Medicaid and Health Choice Clinical Coverage Policy No:1S-8 Amended Date: November 01, 2020

To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

Table of Contents

1.0	Descr	ription of	the Procedure, Product, or Service	1	
	1.1	Definit	ions	2	
		1.1.1	Aberrant Behavior	2	
		1.1.2	Abstinence	2	
		1.1.3	Clinical Laboratory Improvement Amendments (CLIA)	2	
		1.1.4	Definitive Urine Drug Test	2	
		1.1.5	Gas chromatography/mass spectrometry (GC/MS)	2	
		1.1.6	Immunoassay (IA)	2	
		1.1.7	Mass Spectrometry and Liquid Chromatography	2	
		1.1.8	Point of Care Testing (POCT)	2	
		1.1.9	Presumptive Urine Drug Test	3	
		1.1.10	Reflex Testing	3	
		1.1.11	Specimen Validity Test	3	
2.0	Elicil	vility. Dogs	vinama anta	1	
2.0	Eligibility Requirements 2.1 Provisions				
	2.1	2.1.1	General		
		2.1.1	Specific		
	2.2		Provisions		
	2.2	2.2.1	EPSDT Special Provision: Exception to Policy Limitations for a Medicaid	4	
		2.2.1	Beneficiary under 21 Years of Age	/	
		2.2.2	EPSDT does not apply to NCHC beneficiaries		
		2.2.2	Health Choice Special Provision for a Health Choice Beneficiary age 6 through		
		2.2.3	18 years of age		
3.0	When		edure, Product, or Service Is Covered		
	3.1	Genera	l Criteria Covered	5	
	3.2	Specifi	c Criteria Covered		
		3.2.1	Specific criteria covered by both Medicaid and NCHC	5	
			Toxicity		
		3.2.1.2	Treatment of substance use disorder	6	
		3.2.1.3	Treatment of Chronic Pain	7	
		3.2.1.4	Reflex Testing	8	
		3.2.1.5	Direct to Definitive Testing	8	
		3.2.1.6	Definitive Testing to Confirm a Negative Presumptive Result	8	
		3.2.1.7	Definitive Testing to Confirm a Presumptive Positive	8	
	3.3	Medica	nid Additional Criteria Covered	8	
	3.4	NCHC	Additional Criteria Covered.	8	
4.0	W/h ~~	the Dress	adura Praduat or Sarviga Is Not Covared	ſ	
4.0	4.1		edure, Product, or Service Is Not Covered		
	4.1		c Criteria Not Covered		
	4.∠	Speciff	C CHICHA INOL COVEIEU	ر	

20J12 i

NC Medicaid Drug Testing for Opioid Treatment and Controlled Substance Monitoring

Medicaid and Health Choice Clinical Coverage Policy No:1S-8 Amended Date: November 01, 2020

 4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC	9
4.2.3 NOTIC Additional Criteria Not Covered	
5.0 Requirements for and Limitations on Coverage	10
5.1 Prior Approval	
5.2 Prior Approval Requirements	
5.2.1 General	
5.2.2 Specific	10
5.3 Additional Limitations or Requirements	
6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service	11
6.1 Provider Qualifications and Occupational Licensing Entity Regulations	
6.2 Provider Certifications	
7.0 Additional Requirements	11
7.1 Compliance	11
8.0 Policy Implementation and History	12
Attachment A: Claims-Related Information	13
A. Claim Type	
B. International Classification of Diseases and Related Health Problems, Tenth Revisio	ns,
Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)	13
C. Code(s)	
D. Modifiers	15
E. Billing Units	15
F. Place of Service	15
G. Co-payments	16
H. Reimbursement	
Attachment B: Drug Class Listing	17

20J12 ii

NC Medicaid Drug Testing for Opioid Treatment and Controlled Substance Monitoring

Medicaid and Health Choice Clinical Coverage Policy No:1S-8 Amended Date: November 01, 2020

Related Clinical Coverage Policies

Refer to https://medicaid.ncdhhs.gov/ for the related coverage policies listed below: 1A-41 Office Based Opioid Treatment: Use of Buprenorphine and Buprenorphine-Naloxone 1S-3 Laboratory Services

