Clinical Policy: Testing for Select Genitourinary Conditions

Reference Number: WNC.CP.173 Coding Implications
Last Review Date: 02/2025 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.[1] The purpose of this policy is to define medical necessity criteria for the diagnostic evaluation of vaginitis, This policy also defines unnecessary amplified DNA- (deoxyribonucleic acid) probe testing for genitourinary conditions.

Note: Although *Trichomonas vaginalis* is a common cause of vaginitis, testing for it is not restricted with medical necessity criteria and thus it is not included in the scope of this policy.

Policy/Criteria

I. It is the policy of WellCare of North Carolina® that the following diagnostic tests are **medically necessary** for the evaluation of vaginitis symptoms:
- **A.** KOH "whiff test" (i.e., amine odor test);
- **B.** Assay for sialidase activity;
- **C.** Direct and amplified DNA probe tests for microorganisms likely to cause vaginitis.

II. It is the policy of WellCare of North Carolina® that screening of birthing individuals for *bacterial vaginosis* (BV) (without symptoms associated with 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 birthing individuals reduces these complications.[2]

III. It is the policy of WellCare of North Carolina® that the following tests for genitourinary conditions for individuals without symptoms of vaginitis during routine exams, contraceptive management care, or pregnancy care are considered **not medically necessary** as they have not been shown to improve clinical outcomes in this population :[2,4].
- **A.** Unspecified amplified DNA probe testing (CPT 87798);
- **B.** Amplified and direct DNA probe *Candida* testing (CPT 87480 and 87481);
- **C.** Sure Swab (CPT 81513), BD MAX Vaginal Panel (CPT 81514), and Xpert Xpress MVP (CPT 0352U) nucleic acid amplification testing (NAAT) panels for vaginitis.

IV. It is the policy of WellCare of North Carolina® that unspecified amplified DNA-probe testing and direct and amplified DNA probe testing for Candida species for the diagnostic

evaluation of symptomatic individuals for the following genitourinary conditions is considered **not medically necessary** as they have not been shown to improve clinical outcomes:

A. Gynecologic and obstetric conditions, listed in Table 5, that are triggered by etiologies other than complicated vaginitis-inducing mechanisms, 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 scientific literature does not support the use of multiplex/multitarget amplified DNA-probe test Bridge Women's Health Infectious Disease Detection panel (CPT 0330U) for 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]

The KOH specimen is typically used to identify the yeast or pseudo hyphae of *Candida* species. Testing sensitivity is approximately 50% through microscopic examination, so the absence of trichomonads or pseudo hyphae 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]

While clinical tests such as KOH and pH testing can be performed at the point of care, their performance for detecting bacterial vaginosis (BV), vulvovaginal candidiasis (VVC), and trichomonas vaginalis (TV) can be low compared to reference methods and other molecular tests. Clinical testing has particularly low sensitivity for detecting coinfections, which are present in up to 25% of women with vaginitis.[2,5]

Sensitivity of clinical and nucleic acid amplification testing (NAAT) for detecting coinfections among women with vaginitis:[2,5]

Coinfection	Sensitivity, % (95% CI) Clinical testing	NAAT
BV + VVC	17.8 (13.0–24.0)	73.5 (66.7–79.3)
BV + TV	21.2 (13.1–32.5)	92.4 (83.5–96.7)
VVC + TV	20.0 (8.9–39.1)	72.0 (52.4–85.7)
BV + VVC + TV	10.0 (2.8–30.1)	80.0 (58.4–91.9)

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, *Megasphaera phylotype 1 and 2, BV-associated bacteria (BVAB)1, 2, and 3, and other fastidious or uncultivated anaerobes.*[1,4,21] BV is the most prevalent cause of vaginal discharge or malodor; however, in a nationally representative survey, most individuals with BV were asymptomatic.[1,3,4,20]

BV can be diagnosed using clinical criteria such as , Amsel's Diagnostic Criteria, or determining the Nugent score or Hay/Ison grade through a vaginal Gram stain, which is considered the gold standard laboratory method for diagnosing BV.[1,13] If a Gram stain is not available, clinical criteria can be used and require **three** of the following signs or symptoms[1,3,4]:

- Homogeneous, thin, grayish-white discharge that smoothly coats the vaginal walls;
- Presence of >20% clue cells on microscopic examination;
- pH of vaginal fluid >4.5;
- A fishy odor of vaginal discharge before or after addition of 10% potassium hydroxide KOH (i.e., the whiff test).

