Clinical Policy: Drug Testing for Opioid Treatment and Controlled Substance Monitoring

Reference Number: WNC.CP.253
Last Review Date: 08/21

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description[1]

This policy describes the medical necessity criteria for Drug Testing for Opioid Treatment and Controlled Substance Monitoring.

Policy/Criteria[1]

I. WellCare of North Carolina® 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:

A. Toxicity

1. 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.

B. Treatment of substance use disorder

1. Indications for Testing
   a. 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:
      i. history, physical examination, and previous laboratory findings;
      ii. beneficiary report of use and prescribed medications;
      iii. suspected misused substance(s);
      iv. community usage; **and**

v. 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.

2. Frequency of Testing
   a. 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.
   b. 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.
   c. 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.

C. Treatment of Chronic Pain
   1. Indications for Testing
      a. 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:
         i. complete history of pain;
         ii. physical examination;
         iii. previous laboratory findings;
         iv. current treatment plan,
         v. prescribed medications; **and**
         vi. 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.

   2. Frequency of Testing
      a. 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.
         i. 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.
         ii. 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.

iii. 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.

D. Reflex Testing
   1. As reference laboratories do not have access to beneficiary health records, WellCare of North Carolina® 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.

E. Direct to Definitive Testing
   1. WellCare of North Carolina® 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.

F. Definitive Testing to Confirm a Negative Presumptive Result
   1. WellCare of North Carolina® 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 self-report, 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.

G. Definitive Testing to Confirm a Presumptive Positive
   1. WellCare of North Carolina® 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.

II. WellCare of North Carolina® **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, WellCare of North Carolina® **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 Section I.

Background[1]

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.

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.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes That Support Coverage Criteria

CPT®* Codes	Description
0011U	Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites
80184	Phenobarbital
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	Amphetamine; 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
80356	Heroin metabolite
80357	Ketamine and norketamine
80358	Methadone
80359	Methylenedioxyamphetamines (MDA, MDEA, MDMA)
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	Pregbalin
80367	Propoxyphene
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)

CPT Codes That Do Not Support Coverage Criteria

CPT® Codes	Description
0006U	Detection of interacting medications, substances, supplements and foods, 120 or more analytes, definitive chromatography with mass spectrometry, urine, description and severity of each interaction identified, per date of service
0054U	Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service
0143U	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0144U	Drug assay, definitive, 160 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0145U	Drug assay, definitive, 65 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0146U	Drug assay, definitive, 80 or more drugs or metabolites, urine, by quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0147U	Drug assay, definitive, 85 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0148U	Drug assay, definitive, 100 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0149U	Drug assay, definitive, 60 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using

	multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service
0150U	Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, comments including sample validation, per date of service

HCPCS Codes That Support Coverage Criteria

HCPCS Codes	Description
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(s), 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); definitive, qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 8-14 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 drugspecific 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

HCPCS Codes That Do Not Support Coverage Criteria

HCPCS Codes	Description
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 matrixmatched 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 matrixmatched 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

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

+ Indicates a code(s) requiring an additional character

ICD-10-CM	Description
F10.11	Alcohol abuse, in remission
F10.20	Alcohol dependence, uncomplicated
F11.11	Opioid abuse, in remission
F11.20	Opioid dependence, uncomplicated
F11.220	Opioid dependence with intoxication, uncomplicated
F11.221	Opioid dependence with intoxication delirium
F11.222	Opioid dependence with intoxication with perceptual disturbance
F11.229	Opioid dependence with intoxication, unspecified
F11.23	Opioid dependence with withdrawal
F11.24	Opioid dependence with opioid-induced mood disorder
F11.250	Opioid dependence with opioid-induced psychotic disorder with delusions
F11.251	Opioid dependence with opioid-induced psychotic disorder with hallucinations
F11.259	Opioid dependence with opioid-induced psychotic disorder, unspecified
F11.281	Opioid dependence with opioid-induced sexual dysfunction
F11.282	Opioid dependence with opioid-induced sleep disorder
F11.288	Opioid dependence with other opioid-induced disorder
F11.29	Opioid dependence with unspecified opioid-induced disorder
F12.11	Cannabis abuse, in remission
F13.11	Sedative, hypnotic or anxiolytic abuse, in remission
F14.11	Cocaine abuse, in remission
F15.11	Other stimulant abuse, in remission
F16.11	Hallucinogen abuse, in remission
F18.10	Inhalant abuse, uncomplicated
F18.11	Inhalant abuse, in remission
F18.120	Inhalant abuse with intoxication, uncomplicated
F18.90	Inhalant use, unspecified, uncomplicated
F19.11	Other psychoactive substance abuse, in remission
F19.20	Other psychoactive substance dependence, uncomplicated
F55.0	Abuse of antacids
F55.1	Abuse of herbal or folk remedies
F55.2	Abuse of laxatives
F55.3	Abuse of steroids or hormones
F55.4	Abuse of vitamins
F55.8	Abuse of other non-psychoactive substances

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date	05/21	05/21
Reviewed CPT, HCPCS, and ICD-10-CM codes. Updated description for CPT 80370.	08/21	

References

1. State of North Carolina Medicaid. Medicaid and Health Choice Clinical Coverage Policy No: 1S-8 Drug Testing for Opioid Treatment and Controlled Substance Monitoring. https://medicaid.ncdhhs.gov/providers/clinical-coverage-policies. Published November 1, 2020. Accessed August 18, 2021.

North Carolina Guidance

Eligibility Requirements

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 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.

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.

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/

EPSDT does not apply to NCHC beneficiaries.

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.

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).

Claims-Related Information

Provider(s) shall comply with the, NC Tracks 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 - as applicable to the service provided:
   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.
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 - Providers shall follow applicable modifier guidelines.
e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. 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
g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions

expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.