Clinical Policy: Genetic Testing – Carrier and Prenatal

Reference Number: WNC.CP.294
Last Review Date:

Coding Implications
Revision Log

See Important Reminders 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
Carrier genetic screening is a type of genetic test carried out to detect a Member who may be susceptible to producing offspring with inherited recessive single gene disorders. While carriers themselves are typically unaffected by the disease, they can transmit harmful genetic variations to their children. This screening can be conducted during the preconception or prenatal stages.

Prenatal genetic tests consist of non-invasive prenatal testing (cell-free DNA testing, nuchal translucency ultrasound), and prenatal diagnostic testing (amniocentesis, CVS), 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. A screening test 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 Pregnancy-Associated Plasma Protein A (PAPPA) to predict pre-eclampsia or glucose tolerance tests to diagnose gestational diabetes. Screening tests can also detect anatomical defects such as hydrocephalus, anencephaly, heart defects, and amniotic band syndrome.

Policy/Criteria[1]

I. WellCare of North Carolina® **shall cover** Genetic Testing for Carrier Testing when the Member meets the following specific criteria:
- **A.** Member is pregnant or considering pregnancy;
- **B.** Member has not previously been tested for the same disorder;
- **C.** The test possesses sufficient sensitivity and specificity to inform clinical decision-making, and there is a clear understanding of residual risk; **AND**
- **D.** **ONE** of the following are present:

1. Member has a first- or second-degree relative who is affected (refer to background C.);
2. Member is known to be a carrier; or
3. Member belongs to a population where the carrier rate surpasses a threshold deemed suitable for testing a specific condition.

E. WellCare of North Carolina shall cover Genetic Testing for Prenatal Testing as described in the above Description for chromosomal abnormalities for a Member early in pregnancy regardless of maternal age or baseline risk.

II. WellCare of North Carolina®, in addition to the specific criteria covered in Criteria I. of this policy, **shall cover** Genetic Testing for Carrier and Prenatal Testing when **ALL** of the following additional criteria are met**:**

A. A certified genetic counselor or ordering provider shall evaluate and counsel the Member pre- and post-test. Refer to Criteria V. and Background F.;
B. After genetic counseling has been provided, informed consent is obtained prior to, and Member agrees to testing;
C. The test must guide plan of care for current and future pregnancies;
D. The test must not be duplicative of another performed test;
E. The test must be performed by a certified Clinical Laboratories Improvement Amendment (CLIA) laboratory;
F. The test must be clinically valid, based on published peer-reviewed literature, and available for the suspected diagnosis; **AND**
G. The test must be proven scientifically valid for the identification of a specific genetically linked disease or clinical condition.

III. WellCare of North Carolina®, **shall NOT cover** Genetic Testing for Carrier or Prenatal Testing for ANY of the following situations:

A. Reproductive decision-making if the criteria in Criteria I or II are not met;
B. The same test is being repeated after a negative result;
C. Expanded carrier screening panels;
D. The test is repeated when limited to once in a lifetime testing;
E. Male or female infertility;
F. For Member's close relatives (Refer to Background C) other than the biological mother;
G. 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;
H. Cell-free DNA based screening in multifetal gestations (three or more fetuses);
I. Serum blood test or ultrasound following a CVS or amniocentesis that was able to yield results;
J. Paternity testing;
K. The test is solely for sex determination; **OR**
L. The test is used to determine ancestry.

IV. Additional Limitations On Coverage:

A. Prior Approval

WellCare of North Carolina®, may require prior approval for specific tests. Please see WellCare North Carolina Provider Authorization Lookup for service codes requiring prior authorization.

B. The provider(s) shall submit to WellCare of North Carolina®, the following:

1. The prior approval request; **AND**
2. All health records and any other records that support the Member has met the specific criteria in Criteria I and II of this policy.

C. Testing Limitations

Refer to CPT Code Boxes below, for testing limitations for CPT codes covered in this policy.

D. Documentation Requirements

When the provider requests additional units for the CPT Codes found in CPT Code Boxes, below, then, in addition to the prior approval requirements found in Criteria IV., the provider shall submit all of the following supporting documentation to justify the request:

1. The reason for the test(s);
2. Previous related lab results;
3. How the test results contribute to improved health outcomes; **AND**
4. How the test results alter the Member's treatment and management.

V. Provider Certifications

A. Genetic counseling must be provided by a medical (licensed) provider with appropriate clinical expertise, or genetic counselor that is certified by the American Board of Genetic Counseling or has an Active Candidate Status. A genetic counselor shall be employed by or under contract to hospitals or other entities that employ licensed physicians. Licensed physicians shall be responsible for providing on-site clinical supervision and be directly involved in the care of a WellCare of North Carolina Member for whom the counseling service is billed. The services of the Genetic Counselor are billed by the supervising physician. See Definitions E. and F. below for additional requirements for licensed providers and genetic counselors.

B. Clinical laboratory services must be rendered only by medical care entities that are issued certifications that are in compliance with the Clinical Laboratories Improvement Amendment (CLIA) [Public Law 100-578, amended §353 of the Public Health Service Act (PHSA)].