Pharmacy Prior Approval and Renewal Criteria located at https://www.nctracks.nc.gov

1.0 Description of the Procedure, Product, or Service

Various strategies are available to monitor beneficiaries receiving treatment for chronic pain or substance use disorders, and multicomponent interventions are often used. Many settings require a beneficiary to sign a contract before he or she is given a prescription for opioids. The contract generally involves obtaining a beneficiary's agreement on behaviors he or she shall engage in during the treatment period (taking medication as prescribed) and not engage in (selling prescribed medication or obtaining additional prescriptions from other physicians).

Per an evidence assessment by the American Society of Interventional Pain Physicians (ASIPP), approximately one-third of patients with chronic pain either do not use opioids as prescribed or use them inappropriately. Studies also report that a substantial proportion of chronic pain patients inaccurately report adherence to prescribed medications and do not report use of illicit drugs.

Confirming whether a beneficiary follows office guidelines can pose a challenge. Risk-assessment screening instruments can aid in the assessment of a beneficiary's risk for illicit substance use or misuse of prescription medications.

Another strategy for monitoring patients is testing of specimens for the presence or absence of drugs. Currently, urine is the most commonly tested sample. Advantages of urine sampling are that it is readily available, and standardized techniques for detecting drugs in urine exist. Blood, oral fluids, hair and sweat testing may gain in popularity over time as techniques for collecting and analyzing these specimens become more standardized. Currently, drug testing is allowed only from one source per day.

Immunoassay (IA) tests are used for screening and are performed either in a laboratory or in a provider's office and use antibodies to detect a particular drug or drug metabolite in a sample. Immunoassay tests vary in the type of compounds they can detect. Some detect specific drugs and may fail to recognize similarly structured drugs within the same class. Other immunoassays identify only classes of drugs and thus results cannot be used to determine which drug a patient is taking. The degree of cross reactivity varies widely among immunoassays.

Immunoassay findings are generally reported presumptively as either positive (drug level above a pre-specified threshold) or negative (drug level below a pre-specified threshold). Raising or lowering the threshold thus changes the proportion of positive tests. A negative test is interpreted as a level below the threshold and does not necessarily mean that the drug or metabolite is absent. Immunoassays generally have a rapid turnaround time, within minutes for onsite tests and one (1) to four (4) hours for laboratory-based tests.

CPT codes, descriptors, and other data only are copyright 2020 American Medical Association. All rights reserved. Applicable FARS/DFARS apply.

Definitive drug tests are always performed in a laboratory. Definitive tests confirm the presence of a specific drug identified by a screening test and identify drugs that cannot be isolated by currently available immunoassays. There may be a several days turnaround time for definitive testing.

1.1 Definitions

1.1.1 Aberrant Behavior

An action or attitude that breaches mutually established medical boundaries such as ongoing illicit substance use, discordant drug tests, diversion, missed appointments, request for early refills, altering prescriptions, using an alternate route for medication administration, resistance to medication change or decrease in dose, lost medications, or obtaining narcotics from multiple sources.

1.1.2 Abstinence

Continuous abstinence from the drug of choice and no use or asymptomatic use of other substances during a period of time.

1.1.3 Clinical Laboratory Improvement Amendments (CLIA)

Regulates laboratory testing and requires clinical labs to be certified by their state and the Centers for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing. There are multiple levels of CLIA certification available depending on the type of testing to be performed.

1.1.4 Definitive Urine Drug Test

Also known as quantitative or confirmatory testing, identifies specific medications, illicit substances, and metabolites. Results are typically reported in concentrations of nanograms per milliliter (ng/mL).

1.1.5 Gas chromatography/mass spectrometry (GC/MS)

Considered to be the criterion standard for confirmatory testing. This technique involves using GC to separate the analytes in a specimen and MS to identify the specific molecular structures of the drug and its metabolites. The tests are able to quantify the amount of drug or metabolite present in the urine sample. Results are reported as the specific levels of substances detected in the urine. GC/MS generally requires specification of the drug or drugs to be identified.

