Clinical Policy: Testing for Select Genitourinary Conditions

Reference Number: WNC.CP.173 Coding Implications
Last Review Date: 8/22 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

Various diagnostic methods are available to identify the etiology of the signs and symptoms of vaginitis. The purpose of this policy is to define medical necessity criteria for the diagnostic evaluation of vaginitis (*excluding Trichomonas vaginalis, vaginal pH testing, and microscopic examination with saline and KOH*) in members ≥ 13 years of age. This policy also defines unnecessary amplified DNA- (deoxyribonucleic acid) probe testing for genitourinary conditions.

Policy/Criteria

I. It is the policy of WellCare of North Carolina® that the following diagnostic tests for symptomatic women for the evaluation of vaginitis are **medically necessary** for members age ≥ 13:
- A. KOH "whiff test" (i.e. amine odor test);
- B. Assay for sialidase activity;
- C. Direct DNA probe tests to detect the presence of *Candida* and *Gardnerella vaginalis.*

II. It is the policy of WellCare of North Carolina® that screening of asymptomatic pregnant women for *bacterial vaginosis* (BV) to reduce the incidence of preterm birth or other complications of pregnancy is **not medically necessary** as there is no evidence that treatment of BV in asymptomatic pregnant women reduces these complications.[2]

III. It is the policy of WellCare of North Carolina® that unspecified amplified DNA-probe testing for genitourinary conditions for asymptomatic women during routine exams, contraceptive management care, or pregnancy care is considered **not medically necessary** for members ≥ 13 years of age as it has not been shown to improve clinical outcomes over direct DNA-probe testing.

IV. It is the policy of WellCare of North Carolina® that unspecified amplified DNA-probe testing for the diagnostic evaluation of symptomatic women for the following genitourinary conditions is considered **not medically necessary** for members ≥ 13 of age, as it has not been shown to improve clinical outcomes over direct DNA-probe testing:
- A. Acute vaginitis or vulvitis (≤ 4 episodes per year);
- B. Gynecologic and obstetric conditions triggered by etiologies other than complicated vaginitis inducing mechanisms as listed in the second diagnosis table below, including:
  1. Urinary tract infections;
  2. Pelvic inflammatory disease;
  3. Inflammatory disorders of the vagina, vulva, and perineum;
  4. Irregular menstruation or abnormal uterine and vaginal bleeding;
  5. Dysmenorrhea;
  6. Complications with pregnancy, including **all** of the following:
     - a. pre-term labor;

b. ectopic pregnancy;
c. high risk pregnancy.

V. It is the policy of WellCare of North Carolina® that current literature does not support the use of multiplex/multitarget polymerase chain reaction (PCR) panel testing of genitourinary pathogens commonly associated with vaginitis,.

Background

Vaginitis refers to disorders of the vagina caused by infection, inflammation, or changes in normal vaginal flora.3 The infections most frequently associated with vaginitis are bacterial vaginosis (BV), trichomoniasis, and vulvovaginal candidiasis (VVC).1 Various diagnostic methods are available to identify the etiology of the signs and symptoms of vaginitis.[1]The cause of vaginal symptoms can usually be determined by pH testing, a potassium hydroxide (KOH) test, and microscopic examination of fresh vaginal discharge samples.[1] An elevated pH (>4.5) is commonly associated with BV or trichomonas, but because pH testing is not highly specific, the vaginal discharge being tested should be further examined microscopically with both a saline and KOH solution.[1] The saline solution specimen might yield motile T. vaginalis or clue cells (i.e., epithelial cells with borders obscured by small bacteria), which are characteristic of BV, whereas the presence of white blood cells without evidence of trichomonads or yeast in this solution is suggestive of cervicitis.[1]

Testing sensitivity is approximately 50% through microscopic examination, so the absence of trichomonads or pseudohyphae in KOH samples does not rule out these infections.[1]

In settings where pH paper, KOH, and microscopy are not available or are inconclusive, alternative point-of-care tests, such as commercially available, direct DNA-probe tests, or clinical laboratory testing, can be used to diagnose vaginitis.[4]

Bacterial Vaginosis

BV is a polymicrobial clinical syndrome resulting from replacement of the normal hydrogen peroxide-producing *Lactobacillus* species in the vagina with high concentrations of anaerobic bacteria, including *Prevotella* species, *Mobiluncus* species, *G. vaginalis, A.vaginae, and other* fastidious or uncultivated anaerobes.[1,4] BV is the most prevalent cause of vaginal discharge or malodor; however, in a nationally representative survey, most women with BV were asymptomatic.[1,3-4]

BV can be diagnosed by the use of clinical criteria such as , Amsel's Diagnostic Criteria, or determining the Nugent score through a vaginal Gram stain, which is considered the gold standard laboratory method for diagnosing BV.[1]If a Gram stain is not available, clinical criteria can be used and require **three** of the following signs or symptoms[1,3]: or signs:

- Homogeneous, thin, white discharge that smoothly coats the vaginal walls;
- Presence of clue cells on microscopic examination;
- pH of vaginal fluid >4.5;
- A fishy odor of vaginal discharge before or after addition of 10% KOH (i.e. the whiff test).