Detection of three of these criteria has been correlated with results by Gram stain.[1,4] 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.[1,3,4] 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] None of these symptoms is specific for VVC. An estimated 75% of individuals will have at least 1 episode of VVC, and 40% to 45% will have two 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 an individual 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 pseudo hyphae or when a culture or other test yields a yeast species.[5,6] *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 individuals with symptoms or signs of VVC, and individuals with a positive result should receive treatment.[7] For those 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 individuals 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% to 20% of individuals harbor *Candida* species and other yeasts in the vagina. VVC can occur concomitantly with sexually transmitted infections. Most healthy individuals 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 individuals 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 such as nonalbicans species and particularly *Candida glabrata*. Although *C. glabrata* and other nonalbicans *Candida* species are observed in 10% to 20% of patients with RVVC, *C. glabrata* does not form pseudo hyphae 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 individuals with very low cluster of differentiation 4 (CD4) counts and high viral load.[7] However, this population is likely to manifest other acquired immune deficiency syndrome–related sentinel conditions.[7] HIV testing of individuals only for the indication of RVVC is not justified, given that this condition is common in absence of HIV.[1,3]

DNA-probe tests have been developed to directly detect the presence of *Candida, Trichomonas* and *G. vaginalis*.[8,9] 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*.[8] DNA probes amplified by polymerase chain reaction (PCR) testing can also detect these pathogens.[10] 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.[1,10] 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.[10] This multiplex PCR panel also can detect other common causes of vaginitis, such as trichomoniasis and candidiasis.[10]

Centers for Disease Control and Prevention (CDC)[1]

The CDC rrecommends 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.

U.S. Preventive Services Task Force (USPSTF)[2]

The USPFTF does not recommend screening for bacterial vaginosis in birthing individuals 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 birthing individuals at increased risk for preterm delivery.

American College of Obstetricians and Gynecologists (ACOG)[4]

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, pseudo hyphae, 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.

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 2025, 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.

Table 1. CPT codes considered medically necessary when billed with an ICD-10-CM code in Table 2.s below

CPT®* Codes	Description
81513	Infectious disease, bacterial vaginosis, quantitative real-time amplification of RNA markers for Atopobium vaginae, Gardnerella vaginalis, and Lactobacillus species,

CPT®* Codes	Description
	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
82120	Amines, vaginal fluid, qualitative
87510	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, direct probe technique
87511	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, amplified probe technique
87905	Infectious agent enzymatic activity other than virus (e.g., sialidase activity in vaginal fluid)

Table 2. ICD-10-CM Diagnosis Codes that Support Medical Necessity for codes in Table 1.
+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description
B37.31	Acute candidiasis of vulva and vagina
B37.32	Chronic candidiasis of vulva and vagina
L29.2, L29.3	Pruritus of genitals
N76.0 through N76.3	Vaginitis and vulvitis
N77.1	Vaginitis, vulvitis, and vulvovaginitis in diseases classified elsewhere
N89.8	Other specific noninflammatory disorders of vagina
N94.10	Unspecified dyspareunia
N94.11	Superficial (introital) dyspareunia
N94.19	Other specified dyspareunia
O23.00 through O23.03	Infections of kidney in pregnancy
O23.10 through O23.13	Infections of bladder in pregnancy
O23.20 through O23.23	Infections of urethra in pregnancy
O23.30 through O23.43	Infections of urinary tract in pregnancy
O23.511 through O23.93	Infection of genitourinary tract in pregnancy
R30.0	Dysuria
Z72.51 through Z72.53	High risk sexual behavior
Z86.19	Personal history of other infectious and parasitic diseases [history of STDs]

Table 3. CPT code 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

Table 4. CPT codes considered Not Medically Necessary when billed with an ICD-10-CM code listed in Table 5 below.

CPT ®* Codes	Description
87480	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique
87481	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism

Table 5. ICD-10-CM diagnosis codes considered not medically necessary when billed with CPT code 87798 per this policy.

