Clinical Policy: Genetic Testing

Reference Number: WNC.CP.166
Last Review Date: 01/23

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

Genetic testing is used to identify changes or abnormalities in chromosomes, genes, or proteins to confirm or rule out suspected genetic conditions. Testing samples include blood, amniotic fluid, or bodily tissues. A genetic test involves an analysis of human chromosomes, deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or gene products to establish a diagnosis of a genetic condition. In general, three categories of genetic testing—cytogenetic, biochemical, and molecular—are available to detect abnormalities in chromosome structure, protein function, and DNA sequence, respectively.

Please refer to the Authorization Lookup Tool to determine where to submit prior authorization requests for genetic testing service codes.

Policy/Criteria

I. It is the policy of WellCare of North Carolina® that genetic and cytogenetic testing is medically necessary when the following criteria are met:

A. One of the following:
   1. The beneficiary displays clinical features or is experiencing current signs and symptoms of a genetic condition; **OR**
   2. There is documented reasonable expectation that the beneficiary is at high-risk based on family history, personal history, or ethnicity; **OR**
   3. The test yields results that can be used to develop a clinical useful approach or course of treatment, or to cease unnecessary treatments **AND**

B. The results of the test allow providers to treat current symptoms affecting the beneficiary's health, or manage the treatable progress of an established disease or alter recommended screening or monitoring; **AND**

C. The ordering licensed provider shall obtain informed consent (indicating understanding of the testing procedure, the benefits and limitations of the test, and the possible consequences of the test results) from the beneficiary, parent, legal guardian or authorized representative, prior to the genetic test; **AND**

D. Test must be performed by a certified Clinical Laboratories Improvement Amendment (CLIA) laboratory; **AND**

E. A clinically valid test, based on published peer-reviewed literature, is available for the suspected diagnosis; **AND**

F. The test is proven to be scientifically valid for the identification of the specific genetically-linked disease or clinical condition; **AND**

G. A certified genetic counselor or ordering provider shall counsel the beneficiary pre- and post-test.

II. It is the policy of WellCare of North Carolina® that genetic and cytogenetic testing is medically necessary for the diagnosis and treatment of *genetic abnormalities or syndromes* such as:
- A. Any congenital anomalies;
- B. Developmental delays; **and**
- C. Intellectual disabilities.

III. It is the policy of WellCare of North Carolina® that cytogenetic testing is medically necessary for the diagnosis and treatment of the following *neoplastic chromosome abnormalities or syndromes*:
- A. Chronic Myelogenous Leukemia (CML);
- B. Acute Lymphoblastic (also known as lymphocytic) Leukemia (ALL);
- C. Acute Myeloid Leukemia (AML);
- D. Myelodysplastic syndromes (MDS);
- E. Lymphomas (solid tumors); **and**
- F. Multiple myeloma

IV. It is the policy of WellCare of North Carolina® that genetic and cytogenetic testing is medically necessary for the diagnosis and treatment of *cystic fibrosis* when the following criteria are met:
- A. The beneficiary has signs or symptoms of cystic fibrosis;
- B. The beneficiary or guardian has undergone genetic counseling;
- C. When the symptomatic beneficiary has a known familial variant, the test that is ordered should be for that specific variant;
- D. If no mutation is found when testing for common variants **and** the beneficiary is symptomatic, full gene sequencing can be ordered; **or**
- E. After completing the full gene sequencing, if no mutation is found, testing may be done for duplication/deletion variants.

V. Medicaid and NCHC shall cover genetic and cytogenetic testing for the diagnosis and treatment of spinal muscular atrophy (SMA) when the following criteria are met:
- A. The beneficiary has signs or symptoms of SMA;
- B. The beneficiary or guardian has undergone genetic counseling;
- C. When the symptomatic beneficiary has a known familial variant, the test that is ordered should be for that specific variant;
- D. If no mutation is found when testing for common variants and the beneficiary is symptomatic, full gene sequencing can be ordered; or
- E. After completing the full gene sequencing, if no mutation is found, testing may be done for duplication/deletion variants.

