSource must be complete in all respects; and all use of the Health Insurance Claim Form CMS-1500 must comply with the most recent version of the Medicare Claims Processing Manual.

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 screening that is medically necessary for the management of CareSource 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 screening 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 Disorder 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 (when the results of a drug screen are not consistent with the patient's history and prescribed medicines) in all urine drug tests was 53% (in 2014 vs 63% in 2011).

C. DEFINITIONS

- **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.
- **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.

For further definitions please refer to the CareSource Drug Testing Medical Policy (MM-0066) posted here: https://www.caresource.com/providers/ohio/marketplace/medical-policies/.

D. POLICY

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.

I. **General Criteria for Coverage**: Clinical guidelines, standards, and scenarios for drug testing are outlined in detail within the CareSource Drug Testing Medical Policy, MM-0066. Please refer to this policy for in-depth information on medical necessity for drug testing, documentation required for claims, and CareSource monitoring and review of drug testing claims.

II. **Individualized Testing**: In all cases other than routine qualitative/presumptive 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 or other third party requirement.

III. **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.

NOTE: Drug testing codes listed in this policy which may include blood or other non-urine bodily fluids, or other physical samples in their coding definitions, are not billable to and will not be reimbursed by CareSource unless (1) the test is performed in the ER setting AND the sample used is blood, as stated above; or, (2) prior authorization has been obtained by the provider or lab.

IV. **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 when submitted simultaneously with a drug testing CPT code and ICD substance-related disorder code. Failure to back up customized tests with medical necessity information for each individual member and for each of the drug tests ordered will be considered by CareSource to be "routine test orders" and are excluded from our members' coverage and 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. 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.

V. **Provider Orders**: **CareSource requires that the ordering provider's name appear in the appropriate lines of the claims forms;.** A signed and dated provider order for the drug testing is required. The provider's order must specifically match the number, level and complexity of the testing components performed.

VI. **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.

VII. **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 provider/treating provider 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 will take upon the findings.

VIII. **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 and medically necessary. Routine confirmations (quantitative) of drug tests with negative results are not deemed medically necessary and 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.
B. Routine nonspecific or wholesale orders for drug screening (qualitative), confirmation, and quantitative drugs of abuse testing are not billable.

IX. **Independent Laboratories**

A. Drug screening tests 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 tests 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 and any required prior authorizations 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 and any required prior authorizations.
I. Participating laboratories performing drug testing services must bill CareSource directly. CareSource does not allow pass-through billing for 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.

X. **Non-Billable Drug Testing**

A. Standing orders set up between a provider and laboratory which are prewritten and/or result in the same drug 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 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 program 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

Reimbursement is dependent on, but not limited to, submitting CMS approved HCPCS and CPT codes along with appropriate modifiers and ICD-10 codes. Please refer to the CMS fee schedules.

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FeeScheduleGenInfo/index.html

The following list(s) of codes is provided as a reference. This list may not be all inclusive and is subject to updates. Please refer to the above referenced source for the most current coding information.

NOTE: Drug testing codes listed in this policy which may include blood or other non-urine bodily fluids, or other physical samples in their coding definitions, are not billable to and will not be reimbursed by CareSource unless (1) the test is performed in the ER setting AND the sample used is blood, as stated above; or, (2) prior authorization has been obtained by the provider or lab.

Codes	Description
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures (e.g., immunoassay); capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges) includes sample validation when performed, per date of service
80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures (e.g., immunoassay); read by instrument assisted direct optical observation (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures, by instrument chemistry analyzers (e.g., utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (e.g., GC, HPLC), and mass spectrometry either with or without chromatography, (e.g., DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service
G0480	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 1-7 drug class(es), including metabolite(s) if performed
G0481	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 8-14 drug class(es), including metabolite(s) if performed
G0482	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2)

	stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 15-21 drug class(es), including metabolite(s) if performed
G0483	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 22 or more drug class(es), including metabolite(s) if performed
G0659	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes

F. RELATED POLICIES/RULES

Drug Testing Medical Policy (MM-0066)

G. REVIEW/REVISION HISTORY

	DATE	ACTION
Date Issued	03/08/2017	New Policy.
Date Revised	10/01/2017	
	10/01/2017	Updated limits, prior authorization requirements, and covered/defunct codes.
	11/29/2017	Updated limits, prior authorization requirements, and covered/defunct codes.
	02/16/2018	Remove quantity limits and prior authorization.
Date Effective	03/12/2018	

H. REFERENCES

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