1.1.6 Immunoassay (IA)

Used primarily to identify the presence or absence of drugs or drug classes above a preset cutoff level with use of an antibody. This test is read with photometric technology.

1.1.7 Mass Spectrometry and Liquid Chromatography

Newer techniques used by some offices and most commercial laboratories combine the presumptive and definitive testing in a single step. This testing may include up to 50 tests from a single sample. This testing, when done for screening purposes only, is considered to be presumptive testing.

1.1.8 Point of Care Testing (POCT)

Used by clinicians caring for a beneficiary for immediate test results for the immediate management of the beneficiary's care. This is an IA testing method

Medicaid and Health Choice Clinical Coverage Policy No: 1S-8 Amended Date: November 01, 2020

consisting of cups, dipsticks, cassettes, or strips and read by the human eye or instrument assisted direct optical observation.

1.1.9 Presumptive Urine Drug Test

Also known as qualitative testing, determines the presence or absence of a drug class in a urine sample and is reported as a positive, negative, or with a numerical value.

1.1.10 Reflex Testing

Testing performed in a laboratory that is performed after initial test results to identify further diagnostic information essential to the care of the beneficiary. This test is not based on a physician's order, and testing performed to complete a physician's order is not considered reflex testing.

1.1.11 Specimen Validity Test

Testing to ensure sample is unadulterated and may include pH (potential of hydrogen), specific gravity, or creatinine.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term "General" found throughout this policy applies to all Medicaid and NCHC policies)

- a. An eligible beneficiary shall be enrolled in either:
 - 1. the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise); or
 - 2. the NC Health Choice (NCHC is NC Health Choice program, unless context clearly indicates otherwise) Program on the date of service and shall meet the criteria in Section 3.0 of this policy.
- b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.
- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(The term "Specific" found throughout this policy only applies to this policy)

a. <u>Medicaid</u>

None Apply.

b. NCHC

None Apply.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

- 1. that is unsafe, ineffective, or experimental or investigational.
- 2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. EPSDT and Prior Approval Requirements

- 1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- 2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page: https://medicaid.ncdhhs.gov/

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

Medicaid and NCHC shall cover drug testing for the treatment of substance use disorders or chronic pain up to the annual testing limits of **up to twenty-four** (24) **presumptive tests and twenty-four** (24) **definitive tests per fiscal year** when the following criteria are met:

3.2.1.1 Toxicity

A beneficiary who presents to any clinical setting with symptoms of substance use toxicity is treated presumptively to stabilize the beneficiary while awaiting rapid, then definitive testing to determine the cause(s) of presentation. The need for definitive drug testing is based on presumptive screen findings, responses to medical interventions, and treatment plan.

A presumptive drug test may be performed, if deemed appropriate by the medical professional, as part of the evaluation and management of a beneficiary who presents with any one of the following:

- a. Coma;
- b. Altered mental status in the absence of a clinically defined toxic syndrome or toxidrome;
- c. Severe or unexplained cardiovascular instability;
- d. Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome;
- e. Seizures with an undetermined history;
- f. To provide antagonist to a specific drug.

Note: The presumptive findings, definitive drug tests ordered, and reasons for the testing must be documented in the beneficiary's health record

3.2.1.2 Treatment of substance use disorder

a. Indications for Testing

Drug tests for beneficiaries diagnosed with a SUD must be performed at random intervals to properly manage and monitor the beneficiary's care. Testing profiles must be determined by the provider based on the following beneficiary criteria:

- 1. History, physical examination, and previous laboratory findings;
- 2. Beneficiary report of use and prescribed medications;
- 3. Suspected misused substance(s);
- 4. Community usage; and
- 5. Substances that may present high risk for additive or synergistic interactions with prescribed medication such as benzodiazepines or alcohol.

