# Clinical Policy: Genetic Testing – Next Generation Sequencing

Reference Number: WNC.CP.296 Coding Implications
Last Review Date: 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.

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**Description**

Next-generation sequencing, also referred to as next-gen sequencing, has revolutionized genetic research and healthcare by enabling the identification of genetic variations. This innovative technique involves determining the sequence of nucleotides, the building blocks of DNA, in a Member's genetic code, which is known as DNA sequencing. Two commonly employed methods, namely **whole exome sequencing** and **whole genome sequencing**, leverage advanced technologies that enable the rapid sequencing of substantial amounts of DNA. These approaches have significantly propelled the field of genetics and serve as invaluable tools in the detection of genetic disorders.

**Policy/Criteria[1]**

**I.** WellCare of North Carolina® **shall cover** Genetic Testing – Next Generation Sequencing (NGS) when the Member meets the following specific criteria:

**A.** WellCare of North Carolina® **shall cover** whole exome sequencing (WES) (CPT 81415) for the evaluation of unexplained congenital anomalies or neurodevelopmental disorders in a Member 21 years of age and younger when **ALL** of the following criteria are met:

1. The Member has **one** of the following:
   a. A severe global developmental delay or intellectual disability;
   b. A family history that strongly indicates a genetic etiology, including consanguinity; **OR**
   c. A period of developmental regression without a clear explanation, unrelated to autism or epilepsy; **and**
2. The clinical presentation does not match any well-defined syndrome for which single-gene or targeted panel testing (such as comparative genomic hybridization or chromosomal microarray analysis) is available;
3. A genetic etiology is the most probable explanation for the phenotype or clinical scenario regardless of previous genetic testing (such as chromosomal microarray analysis or targeted single gene testing), or when previous genetic testing has failed to produce a diagnosis and the affected Member faces

invasive procedures or testing as the next diagnostic step (such as a muscle biopsy);
4. The symptoms cannot be attributed to any other etiologies such as environmental exposures, injury, or infection; **AND**
5. The results of WES have the potential to significantly influence Member's management and improve the clinical outcome for the Member undergoing testing.

**B.** WellCare of North Carolina® **shall cover** comparator sequence analysis (CPT 81416) when the criteria in Criteria I.A. have been met and WES is being performed simultaneously or has been previously performed.

**C.** WellCare of North Carolina® **shall cover** whole exome reanalysis (CPT 81417) of previously acquired uninformative whole exome sequence when **one** of the following criteria is met:
1. The onset of additional symptoms has emerged, expanding the phenotype assessed during the initial exome evaluation; **OR**
2. There has been the birth or diagnosis of a similarly affected first-degree relative added to the clinical picture.

**D.** WellCare of North Carolina® **shall cover** whole genome sequencing (WGS) (CPT 81425) for the assessment of unexplained congenital anomalies or neurodevelopmental disorders in newborns when **ALL** of the following criteria are met:
1. The Member is 12 months of age and younger and currently admitted to or recently discharged from a Neonatal Intensive Care Unit (NICU) or Pediatric Intensive Care Unit (PICU);
2. When standard clinical workup does not lead to a definitive diagnosis;
3. When the Member's phenotype lacks clear identification of a specific disease with an established single gene or multi-gene panel, or the Member exhibits phenotypic characteristics that extend beyond or differ from what is known for the disease;
4. A genetic etiology is the most probable explanation for the phenotype or clinical scenario regardless of previous genetic testing (such as chromosomal microarray analysis or targeted single gene testing), or when previous genetic testing has failed to produce a diagnosis and the affected Member faces invasive procedures or testing as the next diagnostic step (such as a muscle biopsy);
5. The symptoms cannot be attributed to any other causative factors, such as environmental exposures, injury, or infection; **AND**
6. A confirmed diagnosis will lead to clinical utility, resulting in improved net health outcomes.

**E.** WellCare of North Carolina® **shall cover** comparator genome sequence analysis (CPT 81426) when the criteria in Criteria I.D. have been met and WGS is being performed simultaneously or has been previously performed.

**F.** WellCare of North Carolina® **shall cover** whole genome reanalysis (CPT 81427) of previously acquired uninformative whole genome sequence when **ONE** of the following criteria is met:

1. The onset of additional symptoms has emerged, expanding the phenotype assessed during the initial genome evaluation; **OR**
2. There has been the birth or diagnosis of a similarly affected first-degree relative added to the clinical picture.

**G.** WellCare of North Carolina® **shall cover** molecular profiling for the evaluation of malignancies when ALL of the following criteria are met:
1. The Member has a solid tumor that is inoperable or has spread to other parts of the body (metastatic);
2. The purpose of the test is to evaluate the tumor mutation burden (TMB);
3. The test is employed to identify a Member eligible for checkpoint inhibition immunotherapy; **AND**
4. There are no viable alternative treatment options available for the Member.