VI. It is the policy of WellCare of North Carolina® that *whole exome sequencing (WES)* is medically necessary for the identification and treatment of ill-defined symptoms when the following criteria are met:
- A. Phenotype is suspicious for a genetic diagnosis;
- B. Beneficiary has multiple major structural or functional congenital anomalies affecting unrelated organ systems, including metabolic disorders;

C. Beneficiary has one major structural congenital anomaly and two or more minor structural anomalies; **or**
D. The beneficiary has at least **2** of the following:
    1. Major structural congenital anomaly affecting a single organ system;
    2. Neurological features including either significant intellectual disability, global developmental delay or autism;
    3. Severe psychological/psychiatric disturbance or severe neuropsychiatric condition;
    4. Symptoms of a complex neurodevelopmental disorder;
    5. Family history strongly implicating a genetic etiology; **or**
    6. Period of unexplained developmental regression unrelated to autism or epilepsy; **and**
E. The beneficiary is evaluated and counseled by a certified geneticist or provider with genetic counseling experience prior to the test being ordered and when the results are reviewed; **and**
F. Test ordered will be used to guide treatment; **and**
G. The beneficiary is age 21 or younger.

VII. In addition to the specific criteria covered in Sections I - VI of this policy, Wellcare of North Carolina® shall cover:

A. *Serum screening with or without nuchal translucency ultrasound* or *cell-free DNA screening and diagnostic testing (CVS or amniocentesis) for chromosomal abnormalities* ***after counseling*** shall be offered to all beneficiaries early in pregnancy regardless of maternal age or baseline risk.
B. *Carrier testing for cystic fibrosis (CF)* when the beneficiary meets **any** of the criteria below:
    1. Beneficiary is pregnant or considering pregnancy;
    2. Beneficiary has a biological parent with CF or both biological parents are CF carrier status;
    3. The beneficiary has a family history or first-degree relative with CF; **or**
    4. Echogenic bowel has been identified on fetal ultrasound; **and**
    5. After genetic counseling has been provided, informed consent is obtained prior to, and beneficiary agrees to voluntary carrier testing.
C. *Medicaid shall cover carrier testing for spinal muscular atrophy (SMA) when the beneficiary meets any of the criteria below:*
    1. Beneficiary is pregnant or considering pregnancy and has not previously been tested for SMA.
    2. After genetic counseling has been provided, informed consent is obtained prior to, and beneficiary agrees to voluntary carrier testing
D. *Carrier testing for Ashkenazi Jewish associated disorders (e.g., Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C,* Gaucher disease, Tay-Sachs disease) when the beneficiary meets the criteria below:
    1. At least one partner is Ashkenazi Jewish or at least one partner is a known carrier of an Ashkenazi Jewish associated disorder;
    2. History of a previous child born with an Ashkenazi Jewish associated disorder; **or**

3. One or both partners have a first or second-degree relative affected with an Ashkenazi Jewish associated disorder; **and**
4. Test will guide plan of care for current and future pregnancies.

VIII. It is the policy of WellCare of North Carolina® that genetic testing is **not medically necessary** when:

A. The beneficiary does not meet any of the criteria listed in Sections I – VI;
B. The screening is for the general population;
C. The test is being repeated after a negative test result; **and**
D. A test is repeated when limited to once in a lifetime testing.

IX. In addition to Section VII, WellCare of North Carolina® **shall not** cover genetic testing for:

A. Reproductive decision-making;
B. Male or female infertility;
C. Beneficiary family members;
D. Cell-free DNA based screening in twin pregnancy in the setting of fetal demise, vanishing twin, or one or more anomaly detected in one or both twins;
E. NIPS/NIPT following a CVS or amniocentesis test that was able to yield results;
F. Paternity testing;
G. Sex determination of the fetus;
H. Direct-to-consumer tests.

Background

In general, three categories of genetic testing—cytogenetic, biochemical, and molecular—are available to detect abnormalities in chromosome structure, protein function, and DNA sequence, respectively.

Amniocentesis (also referred to as an amniotic fluid test or, informally, an "amnio") is a medical procedure used primarily in prenatal diagnosis of chromosomal abnormalities and fetal infections. In this procedure, a small amount of amniotic fluid, which contains fetal cells, is sampled from the amniotic sac surrounding a developing fetus. The fetal DNA is then examined for genetic abnormalities. The most common reason to have an amniocentesis performed is to determine whether a fetus has certain genetic disorders or a chromosomal abnormality, such as Down syndrome. An amniocentesis is performed when a pregnant beneficiary is greater than 15 weeks gestation. Pregnant beneficiaries who choose to have this test are primarily those at increased risk for genetic and chromosomal problems.

Chorionic villus sampling (CVS) is a type of prenatal diagnostic test to detect chromosomal problems that can result in genetic diseases and birth defects. It involves taking a small sample of part of the placenta (the chorionic villi) where it is attached to the wall of the uterus. CVS can diagnose chromosomal abnormalities that cause conditions like Down syndrome, sickle cell anemia, cystic fibrosis, and Tay Sachs disease. It does not diagnose neural tube defects. CVS is performed between the 10th and 13th week of pregnancy. It is reported to be 98% to 99% accurate in detecting genetic abnormalities.