Detection of three of these criteria has been correlated with results by Gram stain.[1] Other tests, including a DNA probe-based test for high concentrations of *G. vaginalis* and the OSOM BVBlue test have acceptable performance characteristics compared with Gram stain.[1] The BVBlue test is a colorimetric test that detects sialidase activity. Culture of *G. vaginalis* is not recommended as a diagnostic tool, because it is not specific.[1] Additionally, there is no clinical utility for diagnosing BV with cervical pap tests due to their low sensitivity and specificity.[1]

Vulvovaginal Candidiasis

Vulvovaginal candidiasis (VVC) is usually caused by *C. albicans*, but occasionally is caused by other *Candida* species or yeasts. Typical symptoms of VVC include pruritus, vaginal soreness, dyspareunia, external dysuria, and abnormal vaginal discharge.[3, 5-6] None of these symptoms is specific for VVC. An estimated 75% of women will have at least 1 episode of VVC, and 40%–45% will have 2 or more episodes within their lifetime. On the basis of clinical presentation, microbiology, host factors, and response to therapy, VVC can be classified as either uncomplicated or complicated.[1]

A diagnosis of *Candida* vaginitis is suggested clinically by the presence of external dysuria and vulvar pruritus, pain, swelling, and redness.[5] Signs include vulvar edema, fissures, excoriations, or thick, curdy vaginal discharge.[5] The diagnosis can be made in a woman who has signs and symptoms of vaginitis when either a wet preparation (saline, 10% KOH) or Gram stain of vaginal discharge demonstrates yeasts, hyphae, or pseudohyphae or whena culture or other test yields a yeast species.[5,7] *Candida* vaginitis is associated with a normal vaginal pH (<4.5), so pH testing is not a useful diagnostic tool.[3] Use of 10% KOH in wet preparations improves the visualization of yeast and mycelia by disrupting cellular material that might obscure the yeast or pseudohyphae.[5] Examination of a wet mount with KOH preparation should be performed for all women with symptoms or signs of VVC, and women with a positive result should receive treatment.[7] For women with negative wet mounts who are symptomatic, vaginal cultures for *Candida* should be considered.[5] If the wet mount is negative and *Candida* cultures cannot be done, empiric treatment can be considered for symptomatic women with any sign of VVC on examination.[5] Identifying *Candida* by culture in the absence of symptoms or signs is not an indication for treatment because approximately 10%-20% of women harbor *Candida* species and other yeasts in the vagina. VVC can occur concomitantly with sexually transmitted infections. Most healthy women with uncomplicated VVC have no identifiable precipitating factors.[1]

Complicated or recurrent vulvovaginal candidiasis (RVVC) is usually defined as 4 or more episodes of symptomatic VVC in 1 year, and affects a small percentage of women (<5%). The pathogenesis of RVVC is poorly understood, and most women with RVVC have no apparent predisposing or underlying conditions. Vaginal cultures should be obtained from patients with RVVC to confirm the clinical diagnosis and to identify unusual species (including nonalbicans species), particularly *Candida glabrata*. Although *C. glabrata* and other nonalbicans *Candida* species are observed in 10%-20% of patients with RVVC, *C. glabrata* does not form pseudohyphae or hyphae and is not easily recognized on microscopy.[1]

VVC occurs more frequently and has greater persistence, but not greater severity, in HIV-(human immunodeficiency virus) infected women with very low cluster of differentiation 4 (CD4) counts and high viral load.[8] However, this population is likely to manifest other acquired immune deficiency syndrome–related sentinel conditions.[8] HIV testing of women only for the indication of RVVCis not justified, given that this condition is common in women without HIV.[1,3]