ICD-10-CM Codes	Description
N39.0	Urinary tract infection, site not specified
N72	Inflammatory disease of cervix uteri
N76.81	Mucositis (ulcerative) of vagina and vulva
N76.89	Other specified inflammation of vagina and vulva
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 through 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 through 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 through O09.03	Supervision of pregnancy with history of infertility

ICD-10-CM Codes	Description
O09.10 through O09.13	Supervision of pregnancy with history of ectopic pregnancy
O09.A0 through O09.A3	Supervision of pregnancy with history of molar pregnancy
O09.211 through O09.219	Supervision of pregnancy with history of pre-term labor
O09.291 through O09.299	Supervision of pregnancy with other poor reproductive or obstetric history
O09.30 through O09.33	Supervision of pregnancy with insufficient antenatal care
O09.40 through O09.43	Supervision of pregnancy with grand multiparity
O09.511 through O09.519	Supervision of elderly primigravida
O09.521 through O09.529	Supervision of elderly multigravida
O09.611 through O09.619	Supervision of young primigravida
O09.621 through O09.629	Supervision of young multigravida
O09.70 through O09.73	Supervision of high-risk pregnancy due to social problems
O09.811 through O09.819	Supervision of pregnancy resulting from assisted reproductive technology
O09.821 through O09.829	Supervision of pregnancy with history of in utero procedure during previous pregnancy
O09.891 through O09.899	Supervision of other high-risk pregnancies
O09.90 through 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
Z11.2	Encounter for screening for other bacterial diseases
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
Z11.51	Encounter for screening for human papillomavirus (HPV)
Z13.9	Encounter for screening, unspecified
Z22.330	Carrier of Group B streptococcus
Z23	Encounter for immunization
Z30.011 through 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 through Z30.9	Encounter for surveillance of contraceptives
Z32.00	Encounter for pregnancy test, result unknown
Z33.1	Pregnant state, incidental
Z34.00 through Z34.03	Encounter for supervision of normal first pregnancy
Z34.80 through Z34.83	Encounter for supervision of other normal pregnancy
Z34.90 through Z34.93	Encounter for supervision of normal pregnancy, unspecified
Z36.0 through Z36.5	Encounter for antenatal screening of mother
Z36.81 through Z36.9	Encounter for other antenatal screening
Z38.00 through Z38.01	Single liveborn infant, born in hospital

ICD-10-CM Codes	Description
Z38.30 through Z38.31	Twin liveborn infant, born in hospital
Z38.61 through Z38.69	Other multiple liveborn infant, born in hospital
Z39.0 through Z39.2	Encounter for maternal postpartum care and examination
Z3A.00 through Z3A.49	Weeks of gestation
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 considered not medically necessary for code 87481. References reviewed and updated. Added 0330U to the not medically necessary CPT code table	09/22	11/22
Split code B37.3 for candidiasis of vulva and vagina into new for 2023 acute and chronic codes in tables 2 and 7: B37.31 and B37.32. Added CPT 0352U to Table 3 (not med nec CPT codes). Added CPT 0353U to Table 6, codes considered not medically necessary when billed with ICD-10 codes in Table 7.	11/22	11/22
Annual review completed. Reworded some extraneous language; gender-neutral language added where appropriate with no clinical significance. Updated policy statement V to include multiplex amplified DNA-probe testing as not medically necessary. Background updated. References reviewed and updated. NCHC verbiage removed from NC Guidance Verbiage.	05/23	05/23
Description, Criteria, and Background, Changed: " ≥ 13 years" to "≥ 16 years of age" Description, Deleted: "excluding Trichomonas vaginalis, vaginal pH testing, and microscopic examination with saline & potassium hydroxide (KOH)." Description, Added: "Note: Although *Trichomonas vaginalis* is a common cause of vaginitis, testing for it is not restricted with medical necessity criteria and thus it is not included	11/23	11/23

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
in the scope of this policy." Criteria I.C. Added: "amplified DNA probe testing" as medically necessary. Criteria III. Changed: "unspecified amplified DNA-probe testing" to "that the following tests" Criteria III. Changed: "over direct DNA probe testing." To "in this population" Criteria III.A.B.C. Added: "A. Unspecified amplified DNA probe testing; B.Amplified DNA probe *Candida* testing; C.Sure Swab (81513), BD MAX Vaginal Panel (81514), and Xpert Xpress MVP (0352U) nucleic acid amplification testing (NAAT) panels for vaginitis." Criteria V. changed: "testing/polymerase chain reaction (PCR) panel testing of genitourinary pathogens commonly associated with vaginitis," To "test Bridge Women's Health Infectious Disease Detection panel (0330U) for genitourinary pathogens commonly associated with vaginitis." Background, Added: "While clinical tests such as KOH and pH testing can be performed at the point of care, their performance for detecting bacterial vaginosis (BV), vulvovaginal candidiasis (VVC), and trichomonas vaginalis (TV) can be low compared to reference methods and other molecular tests. Clinical testing has particularly low sensitivity for detecting coinfections, which are present in up to 25% of women with vaginitis." Background, Added: "Sensitivity of clinical and nucleic acid amplification testing (NAAT) for detecting coinfections among women with vaginitis" Background, Added: Sensitivity of Clinical and Nucleic Acid Amplification Testing (NAAT) table. Background, Bacterial Vaginosis, Added: "*A.* vaginae, *Megasphaera phylotype 1 and 2, BV-associated bacteria (BVAB)1, 2, and 3, and other fastidious or uncultivated anaerobes."*Background, Vulvovaginal Candidiasis, Removed: "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." Background, Pediatric Patients, Changed: Individuals less than 13 years of age" to "Prepubertal individuals," Background Pediatric Patients, Added: "Puberty normally occurs between the ages of eight to 13 years for females. In females, delayed puberty is the lack of breast development by 13 years, a delay of over four years between thelarche and completion of puberty, or a lack of menarche by 16 years." Background ACOG, Removed: "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." Moved CPT codes 81513, 81514, 87511, and 0352U codes to Table 1 (medically necessary CPT codes) from Table 3 (CPT codes considered not medically necessary). Added CPT codes O23.0 through O23.03, O23.10 through O23.13, O23.20 through O23.23, and O23.30 through O23.43 to Table 2 (ICD-10-CM diagnosis codes that support medical necessity for codes		