Background[1]

I. DEFINITIONS:

A. Amniocentesis

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 Member is greater than 15 weeks gestation. Pregnant members who choose to have this test are primarily those at increased risk for genetic and chromosomal problems.

B. Chorionic Villus Sampling (CVS)

Chorionic villus sampling is a type of prenatal diagnostic test to detect chromosomal abnormalities 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, such as spina bifida. CVS is performed between the 10th and 13th week of pregnancy. It is reported to be 98 percent to 99 percent accurate in detecting genetic abnormalities.

C. Close Relatives (First-, Second- and Third-Degree Relatives)

1. A **first-degree relative** is a close blood relative which includes the Member's parents, full siblings, and children.
2. A **second-degree relative** is a blood relative which includes the Member's grandparents, grandchildren, aunts, uncles, nephews, nieces, and half-siblings.
3. A **third-degree relative** is a blood relative which includes the Member's first cousins, great-grandparents, great-grandchildren on the same side of the family.

D. Expanded Carrier Screening Panels

Expanded carrier screening panels refer to comprehensive genetic tests that assess a Member's potential to carry and pass on a wide range of genetic disorders or conditions, typically beyond the standard set of conditions in routine carrier screening. These panels examine a broader spectrum of genetic mutations, providing valuable information for family planning and reproductive decision-making.

E. Genetic Counselor

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 a Member understand and adapt to the implications of genetic contributions to disease.

F. Genetic Counseling

Genetic counseling is a process of communication that allows members and their families to make informed medical decisions. These services 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 Member and family. This counseling includes natural history of disease, recurrence risk to family members, and availability of testing, screening and monitoring options. (Refer to Criteria V)

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 Member's health record the following:

1. Likelihood of developing disease;
2. Impact of the disease;
3. Possibility of modification of either the impact or likelihood of disease;
4. Anticipated future developments in diagnosis or treatment; **AND**
5. Informed consent to testing was obtained after the Member verbalized understanding of the testing procedure, the benefits and limitations of the test, and the possible consequences of the test results.

G. Nuchal Translucency (NT) Ultrasound

Nuchal Translucency (NT) ultrasound is a 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 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.

H. Prenatal Cell-Free DNA Screening

Prenatal cell-free DNA screening is a blood test administered to a pregnant Member. Throughout pregnancy, a portion of the fetus's DNA is present in the mother's bloodstream. A cell-free DNA screening examines this DNA to determine if the baby has an increased risk of having chromosome related disorders.

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 2024, 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.

CARRIER SCREENING		
CPT®* Code	**Description**	**Unit Limitation**
81161	DMD (dystrophin) (e.g., Duchenne/Becker muscular dystrophy) deletion analysis, and duplication analysis, if performed	Once in a Lifetime
81220	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene analysis; common variants (e.g., ACMG/ACOG guidelines)	Once in a Lifetime

CARRIER SCREENING		
CPT®* Code	**Description**	**Unit Limitation**
81255	HEXA (hexosaminidase A [alpha polypeptide]) (e.g., Tay-Sachs disease) gene analysis, common variants (e.g., 1278insTATC, 1421+1G>C, G269S)	Once in a Lifetime
81257	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; common deletions or variant (e.g., Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha4.2, alpha20.5, Constant Spring)	Once in a Lifetime
81258	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; known familial variant	Once in a Lifetime
81259	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; full gene sequence	Once in a Lifetime
81269	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; duplication/deletion variants	Once in a Lifetime
81271	HTT (huntingtin) (e.g., Huntington disease) gene analysis; evaluation to detect abnormal (e.g., expanded) alleles	Once in a Lifetime
81274	HTT (huntingtin) (e.g., Huntington disease) gene analysis; characterization of alleles (e.g., expanded size)	Once in a Lifetime
81329	SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy) gene analysis; dosage/deletion analysis (e.g., carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed	Once in a Lifetime
81336	SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy) gene analysis; full gene sequence	Once in a Lifetime
81337	SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy) gene analysis; known familial sequence variant(s)	Once in a Lifetime
81361	HBB (hemoglobin, subunit beta) (e.g., sickle cell anemia, beta thalassemia, hemoglobinopathy); common variant(s) (e.g., HbS, HbC, HbE)	Once in a Lifetime
81362	HBB (hemoglobin, subunit beta) (e.g., sickle cell anemia, beta thalassemia, hemoglobinopathy); known familial variant(s)	Once in a Lifetime
81363	HBB (hemoglobin, subunit beta) (e.g., sickle cell anemia, beta thalassemia, hemoglobinopathy); duplication/deletion variant(s)	Once in a Lifetime
81364	HBB (hemoglobin, subunit beta) (e.g., sickle cell anemia, beta thalassemia, hemoglobinopathy); full gene sequence	Once in a Lifetime

CARRIER SCREENING		
CPT®* Code	**Description**	**Unit Limitation**
81412	Ashkenazi Jewish associated disorders (e.g., Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of at least 9 genes, including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1	Once in a Lifetime
81443	Genetic testing for severe inherited conditions (e.g., cystic fibrosis, Ashkenazi Jewish-associated disorders [e.g., 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 (e.g., ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)	Once in a Lifetime