**H.** WellCare of North Carolina® **shall cover** the use of a circulating tumor DNA (ctDNA) test to direct precise cancer treatments for a Member with a solid tumor when the criteria in Criteria I.G. are met **and** when formalin-fixed paraffin-embedded tumor tissue (FFPET) lacks sufficient quality or quantity or is unavailable for analysis.

## II. Additional Criteria Covered

In addition to the specific criteria covered in Criteria I. of this policy, WellCare of North Carolina® **shall cover** next generation sequencing testing when **ALL** of the following criteria is 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 I.E.;
**B.** After genetic counseling has been provided, informed consent is obtained prior to, and Member agrees to testing;
**C.** The test must guide treatment;
**D.** The test must not be duplicative of another performed test;
**E.** The test must be performed by a certified Clinical Laboratory 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. Specific Criteria Not Covered

**A.** WellCare of North Carolina® **shall NOT cover** whole exome sequencing (WES) or whole genome sequencing (WGS) for **ANY** of the following scenarios:
1. When the criteria in Subsection 3.2.1 are not met;
2. For uncomplicated autism spectrum disorder, developmental delay, and mild to moderate global developmental delay;
3. For screening during pregnancy to diagnose fetal conditions;
4. For testing an embryo before implantation;
5. For screening genetic carriers;
6. Genetic disorders in every other circumstance; **OR**
7. The test is used to determine ancestry.

**B.** WellCare of North Carolina® **shall NOT cover** molecular profiling when the criteria in Criteria I.G. are not met.

## IV. Limitations on Coverage

### A. Prior Approval

WellCare of North Carolina® **shall require** prior approval for certain Genetic Testing – Next Generation Sequencing (NGS). Refer to WellCare North Carolina Provider Authorization Lookup. If prior approval is required, the provider shall obtain prior approval before rendering Genetic Testing – Next Generation Sequencing (NGS).

### B. Prior Approval Requirements

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 above.

### C. Additional Limitations or Requirements

1. **Testing Limitations**
   Refer to CPT Code boxes below, for testing limitations for CPT codes covered in this policy.
2. **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.B., the provider shall submit all of the following supporting documentation is required to justify the request:
   a. The reason for the test(s);
   b. Previous related lab results;
   c. How the test results contribute to improved health outcomes; **AND**
   d. 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 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 an NC Medicaid Member for whom the counseling service is billed. The services of the Genetic Counselor are billed by the supervising physician. See additional requirements for licensed providers and genetic counselors in Definitions D. and E. below.

**B.** Clinical laboratory services must be rendered only by medical care entities that are issued certifications that are in compliance with the Clinical Laboratory Improvement Amendment (CLIA) of 1988 [Public Law 100-578, amended §353 of the Public Health Service Act (PHSA)].

**Background**[1]

**I. Definitions:**

**A. Checkpoint Inhibition Immunotherapy**

Immune checkpoint inhibitors are drugs that target certain proteins known as checkpoints, present on specific immune system cells like T cells, as well as on certain cancer cells. These checkpoints play a role in regulating immune responses to prevent them from becoming overly aggressive and can sometimes hinder T cells from effectively eliminating cancer cells. By blocking these checkpoints, immune checkpoint inhibitors enable T cells to enhance their ability to kill cancer cells more effectively. Immune checkpoint inhibitors are utilized in cancer treatment.

**B. 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.

**C. Consanguinity**

Consanguinity is a term used to describe a close biological relationship between individuals who share a common ancestor. It signifies a blood tie or kinship among family members, particularly those closely related by descent from the same forebear, such as parents, siblings, grandparents, or cousins.

**D. 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 people understand and adapt to the implications of genetic contributions to disease.

**E. Genetic Counseling**

Genetic counseling is a process of communication that allows a Member and their family 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.

**F. Molecular Profiling**

Molecular profiling, also known as comprehensive genomic profiling, is a technique used to detect various biomarkers within cancerous tumor of Member with cancer. These biomarkers provide valuable information to identify potential treatment options.

**G. Phenotype**

Phenotype refers to a Member's observable characteristics resulting from the interaction between an organism's genes and the environment.

**H. Tumor Mutation Burden (TMB)**

Tumor Mutation Burden (TMB) refers to the overall count of somatic mutations (changes) detected in the DNA of cancer cells. Understanding the TMB can aid in devising the most effective treatment strategy. For instance, tumors with a high mutation count are believed to be more responsive to certain forms of immunotherapy. TMB serves as a valuable biomarker in this context.

**I. Whole Exome Sequencing**

Whole exome sequencing (WES) is a laboratory technique employed to identify the nucleotide sequence of a Member's genome, focusing mainly on the exonic regions that code for proteins. These regions, which comprise around 1% of the entire DNA sequence, and their associated sequences are analyzed during this process.

**J. Whole Genome Sequencing**

Whole genome sequencing (WGS) is a laboratory process utilized to ascertain nearly all of a Member's complete DNA sequence, encompassing approximately 3 billion nucleotides. This comprehensive analysis contains both coding and non-coding sequences within the genome.