The beneficiary's health record must contain documentation of appropriate testing frequency based on the stage of treatment or recovery, rationale for all drug class(es) ordered, results of laboratory testing, and how the results are to be used to guide care for both presumptive and definitive drug testing.

b. Frequency of Testing

- 1. For a beneficiary with zero (0) to thirty (30) consecutive days of abstinence, presumptive and definitive drug testing is expected at a frequency not to exceed once per calendar week.
- 2. For a beneficiary with **thirty-one** (31) to ninety (90) consecutive days of abstinence, presumptive and definitive drug testing is expected at a frequency not to exceed twice per thirty (30) consecutive calendar days.
- 3. For a beneficiary with **greater than ninety (90) consecutive days of abstinence**, presumptive and definitive drug testing is expected at a frequency not to exceed once per thirty (30) consecutive calendar days.

3.2.1.3 Treatment of Chronic Pain

a. Indications for Testing

Medical necessity for drug testing must be beneficiary-specific and based on elements identified during clinical assessment. This information must be documented in the health record and consist of the following, at a minimum:

- 1. Complete history of pain;
- 2. Physical examination;
- 3. Previous laboratory findings;
- 4. Current treatment plan,
- 5. Prescribed medications; and
- 6. Potential for misuse, diversion, and risk assessment plan.

The beneficiary's health record must contain documentation of appropriate testing frequency based on the stage of treatment or recovery, rationale for all drug class(es) ordered, results of laboratory testing, and how the results are to be used to guide care for both presumptive and definitive drug testing.

b. Frequency of Testing

Frequency of drug testing must be based on a complete clinical assessment of the beneficiary's risk potential for abuse and diversion, using a validated risk assessment interview or questionnaire, along with the beneficiary's response to prescribed medications and any side effects reported. Determination of risk is made by the provider and is based on interpretation of assessment tools used.

- 1. For a beneficiary classified as **low-risk**, random presumptive and definitive testing is expected at a frequency not to exceed one (1) to two (2) times every 365 consecutive days for prescribed medications, non-prescribed medications that may pose a safety risk if taken concomitantly with prescribed medication(s), and illicit substances based on beneficiary history, clinical presentation, and community usage.
- 2. For a beneficiary classified as **moderate-risk**, random presumptive and definitive testing is expected at a frequency not to exceed two (2) to four (4) times every 365 consecutive days for prescribed medications, non-prescribed medications that may pose a safety risk if taken concomitantly with prescribed medication(s), and illicit substances based on beneficiary history, clinical presentation, and community usage.
- 3. For a beneficiary classified as **high-risk**, random presumptive and definitive testing is expected at a frequency not to exceed one (1) to three (3) times every 90 consecutive days for prescribed medications, non-prescribed medications that may pose a safety risk if taken concomitantly with prescribed medication(s), and illicit substances based on beneficiary history, clinical presentation, and community usage.

Note: Any additional definitive drug testing beyond the criteria listed above must be justified by the provider in the health record, and only for situations in which changes in prescribed medications may be required.

3.2.1.4 Reflex Testing

As reference laboratories do not have access to beneficiary health records, Medicaid and NCHC shall cover reflex testing in the following circumstances:

- a. To verify a presumptive positive drug test using definitive methods before reporting the presumptive finding to the ordering provider and without an additional order from the provider; **or**
- b. To confirm the absence of a prescribed medication when a negative result is obtained by presumptive drug testing in the laboratory for a prescribed medication listed by the ordering provider.

3.2.1.5 Direct to Definitive Testing

Medicaid and NCHC shall cover direct to definitive drug testing when the test is individualized to the beneficiary based on history of use and substance(s) likely to be present.

3.2.1.6 Definitive Testing to Confirm a Negative Presumptive Result

Medicaid and NCHC shall cover definitive testing to confirm a negative presumptive result for the following circumstances when accompanied by a physician order:

- a. The presumptive result is inconsistent with a beneficiary's selfreport, presentation, medical history, or current prescribed medication plan;
- b. Following a review of clinical findings, the provider suspects use a substance that is inadequately detected or not detected by a presumptive drug test; **or**
- c. To rule out an error as the cause of a negative presumptive result.

