REIMBURSEMENT POLICY STATEMENT:

KENTUCKY MEDICAID

Original Effective Date	Next Annual Review	Last Revision
01/01/2014	12/15/2017	12/15/16
Policy Name		**Policy Number**
Drug Screening Tests		PY-0020
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.

Contents of Policy

A. SUBJECT

Drug Screening Tests

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.

CareSource will reimburse charges for drug screening that are 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. CareSource will also reimburse for qualitative drug screening performed as part of routine, prenatal care for pregnant members.

C. DEFINITIONS

See Drug Screening Tests Medical Policy (MM-0064)

D. POLICY

I. Prior Authorization for drug screening as outlined in this policy is not required. However, in all cases other than routine qualitative drug screening 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.

II. A signed and dated physician order for the drug screening and/or testing is required.

III. Copies of test results alone without the proper clinician's order for the test are not sufficient documentation to support a claim.

IV. The physician's order must specifically match the number, level and complexity of the testing panel components performed.

V. Orders for "custom profiles," "standing orders," or to "conduct additional testing as needed," are not sufficiently detailed and will be denied by CareSource since they would not verify medical necessity for the specific tests.

VI. CareSource will not reimburse drug screening tests conducted for its members by non-participating labs or facilities, even if such tests were ordered by a participating provider or physician. All documentation must be maintained in the member's medical record and available to CareSource upon request. The following additional documentation requirements apply:
   A. Every page of the record must be legible and include appropriate member identification information (e.g., complete name, dates of service(s)). The record must include the identity of the physician or non- physician practitioner responsible for and providing the care of the member.
   B. The submitted medical record should support the use of the selected ICD-10-CM

code(s). The submitted CPT/HCPCS code should accurately describe the service performed.

C. 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.

D. The treating provider must reduce all testing orders to written form and must indicate all drugs/drug classes to be tested in the test order.

1. The treatment agreement (sometimes called a "contract") notifying the member of his or her responsibility to provide urine/serum samples upon request is not sufficient by itself to support medical necessity.
2. The treating provider performing in-office/onsite POCT should use a CLIA-waived device or CLIA-approved test (FDA cleared/approved) containing specimen validity components to measure creatinine specific gravity and temperature. Results of the drug test must be read according to the manufacturer's instructions. Specimen validity measures are not a billable service and should be used solely as a quality control measure to ensure a valid specimen. If the treating provider has a concern about the validity of the specimen, the provider should document these concerns and take steps to obtain a valid specimen for testing. Inability to obtain a valid specimen should be factored into the ongoing management of the member.
3. Member drug testing should be conducted and reviewed prior to the initial issuance or dispensing of a controlled substance prescription.

VII. Clinicians should exercise caution when relying on customized test panels and standing orders and ensure that medical necessity exists for the testing of all drugs/drug classes within the panel. Failure to back up customized test panels with medical necessity information for each individual member and for each of the drug test panels ordered will be considered "routine test orders" and are excluded from coverage, resulting in the denial of the claim, audit, and/or overpayment request, among other means for enforcement of this policy by CareSource.

VIII. If the provider of the service is other than the ordering/referring physician, that provider must maintain hard copy documentation of the lab results, along with copies of the ordering/referring physician's order for the drug test. The ordering/referring physician must include the clinical indication/medical necessity in the order for the drug test.

IX. Drug Screening

A. 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.

X. Confirmation and Quantitative Testing - CareSource considers confirmatory and/or quantitative drug testing reasonable and necessary when the results of a qualitative screen are:

A. Presumptive positive drug(s) on a drug screen Example: A member has been prescribed oxycodone. The POC drug screen is negative. Quantitative confirmation of the parent drug and metabolite(s) should be ordered. Significant lower levels of parent drug and metabolite(s) levels can be ascertained by quantitative testing compared to screening methodologies.

1. **Exception 1:** The need for cocaine confirmation is rare but appropriate to identify the member is a chronic cocaine user.
2. **Exception 2:** The need for THC confirmation is rare but appropriate to document that the member is discontinuing THC use according to the treatment plan.
3. Presumptive positive for stimulant (amphetamine), barbiturate and benzodiazepine class of drugs. POC drug testing cannot differentiate all the drugs in the stimulant (amphetamine), barbiturate and benzodiazepine class of drugs. A positive qualitative

screen may require confirmation in the absence of reliable validation (member self-report, prescription drug monitoring data, pharmacy profile, or communication from prescribing clinician).

