MEDICAID POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
01/01/2014	04/05/2017	04/05/2016

Policy Name	Policy Number
Drug Screening Tests	MM-0054

Policy Type		
☒ Medical	☐ Administrative	☐ Payment

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Medicaid 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 benefit document (i.e., Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medicaid Policy Statement and the plan benefit document, then the plan benefit document will be the controlling document used to make the determination. In the absence of any applicable controlling federal or state coverage mandate, benefits are ultimately determined by the applicable plan benefit document.

A. SUBJECT

Drug Screening Tests

B. BACKGROUND

Effective January 1, 2014, 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

- **Analyte** – A substance which is, or can be, identified and measured through a process of chemical analysis frequently involving the process of chromatography.
- **Chromatography** – A common process by which drug screens are performed in which a mixture of compounds that are dissolved in a mobile phase is passed through an absorbent (i.e. clay, gel or paper), thereby separating the constituents for the purpose of qualitative identification and/or quantitative measurement.
- **CLIA** – Clinical Laboratory Improvement Amendments – Federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States except clinical trials and basic research.
- **Contracted Laboratories** – Laboratories that have a current, independent formal agreement with CareSource.
- **Current Procedural Terminology** ("**CPT**") codes are numbers assigned to every task, medical procedure, and service a medical practitioner may provide to a patient. CPT codes

are developed, maintained and updated annually, and copyrighted by the American Medical Association.

- **Drug Screen** – Drug screening involves one or more analytical techniques used to identify specific drugs or their metabolites in biologic specimens, usually the urine. .
- **Drug Test Panels** – A drug test panel is a list or menu of drugs or drug classes that can be tested for in a specimen. These can be ordered to identify drugs of abuse or in pain management. No single drug panel is suitable for all clinical uses; many testing options exist that can be adapted to clinical needs through proper exercise of clinical decision-making. Panels must be related to the individual member's medical history and treatment needs. Existing test panels in point-of-care testing devices and as marketed by independent clinical laboratories may result in medically unnecessary and unreasonable testing and should be carefully evaluated by the ordering provider.
- **Healthcare Common Procedure Coding System** (**HCPCS**) – is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes.
- **Immunoassay** – A chemical test used to detect the presence or quantity of a substance using immunological reactions.
- **Point of Care (POC) Test Kit** – A CLIA Waived, usually 5 to 12 panel drug test kit that detects 5 to 12 drugs simultaneously in one testing. The cup includes a 5 to 12 panel spot test cup with built in adulterant test strips and urine temperature test strip.
- **Qualitative Drug Screen –** A screen to merely detect the presence of a drug (analyte) in a body fluid such as blood or urine.
- **Quantitative Drug Screen** – A testing of body fluids to measure how much of a drug or other substance (analyte) is present.

D. POLICY

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. A signed and dated physician order for the drug screening and/or testing is required. Copies of test results alone without the proper clinician's order for the test are not sufficient documentation to support a claim. The physician's order must specifically match the number, level and complexity of the testing panel components performed. 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.

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.

I. 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- 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.

E. 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.

F. 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.

II. **Drug Screening** (See below for the appropriate billing codes)

A. As a condition of reimbursement, 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.

III. **Confirmation and Quantitative Testing**

A. CareSource considers confirmatory and/or quantitative drug testing reasonable and necessary when the results of a qualitative screen are:
   1. 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.
      1.1 **Exception 1:** The need for cocaine confirmation is rare but appropriate to identify the member is a chronic cocaine user.
      1.2 **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.
   2. 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).

3. Negative screen, and the negative finding is inconsistent with the member's medical history or current documented chronic pain medication list.
   3.1 **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.

4. When the coverage criteria of this policy are met **AND** there is no qualitative test available (locally or commercially).
   4.1 **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.

IV. 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. Only laboratories and physicians contracted with CareSource are eligible for reimbursement.
E. Laboratories or physicians not individually contracted as a CLIA certified lab with CareSource and billing under the billing number of a contracted physician will not be reimbursed.
F. 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).
G. Code of Federal Regulations:
42 CFR, Section 410.32, indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements) who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician (or other qualified non-physician provider) who is treating the beneficiary are not reasonable and necessary (see Sec. 411.15(k)(1)).