3.2.1.7 Definitive Testing to Confirm a Presumptive Positive

Medicaid and NCHC shall cover definitive testing to confirm a positive presumptive result for the following circumstances when accompanied by a physician order:

a. When the presumptive result is inconsistent with the expected result, beneficiary self-report, presentation, medical history, or current medication plan.

3.3 Medicaid Additional Criteria Covered

None Apply.

3.4 NCHC Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in Section 2.0;
- b. the beneficiary does not meet the criteria listed in **Section 3.0**;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

Medicaid and NCHC shall not cover drug testing for opioid treatment and controlled substance monitoring for the following:

- a. Reflex definitive drug testing when presumptive testing is performed at point of care as the provider may have sufficient information to manage the beneficiary's care. If the provider is not satisfied with the presumptive testing, they must determine the clinical appropriateness of and order specific subsequent definitive testing;
- b. Point of care testing at the provider's office followed by presumptive IA testing in a reference lab;
- c. Presumptive IA testing in the provider's office, followed by an order for a presumptive test by a reference lab;
- d. Reference laboratories performing and billing for an IA presumptive test prior to definitive testing, without a specific provider order for the presumptive testing;
- e. IA testing used to confirm a presumptive result obtained by cups, dipsticks, cards, cassettes, or other IA testing methods;
- f. Drug testing of two (2) different specimen types from the same beneficiary on the same date of service;
- g. Testing for medico-legal or employment purposes or to protect a physician from drug diversion charges or malpractice; **or**
- h. Specimen validity testing consisting of pH, specific gravity, oxidants, or creatinine.

Note: In addition to the above, Medicaid and NCHC shall not cover presumptive or definitive drug testing for the treatment of substance use disorder or chronic pain in excess of the annual limits listed in subsection **3.2.1.**

4.2.2 Medicaid Additional Criteria Not Covered

None Apply

4.2.3 NCHC Additional Criteria Not Covered

- a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 - 1. No services for long-term care.
 - 2. No nonemergency medical transportation.
 - 3. No EPSDT.
 - 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

5.1 Prior Approval

- a. Medicaid and NCHC shall not require prior approval for drug testing for opioid treatment and controlled substance monitoring;
- Medicaid and NCHC shall require Pharmacy Prior Authorization for use of buprenorphine or buprenorphine-naloxone combination medication (refer to pharmacy prior approval and renewal criteria located at https://www.nctracks.nc.gov/); and
- c. Medicaid and NCHC shall require Pharmacy Prior Authorization for use of opioids for chronic pain (refer to pharmacy prior approval and renewal criteria located at https://www.nctracks.nc.gov/).

Prior Approval signifies medical necessity only; it does not address the beneficiary's eligibility or guarantee claim payment.

5.2 Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

- a. the prior approval request; and
- b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

5.2.2 Specific

None Apply

5.3 Additional Limitations or Requirements

None Apply.

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

- a. meet Medicaid or NCHC qualifications for participation;
- b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity RegulationsNone Apply.

6.2 Provider Certifications

Medicaid and NCHC require all laboratories to have a valid CLIA certification number on file to receive reimbursement for any laboratory procedures. Physicians are reminded that they may only bill for those tests for which they are certified.

Providers who have questions regarding CLIA Certification may contact the Division of Health Service Regulation Acute and Home Care Licensure and Certification and CLIA Program.

Providers may also view information on the CMS website for CLIA and Categorization of Tests at: https://www.cms.gov/ Additional Requirements

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

In addition to the above, provider(s) shall comply with the following:

- a. 42 CFR Part §493 Laboratory Requirements;
- b. 42 CFR Part § 8.12 (f)(6) Drug Abuse Testing Services;
- c. NCAC 27G .3604(h) Random Testing;
- d. NCAC 27G .3604 (k)(4) Diversion Control Plan; and
- e. Policies of the North Carolina Medical Board.