## 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.

| MOLECULAR PROFILING | | |
|---|---|---|
| **CPT® Code** | **Description** | **Unit Limitations** |
| 81457 | Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, microsatellite instability | Once per primary cancer occurrence |
| 81458 | Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, copy number variants and microsatellite instability | Once per primary cancer occurrence |
| 81459 | Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and rearrangements | Once per primary cancer occurrence |
| 81462 | Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (e.g., plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants and rearrangements | Once per primary cancer occurrence |
| 81463 | Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (e.g., plasma), interrogation for sequence variants; DNA analysis, copy number variants, and microsatellite instability | Once per primary cancer occurrence |
| 81464 | Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (e.g., plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and rearrangements | Once per primary cancer occurrence |
| 0037U | Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden | Once per primary cancer occurrence |
| 0048U | Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s) | Once per primary cancer occurrence |
| 0211U | Oncology (pan-tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded tissue, interpretative report for single nucleotide variants, copy number alterations, tumor mutational burden, and microsatellite instability, with therapy association | Once per primary cancer occurrence |
| 0242U | Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements | Once per primary cancer occurrence |

| MOLECULAR PROFILING | | |
|---|---|---|
| **CPT® Code** | **Description** | **Unit Limitations** |
| 0244U | Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single-nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor-mutational burden and microsatellite instability, utilizing formalin-fixed paraffin-embedded tumor tissue | Once per primary cancer occurrence |
| 0250U | Oncology (solid organ neoplasm), targeted genomic sequence DNA analysis of 505 genes, interrogation for somatic alterations (SNVs [single nucleotide variant], small insertions and deletions, one amplification, and four translocations), microsatellite instability and tumor-mutation burden | Once per primary cancer occurrence |
| 0326U | Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden | Once per primary cancer occurrence |
| 0329U | Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations | Once per primary cancer occurrence |
| 0334U | Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, DNA analysis, 84 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden | Once per primary cancer occurrence |
| 0364U | Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (PCR) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as presence or absence of minimal residual disease (MRD) with quantitation of disease burden, when appropriate | Once per primary cancer occurrence |
| 0379U | Targeted genomic sequence analysis panel, solid organ neoplasm, DNA (523 genes) and RNA (55 genes) by next-generation sequencing, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutational burden | Once per primary cancer occurrence |
| 0388U | Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in | Once per primary cancer occurrence |

| MOLECULAR PROFILING | | |
|---|---|---|
| **CPT® Code** | **Description** | **Unit Limitations** |
| | 37 cancer-related genes, plasma, with report for alteration detection | |
| 0391U | Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splice-site variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score | Once per primary cancer occurrence |
| 0395U | Oncology (lung), multi-omics (microbial DNA by shotgun next-generation sequencing and carcinoembryonic antigen and osteopontin by immunoassay), plasma, algorithm reported as malignancy risk for lung nodules in early-stage disease | Once per primary cancer occurrence |
| 0409U | Oncology (solid tumor), DNA (80 genes) and RNA (36 genes), by next-generation sequencing from plasma, including single nucleotide variants, insertions/deletions, copy number alterations, microsatellite instability, and fusions, report showing identified mutations with clinical actionability | Once per primary cancer occurrence |
| 0414U | Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (ALK, BRAF, EGFR, ERBB2, MET, NTRK1-3, RET, ROS1), and KRAS G12C and PD-L1, if performed, formalin-fixed paraffin-embedded (FFPE) tissue, reported as positive or negative for each biomarker | Once per primary cancer occurrence |

| WHOLE EXOME SEQUENCING / WHOLE GENOME SEQUENCING | | |
|---|---|---|
| **CPT® Code** | **Description** | **Unit Limitations** |
| 81415 | Exome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis | Once in a lifetime |
| 81416 | Exome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (e.g., parents, siblings) (List separately in addition to code for primary procedure) | Once per comparator per lifetime |
| 81417 | Exome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (e.g., updated knowledge or unrelated condition/syndrome) | Once in a lifetime |
| 81425 | Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis | Once in a lifetime |

| WHOLE EXOME SEQUENCING / WHOLE GENOME SEQUENCING | | |
|---|---|---|
| CPT® Code | Description | Unit Limitations |
| 81426 | Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (e.g., parents, siblings) (List separately in addition to code for primary procedure) | Once per comparator per lifetime |
| 81427 | Genome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (e.g., updated knowledge or unrelated condition/syndrome) | Once in a lifetime |
| 0094U | Genome (e.g., unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis | Once in a lifetime |
| 0212U | Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband | Once in a lifetime |
| 0213U | Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator genome (e.g., parent, sibling) | Once in a lifetime |
| 0417U | Rare diseases (constitutional/heritable disorders), whole mitochondrial genome sequence with heteroplasmy detection and deletion analysis, nuclear-encoded mitochondrial gene analysis of 335 nuclear genes, including sequence changes, deletions, insertions, and copy number variants analysis, blood or saliva, identification and categorization of mitochondrial disorder-associated genetic variants | Once in a lifetime |

| GENETIC COUNSELING | | |
|---|---|---|
| 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:1A-12 Genetic Testing – Next Generation Sequencing. 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.