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

CONDITIONS OF COVERAGE

CODES

CPT	Presumptive Drug Class Screening codes:
80300	Drug screen, any number of drug classes from Drug Class List A; any number of non-TLC devices or procedures (eg, immunoassay) capable of being read by direct optical observation, including instrumented-assisted when performed (eg, dipsticks, cups, cards, cartridges), per date of service
80301	Drug screen, any number of drug classes from Drug Class List A; single drug class method, by instrumented test systems (eg, discrete multichannel chemistry analyzers utilizing immunoassay or enzyme assay), per date of service
80302	Drug screen, presumptive, single drug class from Drug Class List B, by immunoassay (eg, ELISA) or non-TLC chromatography without mass spectrometry (eg, GC, HPLC), each procedure
80303	Drug screen, any number of drug classes, presumptive, single or multiple drug class method; thin layer chromatography procedure(s) (TLC) (eg, acid, neutral, alkaloid plate), per date of service
80304	Drug screen, any number of drug classes, presumptive, single or multiple drug class method; not otherwise specified presumptive procedure (eg, TOF, MALDI, LDTD, DESI, DART), each procedure

	Definitive Drug Testing codes:
80320	Alcohols
80321	Alcohol biomarkers; 1 or 2
80322	Alcohol biomarkers; 3 or more
80323	Alkaloids, not otherwise specified
80324	Amphetamines; 1 or 2
80325	Amphetamines; 3 or 4
80326	Amphetamines; 5 or more
80327	Anabolic steroids; 1 or 2
80328	Anabolic steroids; 3 or more
80332	Antidepressants, serotonergic class; 1 or 2
80333	Antidepressants, serotonergic class; 3-5
80334	Antidepressants, serotonergic class; 6 or more
80335	Antidepressants, tricyclic and other cyclicals; 1 or 2
80336	Antidepressants, tricyclic and other cyclicals; 3-5
80337	Antidepressants, tricyclic and other cyclicals; 6 or more
80338	Antidepressants, not otherwise specified
80339	Antiepileptics, not otherwise specified; 1-3
80340	Antiepileptics, not otherwise specified; 4-6
80341	Antiepileptics, not otherwise specified; 7 or more
80342	Antipsychotics, not otherwise specified; 1-3
80343	Antipsychotics, not otherwise specified; 4-6
80344	Antipsychotics, not otherwise specified; 7 or more
80345	Barbiturates
80346	Benzodiazepines; 1-12
80347	Benzodiazepines; 13 or more
80348	Buprenorphine
80349	Cannabinoids, natural
80350	Cannabinoids, synthetic; 1-3
80351	Cannabinoids, synthetic; 4-6
80352	Cannabinoids, synthetic; 7 or more
80353	Cocaine
80354	Fentanyl
80355	Gabapentin, non-blood
80356	Heroin metabolite
80357	Ketamine and norketamine
80358	Methadone
80359	Methylenedioxyamphetamines
80360	Methylphenidate
80361	Opiates, 1 or more
80362	Opioids and opiate analogs; 1 or 2
80363	Opioids and opiate analogs; 3 or 4
80364	Opioids and opiate analogs; 5 or more
80365	Oxycodone
80366	Pregabalin
80368	Sedative hypnotics (non-benzodiazepines)
80369	Skeletal muscle relaxants; 1 or 2
80370	Skeletal muscle relaxants; 3 or more
80371	Stimulants, synthetic
80372	Tapentadol
80373	Tramadol
80374	Stereoisomer (enantiomer) analysis, single drug class
80375	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 1-3

80376	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 4-6
80377	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 7 or more
83992	Phencyclidine (PCP)

AUTHORIZATION PERIOD

E. RELATED POLICIES/RULES

Drug Screening Tests Payment Policy (PY-0020):
https://www.caresource.com/providers/ohio/ohio-providers/payment-policies/

F. REVIEW/REVISION HISTORY

Date Issued: 01/01/2014
Date Reviewed: 01/01/2014, 04/05/2016
Date Revised: 04/05/2016

G. REFERENCES

1. OAC 5160-30 Alcohol and Drug Addiction Services
2. OAC 3793:2-1-08 Treatment services
3. 907 KAR 3:110. Community mental health center substance abuse services

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