8.0 Policy Implementation and History

Original Effective Date: January 1, 2016

History:

Date	Section or Subsection	Change
	Amended	
11/01/2017	All Sections and Attachment(s)	New policy on drug testing for the treatment of substance use disorders and chronic pain
03/15/2019	Table of Contents	Added, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP."
03/15/2019	All Sections and Attachments	Updated policy template language.
01/03/2020	Table of Contents	Updated policy template language, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP."
01/03/2020	Attachment A	Added, "Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines".
11/01/2020	3.2.1 Specific Criteria Covered both by Medicaid and NCHC	Updated policy template language," the annual limit of up to twenty-four (24) presumptive and twenty-four (24) definitive tests per fiscal year."

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

ICD-10-CM Code(s) Supporting Medical Necessity for Drug Testing			
E87.2	M51.14	T39.2X2A	T43.203A
F10.20	M51.15	T39.2X3A	T43.204A
F11.10	M51.16	T39.2X4A	T43.211A
F11.120	M51.17	T39.311A	T43.212A
F11.129	M51.36	T39.312A	T43.213A
F11.20	M51.37	T39.313A	T43.214A
F11.220	M54.10	T39.314A	T43.221A
F11.221	M54.14	T39.391A	T43.222A
F11.222	M54.15	T39.392A	T43.223A
F11.229	M54.16	T39.393A	T43.224A
F11.23	M54.17	T39.394A	T43.291A
F11.24	M54.18	T40.0X1A	T43.292A
F11.250	M54.2	T40.0X2A	T43.293A
F11.251	M54.5	T40.0X3A	T43.294A
F11.259	M60.811	T40.0X4A	T43.3X1A
F11.281	M60.812	T40.1X1A	T43.3X2A
F11.282	M60.821	T40.1X2A	T43.3X3A
F11.288	M60.822	T40.1X3A	T43.3X4A
F11.29	M60.831	T40.1X4A	T43.4X1A
F12.10	M60.832	T40.2X1A	T43.4X2A
F13.10	M60.841	T40.2X2A	T43.4X3A
F13.120	M60.842	T40.2X3A	T43.4X4A
F13.129	M60.851	T40.2X4A	T43.501A
F14.10	M60.852	T40.3X1A	T43.502A
F14.120	M60.861	T40.3X2A	T43.503A
F14.121	M60.862	T40.3X3A	T43.504A
F14.129	M60.871	T40.3X4A	T43.591A

-			
F14.180	M60.872	T40.4X1A	T43.592A
F15.10	M60.88	T40.4X2A	T43.593A
F15.120	M60.89	T40.4X3A	T43.594A
F15.129	M60.9	T40.4X4A	T43.601A
F18.10	M79.1	T40.601A	T43.602A
F18.120	M79.2	T40.602A	T43.603A
F18.90	M79.7	T40.603A	T43.604A
F19.10	R40.0	T40.604A	T43.611A
F19.120	R40.1	T40.691A	T43.612A
F19.129	R40.20	T40.692A	T43.613A
F19.20	R40.2110	T40.693A	T43.614A
F20.0	R40.2111	T40.694A	T43.621A
F20.1	R40.2112	T40.7X1A	T43.622A
F20.2	R40.2113	T40.7X2A	T43.623A
F20.89	R40.2114	T40.7X3A	T43.624A
F55.0	R40.2120	T40.7X4A	T43.631A
F55.1	R40.2121	T40.8X1A	T43.632A
F55.2	R40.2122	T40.8X2A	T43.633A
F55.3	R40.2123	T40.8X3A	T43.634A
F55.4	R40.2124	T40.8X4A	T43.691A
F55.8	R40.2210	T40.901A	T43.692A
G40.301	R40.2211	T40.902A	T43.693A
G40.309	R40.2212	T40.903A	T43.694A
G40.311	R40.2213	T40.904A	T43.8X1A
G40.319	R40.2214	T40.991A	T43.8X2A
G40.401	R40.2220	T40.992A	T43.8X3A
G40.409	R40.2221	T40.993A	T43.8X4A
G40.411	R40.2222	T40.994A	T43.91XA
G40.419	R40.2223	T42.0X1A	T43.92XA
G40.901	R40.2224	T42.0X2A	T43.93XA
G40.909	R40.2310	T42.0X3A	T43.94XA
G40.911	R40.2311	T42.0X4A	T45.0X1A
G40.919	R40.2312	T42.3X1A	T45.0X2A
G89.29	R40.2313	T42.3X2A	T45.0X3A
G89.4	R40.2314	T42.3X3A	T45.0X4A
I44.0	R40.2320	T42.3X4A	T46.0X1A
I44.1	R40.2321	T42.4X1A	T46.0X2A
I44.30	R40.2322	T42.4X2A	T46.0X3A
I45.81	R40.2323	T42.4X3A	T46.0X4A
I47.0	R40.2324	T42.4X4A	T50.901A
I47.1	R40.2340	T42.6X1A	T50.902A
I47.2	R40.2341	T42.6X2A	T50.903A
I49.2	R40.2342	T42.6X3A	T50.904A
M25.50	R40.2343	T42.6X4A	Z03.89
M47.21	R40.2344	T42.71XA	Z51.81
M47.22	R44.0	T42.72XA	Z79.3
M47.23	R44.2	T42.73XA	Z79.891
M47.26	R44.3	T42.74XA	Z79.899
M47.27	R56.9	T43.011A	Z91.19