PRENATAL TESTING		
CPT®* Code	**Description**	**Unit Limitations**
81228	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number variants, comparative genomic hybridization [CGH] microarray analysis	Once per Pregnancy
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	Once per Pregnancy
81349	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and loss-of-heterozygosity variants, low-pass sequencing analysis	Once per Pregnancy
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	Once per Pregnancy

PRENATAL TESTING		
CPT®* Code	**Description**	**Unit Limitations**
81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (e.g., DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood	Once per Pregnancy
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	Once per Pregnancy
81508	Fetal congenital abnormalities, biochemical assays of two proteins (PAPP-A, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score	Once per Pregnancy
81509	Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score	Once per Pregnancy
81510	Fetal congenital abnormalities, biochemical assays of three analytes (AFP, uE3, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score	Once per Pregnancy
81511	Fetal congenital abnormalities, biochemical assays of four analytes (AFP, uE3, hCG [any form], DIA) utilizing maternal serum, algorithm reported as a risk score (may include additional results from previous biochemical testing)	Once per Pregnancy
81512	Fetal congenital abnormalities, biochemical assays of five analytes (AFP, uE3, total hCG, hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score	Once per Pregnancy
88230	Tissue culture for non-neoplastic disorders; lymphocyte	Once per Pregnancy
88233	Tissue culture for non-neoplastic disorders; skin or other solid tissue biopsy	Once per Pregnancy
88237	Tissue culture for neoplastic disorders; bone marrow, blood cells	Once per Pregnancy
88239	Tissue culture for neoplastic disorders; solid tumor	Once per Pregnancy
88245	Chromosome analysis for breakage syndromes; baseline Sister Chromatid Exchange (SCE), 20-25 cells	Once per Pregnancy
88248	Chromosome analysis for breakage syndromes; baseline breakage, score 50-100 cells, count 20 cells, 2 karyotypes (e.g., for ataxia telangiectasia, Fanconi anemia, fragile X)	Once per Pregnancy
88249	Chromosome analysis for breakage syndromes; score 100 cells, clastogen stress (e.g., diepoxybutane, mitomycin C, ionizing radiation, UV radiation)	Once per Pregnancy
88261	Chromosome analysis; count 5 cells, 1 karyotype, with banding	Once per Pregnancy
88262	Chromosome analysis; count 15-20 cells, 2 karyotypes, with banding	Once per Pregnancy

PRENATAL TESTING		
CPT®* Code	**Description**	**Unit Limitations**
88263	Chromosome analysis; count 45 cells for mosaicism, 2 karyotypes, with banding	Once per Pregnancy
88264	Chromosome analysis; analyze 20-25 cells	Once per Pregnancy
88267	Chromosome analysis, amniotic fluid or chorionic villus, count 15 cells, 1 karyotype, with banding	Once per Pregnancy
88269	Chromosome analysis, in situ for amniotic fluid cells, count cells from 6-12 colonies, 1 karyotype, with banding	Once per Pregnancy
88271	Molecular cytogenetics; DNA probe, each (e.g., FISH)	Once per Pregnancy
88272	Molecular cytogenetics; chromosomal in situ hybridization, analyze 3-5 cells (e.g., for derivatives and markers)	Once per Pregnancy
88273	Molecular cytogenetics; chromosomal in situ hybridization, analyze 10-30 cells (e.g., for microdeletions)	Once per Pregnancy
88274	Molecular cytogenetics; interphase in situ hybridization, analyze 25-99 cells	Once per Pregnancy
88275	Molecular cytogenetics; interphase in situ hybridization, analyze 100-300 cells	Once per Pregnancy
88280	Chromosome analysis; additional karyotypes, each study	Once per Pregnancy
88283	Chromosome analysis; additional specialized banding technique (e.g., NOR, C-banding)	Once per Pregnancy
88285	Chromosome analysis; additional cells counted, each study	Once per Pregnancy
88289	Chromosome analysis; additional high resolution study	Once per Pregnancy
88291	Cytogenetics and molecular cytogenetics, interpretation and report	Once per Pregnancy
0209U	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities	Once per Pregnancy

Chromosome analysis; additional cells counted, each study		
CPT®* Code	**Description**	**Unit Limitations**
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: Refer to Criteria II.A.

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original approval date		

References

1. State of North Carolina Medicaid Clinical Coverage Policy No:1S-10 Genetic Testing – Carrier & Prenatal. Program Specific Clinical Coverage Policies | NC Medicaid (ncdhhs.gov). Published July 1, 2024. Accessed July 2, 2024.

North Carolina Guidance

Eligibility Requirements

1. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
2. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
3. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

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

- 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:

I. that is unsafe, ineffective, or experimental or investigational.
II. 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

- 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.
- **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/

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:

i. meet Medicaid qualifications for participation;
ii. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
iii. 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:

- 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.
- 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.

- 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
- Modifiers - Providers shall follow applicable modifier guidelines.
- Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
- Co-payments -
  For Medicaid refer to Medicaid State Plan:
  https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

- 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.