DNA-probe tests have been developed to directly detect the presence of *Candida*, *Trichomonas* and *G. vaginalis*.[9-10] Since *G. vaginalis* is a normal part of the vaginal flora, the DNA probe test is designed to be relatively insensitive, detecting only pathogenic levels of *G. vaginalis*.[9] DNA probes amplified by polymerase chain reaction (PCR) testing can also detect these pathogens.[11] In PCR tests, the sample is treated with enzymes that amplify specific regions of the DNA. After amplification, the number of DNA fragments is quantified. PCR testing has proven to be the most accurate diagnostic method in recent studies; however PCR testing has not been shown to

improve clinical outcomes over direct DNA-probe testing.[1,11] An advanced single-swab panel test that combines multiplex PCR and DNA probe technology can diagnose bacterial vaginosis by determining the ratio of lactobacilli species ("good bacteria") to several bacterial vaginosis-associated bacterial species ("bad bacteria") in a patient-collected or physician-collected single-swab sample and has demonstrated comparable diagnostic sensitivity and specificity to Nugent scoring and Amsel criteria.[11] This multiplex PCR panel also can detect other common causes of vaginitis, such as trichomoniasis and candidiasis.[11] The clinical utility of multiplex PCR testing for the diagnosis of bacterial vaginosis is still being evaluated. There are a lack of studies that demonstrate the clinical utility of panel testing for multiple genitourinary pathogens.

Pediatric Patients

Females less than 13 years of age tend to have a different etiology for vaginitis than do older Females, due to the lack of estrogenization of the vagina, and the consequential alkalinity and vaginal atrophy.[4] Common causes of vulvovaginal symptoms may include respiratory organisms such as group A streptococci and *Hemophilus influenzae,* as well as enteric and sexually transmitted pathogens. Pinworms or foreign bodies may also lead to vaginitis in this population.[6]

Centers for Disease Control and Prevention

Recommends the gram stain as the gold standard for diagnosis of bacterial vaginosis, and recommend use of Amsel's criteria if a gram stain is not available.[3]

U.S. Preventive Services Task Force

The USPFTF does not recommend screening for bacterial vaginosis in pregnant women at low-risk for pre-term delivery.[2] In addition, the USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for bacterial vaginosis in pregnant persons at increased risk for preterm delivery.

American College of Obstetricians and Gynecologists

ACOG recommends the use of Amsel clinical criteria or Gram stain with Nugent scoring for the diagnosis of bacterial vaginosis.[4] In a symptomatic patient, diagnosis of vulvovaginal candidiasis requires one of the following two findings: 1) visualization of spores, pseudohyphae, or hyphae on wet-mount microscopy or 2) vaginal fungal culture or commercial diagnostic test results positive for Candida species. Per ACOG, new commercially available single swab multiplex PCR panels can detect other common causes of vaginitis, such as trichomoniasis and candidiasis. The clinical utility of multiplex PCR testing for the diagnosis of bacterial vaginosis is still being evaluated and may be a promising alternative to microscopy.[11]

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 2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.**CPT codes considered medically necessary when billed with an ICD-10-CM codes below**

CPT®* Codes	Description
82120	Amines, vaginal fluid, qualitative

CPT®* Codes	Description
87480	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique
87510	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, direct probe technique
87905	Infectious agent enzymatic activity other than virus (eg, sialidase activity in vaginal fluid)

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

ICD-10-CM Code	Description
B37.3	Candidiasis of vulva and vagina
L29.2, L29.3	Pruritus of genitals
N76.0–N76.3	Vaginitis and vulvitis
N77.1	Vaginitis, vulvitis, and vulvovaginitis in diseases classified elsewhere
N89.8	Other specific noninflammatory disorders of vagina
O23.511–O23.93	Infection of genitourinary tract in pregnancy
Z72.51–Z72.53	High risk sexual behavior
Z86.19	Personal history of other infectious and parasitic diseases [history of STDs]

CPT Codes considered not medically necessary

CPT ®* Codes	Description
0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab
81513	Infectious disease, bacterial vaginosis, quantitative real-time amplification of RNA markers for Atopobium vaginae, Gardnerella vaginalis, and Lactobacillus species, utilizing vaginal-fluid specimens, algorithm reported as a positive or negative result for bacterial vaginosis
81514	Infectious disease, bacterial vaginosis and vaginitis, quantitative real-time amplification of DNA markers for Gardnerella vaginalis, Atopobium vaginae, Megasphaera type 1, Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), and Lactobacillus species (L. crispatus and L. jensenii), utilizing vaginal-fluid specimens, algorithm reported as a positive or negative for high likelihood of bacterial vaginosis, includes separate detection of Trichomonas vaginalis and/or Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata, Candida krusei, when reported
87511	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, amplified probe technique

CPT Codes considered not medically necessary when billed with an ICD-10-CM code below

CPT ®* Codes	Description

CPT ®* Codes	Description
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism

ICD-10-CM diagnosis codes considered not medically necessary when billed with CPT code 87798 per this policy.