Cytogenetics is defined as testing that involves the examination of chromosomes to identify structural abnormalities.

Genetic counselors are health professionals with specialized education, training, and experience in medical genetics and counseling. They are certified by the American Board of Genetic Counseling or have an Active Candidate Status for certification. They help people understand and adapt to the implications of genetic contributions to disease.

Genetic counseling is a process of communication that allows beneficiaries and their families to make informed medical decisions. These services may include obtaining a structured family medical and genetic history, constructing a multiple-generation genetic pedigree, performing an analysis of available medical information for genetic risk assessment, and counseling the beneficiary and family. This counseling includes natural history of disease, recurrence risk to family members, and availability of testing, screening and monitoring options. A licensed provider may provide genetic counseling when there is no access to a fellowship-trained genetic subspecialty physician or a certified genetic counselor. Similar to other genetic counselors, the licensed provider shall discuss and document in the beneficiary's health record the following:

- likelihood of developing disease;
- impact of the disease;
- possibility of modification of either the impact or likelihood of disease;
- anticipated future developments in diagnosis or treatment; **and**
- informed consent to testing was obtained after the beneficiary verbalized understanding of the testing procedure, the benefits and limitations of the test, and the possible consequences of the test results.

Nuchal Translucency (NT) Ultrasound is a diagnostic prenatal screening assessment prescribed to detect chromosomal abnormalities associated with Down syndrome (trisomy 21), one of the most common genetic conditions affecting 1 in 700 U.S. babies each year. The screening also determines risk of trisomy 13 and trisomy 18 syndromes, rare and often fatal chromosomal abnormalities. The NT ultrasound is done between 10 and 13 weeks, when nuchal translucency, the clear fluid located at the back of the fetal neck, can be measured. A higher NT measurement during assessment increases the potential risk of fetal abnormalities being present.

Prenatal testing consists of non-invasive prenatal screening (NIPS) and non-invasive prenatal testing (NIPT) and prenatal diagnosis, which are aspects of prenatal care that focus on detecting problems with the pregnancy as early as possible. These may be anatomic and physiologic problems with the health of the zygote, embryo, or fetus, either before gestation even starts or as early in gestation as practicable. Screening can detect problems such as neural tube defects, chromosome abnormalities, and gene mutations that would lead to genetic disorders and birth defects, such as spina bifida, cleft palate, Down syndrome, Tay–Sachs disease, sickle cell anemia, thalassemia, cystic fibrosis, muscular dystrophy, and fragile X syndrome. Some tests are designed to discover problems which primarily affect the health of the mother, such as PAPP-A to detect pre-eclampsia or glucose tolerance tests to diagnose gestational diabetes. Screening can also detect anatomical defects such as hydrocephalus, anencephaly, heart defects, and amniotic band syndrome.

Whole Exome Sequencing is defined as an efficient strategy to selectively sequence the protein coding regions (exons) of a genome (the complete set of genes or genetic material present in a cell or organism), typically human, to discover rare or common variants associated with a genetic disorder or phenotype.

Spinal Muscular Atrophy (SMA) is a genetic neuromuscular disease characterized by muscle atrophy and weakness. The disease generally manifests early in life and is the leading genetic cause of death in infants and toddlers. SMA is caused by defects in the Survival Motor Neuron 1 (SMN1) gene that encodes the SMN protein. The SMN protein is critical to the health and survival of the nerve cells in the spinal cord responsible for muscle contraction (motor neurons)

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 2021 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.

Codes that Support Medical Necessity

CPT®* Codes	Description	Unit Limitations
81220	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; common variants	Once in a lifetime
81221	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; known familial variants	Once in a lifetime
81222	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; duplication/deletion variants	Once in a lifetime
81223	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; full gene sequence	Once in a lifetime
81224	CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; intron 8 poly-T analysis	Once in a lifetime
81228	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number variants, comparative genomic hybridization [CGH] microarray analysis	1 unit per day
81229	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants, comparative genomic hybridization (CGH) microarray analysis	1 unit per day
81240	F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant	Once in a lifetime
81241	F5 (coagulation factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant	Once in a lifetime