M47.28	T39.011A	T43.012A	
M47.811	T39.012A	T43.013A	
M47.812	T39.013A	T43.014A	
M47.813	T39.014A	T43.021A	
M47.816	T39.091A	T43.022A	
M47.817	T39.092A	T43.023A	
M47.818	T39.093A	T43.024A	
M47.891	T39.094A	T43.1X1A	
M47.892	T39.1X1A	T43.1X2A	
M47.893	T39.1X2A	T43.1X3A	
M47.896	T39.1X3A	T43.1X4A	
M47.897	T39.1X4A	T43.201A	
M47.898	T39.2X1A	T43.202A	

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Modifiers

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

CPT codes for presumptive or definitive testing will not be recognized when there is an active HCPCS code. There is a limit of one presumptive and one definitive test per beneficiary, per date of service regardless of the number of providers billing for the service.

F. Place of Service

Office, outpatient, laboratory

Medicaid and Health Choice Clinical Coverage Policy No: 1S-8 Amended Date: November 01, 2020

G. Co-payments

For Medicaid refer to Medicaid State Plan: https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

For NCHC refer to NCHC State Plan: https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

H. Reimbursement

Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/

Attachment B: Drug Class Listing

Drug Class	Drugs
Alcohol	Acetone, ethanol, ethchlorvynol, ethylene glycol, isopropanol, isopropyl alcohol,
	methanol, ethanol conjugates
Alcohol Biomarkers	ethanol conjugates
Alkaloids, not	7-Hydroxymitragynine, atropine, cotinine, lysergic acid diethylamide, mescaline,
otherwise specified	mitragynine, nicotine, psilocin, psilocybin, scopolamine
Amphetamines	Amphetamine, methamphetamine, ephedrinelisdexamphetamine, phentermine,
•	phenylpropanolamine, pseudoephedrine
Anabolic Steroids	1- Andostenediol, 1-andostenedione, 1-testosterone, 4-hydroxy-tesosterone, 6-oxo, 19-norandrostenedione, androstenedione, androstanolone, bolandiol, bolasterone, boldenone, boldione, calusterone, clostebol, danazol, dehydrochlormethyltestosterone, dihydrotestosterone, drostanolone, epiandrosterone, epitestosterone, fluoxymesterone, furazabol, mestanolone, mesterolone, methandienone, methandriol, methenolone,
	methydienolone, methyl-1-testosterone, methylnortestosterone, methyltestosterone, mibolerone, nandrolone, norbolethone, norclostebol, norethandrolone, norethindrone, oxabolone, oxandrolone, oxymesterone, oxymetholone, stanozolol, syenbolone, tibolone, trenbolone, zeranol
Analgesics, non- opioid	Acetaminophen, diclofenac, ibuprofen, ketoprofen, naproxen, oxaprozin, salicyclate
Antidepressants,	Citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline
serotonergic class	
Antidepressants,	Amitriptyline, amoxapine, clomipramine, demexiptiline, desipramine, doxepin,
tricyclic and other	imipramine, maprotiline, mirtazapine, nortriptyline, protriptyline
cyclicals	
Antidepressants, not	Bupropion, desvenlafaxine, isocarboxaxid, nefazodone, phenelzine, selegiline,