ICD-10-CM Code	Description
N39.0	Urinary tract infection, site not specified
N72	Inflammatory disease of cervix uteri
N76.0	Acute vaginitis
N76.2	Acute vulvitis
N89.9	Noninflammatory disorder of vagina, unspecified
N90.89	Other specified noninflammatory disorders of vulva and perineum
N90.9	Noninflammatory disorder of vulva and perineum, unspecified
N91.0–N91.5	Absent, scanty and rare menstruation
N92.0	Excessive, frequent menstruation with regular cycle
N93.0	Postcoital and contact bleeding
N93.8	Other specified abnormal uterine and vaginal bleeding
N93.9	Abnormal uterine and vaginal bleeding, unspecified
N94.3	Premenstrual tension syndrome
N94.4–N94.6	Dysmenorrhea
N94.89	Other specified conditions associated with female genital organs and menstrual cycle
N94.9	Unspecified condition associated with female genital organs and menstrual cycle
O09.00-O09.03	Supervision of pregnancy with history of infertility
O09.10-O09.13	Supervision of pregnancy with history of ectopic pregnancy
O09.A0-O09.A3	Supervision of pregnancy with history of molar pregnancy
O09.211-O09.219	Supervision of pregnancy with history of pre-term labor
O09.291-O09.299	Supervision of pregnancy with other poor reproductive or obstetric history
O09.30-O09.33	Supervision of pregnancy with insufficient antenatal care
O09.40-O09.43	Supervision of pregnancy with grand multiparity
O09.511-O09.519	Supervision of elderly primigravida
O09.521-O09.529	Supervision of elderly multigravida
O09.611-O09.619	Supervision of young primigravida
O09.621-O09.629	Supervision of young multigravida
O09.70-O09.73	Supervision of high risk pregnancy due to social problems
O09.811-O09.819	Supervision of pregnancy resulting from assisted reproductive technology
O09.821-O09.829	Supervision of pregnancy with history of in utero procedure during previous pregnancy
O09.891-O09.899	Supervision of other high risk pregnancies
O09.90-O09.93	Supervision of high risk pregnancy, unspecified

Z00.00	Encounter for general adult medical examination without abnormal findings
Z00.8	Encounter for other general examination
Z01.419	Encounter for gynecological examination (general) (routine) without abnormal findings
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
Z11.51	Encounter for screening for human papillomavirus (HPV)
Z22.330	Carrier of Group B streptococcus
Z23	Encounter for immunization
Z30.011–Z30.019	Encounter for initial prescription of contraceptives
Z30.02	Counseling and instruction in natural family planning to avoid pregnancy
Z30.09	Encounter for other general counseling and advice on contraception
Z30.40–Z30.9	Encounter for surveillance of contraceptives
Z32.00	Encounter for pregnancy test, result unknown
Z33.1	Pregnant state, incidental
Z34.00–Z34.03	Encounter for supervision of normal first pregnancy
Z34.80–Z34.83	Encounter for supervision of other normal pregnancy
Z34.90–Z34.93	Encounter for supervision of normal pregnancy, unspecified
Z36.0-Z36.5	Encounter for antenatal screening of mother
Z36.81-Z36.9	Encounter for other antenatal screening
Z38.00–Z38.01	Single liveborn infant, born in hospital
Z38.30–Z38.31	Twin liveborn infant, born in hospital
Z38.61–Z38.69	Other multiple liveborn infant, born in hospital
Z39.0–Z39.2	Encounter for maternal postpartum care and examination
Z3A.00–Z3A.49	Weeks of gestation
Z97.5	Presence of (intrauterine) contraceptive device

Table 6. CPT codes considered not medically necessary when billed with an ICD-10-CM code listed in Table 7 below.

ICD-10-CM Code	Description
87481	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique

Table 7. ICD-10-CM diagnosis codes considered not medically necessary when billed with CPT code 87481 per this policy.

ICD-10-CM Code	Description
B37.3	Candidiasis of vulva and vagina
L29.2, L29.3	Pruritus of genitals
N39.0	Urinary tract infection, site not specified
N72	Inflammatory disease of cervix uteri
N76.0	Acute vaginitis
N76.1	Subacute and chronic vaginitis
N76.2	Acute vulvitis
N76.3	Subacute and chronic vulvitis
N76.81	Mucositis (ulcerative) of vagina and vulva
N76.89	Other specified inflammation of vagina and vulva