4. Negative screen, and the negative finding is inconsistent with the member's medical history or current documented chronic pain medication list.
   4.1 **Example:** Drugs such as Fentanyl and Meperdine are not identified by POC testing. It may be reasonable for the physician to order a separate initial drug test for one or both of these drugs and their metabolites at baseline or to address risk issues. These orders are subject to the criteria and indications in this document. Automatic confirmatory testing for Fentanyl and Meperdine are not reasonable and necessary without member specific indications.

Note: When the initial screen is negative, CareSource would not expect to see claims for confirmatory testing on COC, THC, AMP and methamphetamine except in rare, documented situations, i.e. when a member is receiving a prescription for AMP for attention deficit (ADD) or other documented medical condition. Exceptions should be documented with the physician's rational for the confirmation testing order in the medical record.

5. When the coverage criteria of this policy are met **AND** there is no qualitative test available (locally or commercially).
   5.1 **Example:** Selected synthetic or semi-synthetic opioids.

B. 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. Urine samples can be diluted, swapped for another individual's, or tampered with using commercially available or homemade products that change the chemical profile of the urine. If the clinician suspects that a sample has been adulterated, substituted, swapped, or otherwise altered in attempt to defeat evaluation and monitoring, the clinician may choose to evaluate specimen validity using built-in validity tests such as temperature, creatinine, and pH readings. As a general rule, specimen validity testing is considered to be a quality control issue and should not be separately billed. Most basic urine immunoassays have specimen validity checks built into the screening process, and allow for a basic determination of potential urine sample tampering (dilution, substituted specimen, etc.). Pain management laboratories may have specimen validity testing protocols. However, these too are deemed quality control measures. Clinicians should exercise caution when relying on customized test panels and standing orders and ensure that medical necessity exists for the testing of all drugs/drug classes within the panel. Failure to back up customized test panels with medical necessity information for each individual member and for each of the drug test panels 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, among other program means for enforcing this policy.

XI. Payment Limitations

A. Except as specifically outlined in this policy, CareSource will not reimburse for routine multi-drug confirmatory testing. Confirmatory testing must be individualized and medically necessary. Routine confirmations (quantitative) of drug screens with negative results are not deemed medically necessary and are not covered by CareSource. Confirmatory testing is covered for a negative drug/drug class screen when the negative finding is inconsistent with the member's medical history or current documented chronic pain medication list.

B. CareSource will not reimburse for routine nonspecific or wholesale orders for drug screening (qualitative), confirmation, and quantitative drugs of abuse testing.

C. CareSource will not reimburse testing for the same drug with both a blood and a urine specimen simultaneously.
D. Both participating (contracted) physicians with Caresource, as well as, non-participating (not contracted) physicians may order laboratory tests for CareSource members
E. Those participating physicians with Practice Services Agreements only, may not bill CareSource for quantitative drug screen testing.
F. Only providers with an Independent Laboratory Contract with CareSource can perform and bill for quantitative drug screens.
G. Laboratories MUST be both CLIA certified AND contracted (participating) with Caresource.
H. Claims submitted by laboratories that are non-participating (not contracted) with CareSource will NOT be reimbursed.
I. CareSource will not reimburse 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).

NOTE: Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

E. CONDITIONS OF COVERAGE

Code	Presumptive Drug Class Screening codes:
G0477	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
G0478	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
G0479	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers utilizing immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry), includes sample validation when performed, per date of service
G0480	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) and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed
G0481	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) and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed
G0482	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) and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 15-21 drug class(es), including metabolite(s) if performed

G0483	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) and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed

AUTHORIZATION PERIOD

F. RELATED POLICIES/RULES

See Drug Screening Tests Medical Policy (MM-0064)

G. REVIEW/REVISION HISTORY

	DATE	ACTION
Date Issued	01/01/2014	
Date Reviewed	12/15/2016	
Date Revised	12/15/2016	

H. REFERENCES

1. Clinical Diagnostic Laboratory Fee Schedule 2016 (2016). Retrieved on 8/18/2016 from http://chfs.ky.gov/NR/rdonlyres/B7561EB5-C136-4722-A3F4-BF9CC0AF1E94/0/ClinicalDiagnosticLaboratoryFeeSchedule2016web.pdf.

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

Independent medical review – 2/2015