otherwise specified	tranylcypromine, trazadone, venlafaxine
Antiepileptics, not otherwise specified	Carbamazepine, clobazam, dimethadone, ethosuximide, ezogabine, lamotrigine, levetiracetam, methsuxamide, oxcarbazepine, phenytoin, primidone, rufinamide, tiagabine, topiramate, trimethadione, valproic acid, zonisamide
Antipsychotics, not otherwise specified	Aripiprazole, chlorpromazine, clozapine, fluphenazine, haloperidol, loxapine, mesoridazine, molindone, olanzapine, paliperidone, perphenazine, phenothiazine, pimozide, prochlorperazine, quetiapine, risperidone, trifluoperazine, thiothixene, thioridazine, ziprasidone
Barbiturates	Amobarbital, aprobarbital, butalbital, cyclobarbital, mephobarbital, pentobarbital, phenobarbital, secobarbital, talbutal, thiopental
Benzodiazepines	Alpha-hydroxyalprazolam, alprazolam, chlordiazepoxide, clonazepam, chlorazepate, diazepam, estazolam, flunitrazepam, flurazepam, halazepam, lorazepam, midazolam, nitrazepam, nordazepam, oxazepam, prazepam, quazepam, temazepam, 7-Aminoclonazepam
Buprenorphine	buprenorphine
Cannabinoids, Natural	Marijuana, dronabinol carboxy-THC
Cannabinoids, Synthetic	CP-47, 497, CP497 C8-homolog, JWH-018 and AM678, JWH-073, JWH-019, JWH-200, JWH-210, JWH-250, JWH-081, JWH-122, HWH-398, AM-2001, AM-694, SR-19 and RCS-4, SR-18 and RCS-8, JWH-203, UR-144, XLR-11, MAM-2201, AKB-48

NC Medicaid	Medicaid and Health Choice
Drug Testing for Opioid Treatment and	Clinical Coverage Policy No: 1S-8
Controlled Substance Monitoring	Amended Date: November 01, 2020

G .			
Cocaine	Benzoylecgonine, cocaethylene, cocaine, ecgonine methyl ester, norcocaine		
Fentanyl	Acetylfentanyl, alfentanil, fentanyl, remifentanil, sufentanil		
Gabapentin	Gabapentin		
Heroin Metabolite	6-acetylmorphine, acetylcodeine, diacetylmorphine		
Ketamine Ketamine, norketamine			
Methadone	Methadone, EDDP		
Methylenedioxy-	MDA, MDEA, MDMA		
amphetamines			
Methylphenidate	Methylphenidate, ritalinic acid		
Opiates	Codeine, dihydrocodeine, hydrocodone, hydromorphone, morphine		
Opioids and Opioid	Butorphanol, desomorphine, dextromethorphan, dextrorphan, levorphanol,		
Analogs	meperidine, maloxone, naltrexone, normeperidine, pentazocine		
Oxycodone Oxycodone, oxymorphone			
Phencyclidine	Phencyclidine		
Pregabalin	pregabalin		
Propoxyphene	Norpropoxyphene, propoxyphene		
Sedative Hypnotics	Eszopiclone, zalepon, zolpidem		
Skeletal Muscle	Baclofen, carisoprodol, cyclobenzaprine, meprobamate, metaxalone, methocarbamol,		
Relaxants	orphenadrine, tizanidine		
Stimulants,	2C-B, 2C-E, 2C-I, 2C-H, 3TFMPP, 4-methylcathinone, alpha-PVP, benzylpiperazine,		
Synthetic	bromodragonfly, cathinone, m-CPP, MDPBP, MDPV, mephedrone, methcathinone,		
	methylone, phenethylamines, salvinorin, tryptamines		
Tapentadol	Tapentadol		
Tramadol	Tramadol		