ICD-10-CM Code	Description
N77.1	Vaginitis, vulvitis, and vulvovaginitis in diseases classified elsewhere
N89.8	Other specific noninflammatory disorders of vagina
N89.9	Noninflammatory disorder of vagina, unspecified
N90.89	Other specified noninflammatory disorders of vulva and perineum
N90.9	Noninflammatory disorder of vulva and perineum, unspecified
N91.0–N91.5	Absent, scanty and rare menstruation
N92.0	Excessive, frequent menstruation with regular cycle
N93.0	Postcoital and contact bleeding
N93.8	Other specified abnormal uterine and vaginal bleeding
N93.9	Abnormal uterine and vaginal bleeding, unspecified
N94.3	Premenstrual tension syndrome
N94.4–N94.6	Dysmenorrhea
N94.89	Other specified conditions associated with female genital organs and menstrual cycle
N94.9	Unspecified condition associated with female genital organs and menstrual cycle
O09.00-O09.03	Supervision of pregnancy with history of infertility
O09.10-O09.13	Supervision of pregnancy with history of ectopic pregnancy
O09.A0-O09.A3	Supervision of pregnancy with history of molar pregnancy
O09.211-O09.219	Supervision of pregnancy with history of pre-term labor
O09.291-O09.299	Supervision of pregnancy with other poor reproductive or obstetric history
O09.30-O09.33	Supervision of pregnancy with insufficient antenatal care
O09.40-O09.43	Supervision of pregnancy with grand multiparity
O09.511-O09.519	Supervision of elderly primigravida
O09.521-O09.529	Supervision of elderly multigravida
O09.611-O09.619	Supervision of young primigravida
O09.621-O09.629	Supervision of young multigravida
O09.70-O09.73	Supervision of high risk pregnancy due to social problems
O09.811-O09.819	Supervision of pregnancy resulting from assisted reproductive technology
O09.821-O09.829	Supervision of pregnancy with history of in utero procedure during previous pregnancy
O09.891-O09.899	Supervision of other high risk pregnancies
O09.90-O09.93	Supervision of high risk pregnancy, unspecified
O23.511–O23.93	Infection of genitourinary tract in pregnancy
Z00.00	Encounter for general adult medical examination without abnormal findings
Z00.8	Encounter for other general examination
Z01.419	Encounter for gynecological examination (general) (routine) without abnormal findings

ICD-10-CM Code	Description
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
Z11.51	Encounter for screening for human papillomavirus (HPV)
Z22.330	Carrier of Group B streptococcus
Z23	Encounter for immunization
Z30.011–Z30.019	Encounter for initial prescription of contraceptives
Z30.02	Counseling and instruction in natural family planning to avoid pregnancy
Z30.09	Encounter for other general counseling and advice on contraception
Z30.40–Z30.9	Encounter for surveillance of contraceptives
Z32.00	Encounter for pregnancy test, result unknown
Z33.1	Pregnant state, incidental
Z34.00–Z34.03	Encounter for supervision of normal first pregnancy
Z34.80–Z34.83	Encounter for supervision of other normal pregnancy
Z34.90–Z34.93	Encounter for supervision of normal pregnancy, unspecified
Z36.0-Z36.5	Encounter for antenatal screening of mother
Z36.81-Z36.9	Encounter for other antenatal screening
Z38.00–Z38.01	Single liveborn infant, born in hospital
Z38.30–Z38.31	Twin liveborn infant, born in hospital
Z38.61–Z38.69	Other multiple liveborn infant, born in hospital
Z39.0–Z39.2	Encounter for maternal postpartum care and examination
Z3A.00–Z3A.49	Weeks of gestation
Z72.51–Z72.53	High risk sexual behavior
Z86.19	Personal history of other infectious and parasitic diseases [history of STDs]
Z97.5	Presence of (intrauterine) contraceptive device

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
Original approval date	03/21	06/21
Noted in the description that the policy does not apply to the diagnosis of Trichomonas vaginalis, vaginal pH testing, and wet mount microscope tests, and updated background accordingly. Removed 83986 and 87210 from the coding table requiring symptom diagnosis codes, as they could be used for testing for conditions other than vaginitis. Removed the following codes from table 2: A59.01, F11.10 - F11.19, F11.20 – F11.29, F14.10 – F14.19, F14.20 – F14.29, F15.10 – F15.19, F15.20 – F15.29, F18.10 – F18.19, F18.20 – F18.29, F19.10 – F19.19, F19.20 – F19.29, Z11.2, Z11.8, Z13.89. References reviewed, reformatted and updated.	10/21	02/22
Annual review. "Investigational" verbiage replaced in criteria V. with descriptive language. Updated description and background with no impact on criteria. Moved code 87481 from "CPT codes considered not medically necessary" to Table 6 and added Table 7, ICD-10 codes	09/22	

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
considered not medically necessary for code 87481. References reviewed and updated. Added 0330U to the not medically necessary CPT code table		

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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.