CPT®* Codes	Description	Unit Limitations
81243	FMR1 (fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	Once in a lifetime
81244	FMR1 (fragile X mental retardation 1) (eg, fragile X mental retardation) gene analysis; characterization of alleles	Once in a lifetime
81256	HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis, common variant	Once in a lifetime
81329	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed	Once in a lifetime
81331	SNRPN/UBE3A (small nuclear ribonucleoprotein polypeptide N and ubiquitin protein ligase E3A) (eg, Prader-Willi syndrome and/or Angelman syndrome), methylation analysis	Once in a lifetime
81336	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence	Once in a lifetime
81337	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)	Once in a lifetime
81415	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis	Once in a lifetime
81420	Fetal chromosomal aneuploidy (e.g., trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21.	3 units within a 12 month period
81443	Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes	Once in a lifetime
81507	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy	3 units within a 12 month period
88230	Tissue culture for non-neoplastic disorders; lymphocyte	4 units within a 12 month period
88233	Tissue culture for non-neoplastic disorders; skin or other solid tissue biopsy	4 units within a 12 month period
88235	Tissue culture for non-neoplastic disorders; amniotic fluid or chorionic villus cells	4 units within a 12 month period “not covered under NC Health Choice”
88237	Tissue culture for neoplastic disorders; bone marrow, blood cells	4 units within a 12 month period
88239	Tissue culture for neoplastic disorders; solid tumor	4 units within a 12 month period

CPT®* Codes	Description	Unit Limitations
88245	Chromosome analysis for breakage syndromes; baseline Sister Chromatid Exchange (SCE), 20-25 cells	4 units within a 12 month period
88248	Chromosome analysis for breakage syndromes; baseline breakage, score 50-100 cells, count 20 cells, 2 karyotypes	4 units within a 12 month period
88261	Chromosome analysis; count 5 cells, 1 karyotype, with banding	4 units within a 12 month period
88262	Chromosome analysis; count 15-20 cells, 2 karyotypes, with banding	4 units within a 12 month period
88263	Chromosome analysis; count 45 cells for mosaicism, 2 karyotypes, with banding	4 units within a 12 month period
88264	Chromosome analysis; analyze 20-25 cells	4 units within a 12 month period
88267	Chromosome analysis, amniotic fluid or chorionic villus, count 15 cells, 1 karyotype, with banding	4 units within a 12 month period
88269	Chromosome analysis, in situ for amniotic fluid cells, count cells from 6-12 colonies, 1 karyotype, with banding	4 units within a 12 month period
88271	Molecular cytogenetics; DNA probe, each	41 units within a 12 month period
88272	Molecular cytogenetics; chromosomal in situ hybridization, analyze 3-5 cells	1 unit within a 12 month period
88273	Molecular cytogenetics; chromosomal in situ hybridization, analyze 10-30 cells	1 unit within a 12 month period
88274	Molecular cytogenetics; interphase in situ hybridization, analyze 25-99 cells	1 unit within a 12 month period
88275	Molecular cytogenetics; interphase in situ hybridization, analyze 100-300 cells	1 unit within a 12 month period
88280	Chromosome analysis; additional karyotypes, each study	2 units within a 12 month period
88283	Chromosome analysis; additional specialized banding technique	1 unit within a 12 month period
88285	Chromosome analysis; additional cells counted, each study	1 unit within a 12 month period
88289	Chromosome analysis; additional high resolution study	1 unit within a 12 month period
88291	Cytogenetics and molecular cytogenetics, interpretation and report	25 units within a 12 month period
96040	Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family	3 units (1 unit = 30 minutes) 90 minutes total

ICD-10-CM Diagnosis Codes that Support Coverage Criteria
+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description
No applicable codes.	

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date	03/21	05/21
CPT codes reviewed.	07/21	08/21
Additional coverage criteria added in Section II. Deleted criteria in Section III.A. Deleted CPT 0168U. Added addtional reference.	01/22	02/22
Updated title, criteria, background, CPT codes, and references due to retirement of referenced policy.	05/22	08/22
CPT 88235 added "not covered under NC Health Choice" verbiage	08/22	08/22
Under Description, added definition for genetic test. Criteria V. Added Spinal Muscular Atrophy (SMA) coverage. Criteria VII. C. letter "c" for SMA carrier testing; Under Background, deleted "genetic test involves an analysis of human chromosomes, deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or gene products to establish a diagnosis of a genetic condition," Added definition for spinal muscular atrophy. Under Background "Amniocentesis," changed the term pregnant woman to pregnant beneficiary. CPT Codes added:, 81329, 81336, 81337, Each with Unit Limitation: Once in a lifetime	01/23	

References

1. State of North Carolina Medicaid. Medicaid and Health Choice Clinical Coverage Policy No: 1S-4 Genetic Testing. https://medicaid.ncdhhs.gov/providers/clinical-coverage-policies. Published May 25, 2022. Accessed January 19, 2023.

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.