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date
in Table 1). Table 5 updated to include screening codes Z11.2 and Z13.9 as not medically necessary when billed with CPT 87798. Table 6, Deleted CPT Code 0353U. Table 7 updated to remove codes B37.31, B37.32, L29.2, L29.3, N76.0 through N76.3, N77.1, N89.8, O23.511 through O23.93, Z72.51 through Z72.53, and Z86.19 allowing for payment of CPT code 87481 for vaginitis. Added codes Z11.2 and Z13.9 to Table 7. References reviewed and updated.		
Annual Review.	05/24	05/24
Annual review. Under Description, Criteria I, Criteria III, removed "…members/enrollees ≥16 years of age…." Criteria I. added "the evaluation of vaginitis symptoms," and deleted "for symptomatic individuals for the evaluation of vaginitis.' Criteria I.C., changed "to detect the presence of Candida or Gardnerella vaginitis." To "for microorganisms likely to cause vaginitis." Criteria II. Removed 'asymptomatic' and added "(without symptoms associated with BV)"Criteria III. Removed 'asymptomatic' and added 'without symptoms of vaginitis." Added CPT codes to Criteria III.A 87798. Criteria III.B. added 'and direct' and CPT codes 87480 & 87481. Criteria IV. Added "and direct and amplified probe testing for Candida species," and deleted "over direct DNA probe testing." Deleted "Acute vaginitis or vulvitis (≤ four episodes per year)" Then IV.B became IV.A. and added "listed in Table 5, that are" Background references updated and deleted "Pediatric Patients" text. Table 1 deleted 87480 and 0352U. Table 2 added N94.10 N94.11 N94.19 R30.0. Table 4 added 87480 87481. Table 5 added N76.8 N76.89 and deleted N76.0 N76.2. Tables 6 and 7 deleted. References reviewed and updated.	02/25	02/25

References

1. Workowski KA, Bachmann LH, Chan PA, et al. Sexually transmitted infections treatment guidelines, 2021. MMWR Recomm Rep. 2021;70(4):1 to 187. Published 2021 Jul 23. doi:10.15585/mmwr.rr7004a1
2. US Preventive Services Task Force, Owens DK, Davidson KW, et al. Screening for bacterial vaginosis in pregnant persons to prevent preterm delivery: US Preventive Services Task Force Recommendation Statement. JAMA. 2020;323(13):1286 to 1292. doi:10.1001/jama.2020.2684
3. Sobel JD. Vaginitis in adults: Initial evaluation. UpToDate. www.uptodate.com. Updated November 6, 2023. Accessed April 29, 2024.
4. American College of Obstetricians and Gynecologists. Committee on Practice Bulletins-Gynecology. ACOG Practice Bulletin No. 215 (Replaces practice bulletin number 72, May 2006). Vaginitis in nonpregnant patients. www.acog.org. Published January 2020 (reaffirmed 2022). Accessed April 29, 2024.
5. Kaufman CA. Overview of candida infections. UpToDate. www.uptodate.com. Updated March 30, 2022. Accessed April 29, 2024.

6. Schwebke JR, Taylor SN, Ackerman R, et al. Clinical validation of the aptima bacterial vaginosis and aptima Candida/Trichomonas vaginitis assays: results from a prospective multicenter clinical study. J Clin Microbiol. 2020;58(2):e01643-19. Published 2020 Jan 28. doi:10.1128/JCM.01643-19
7. Aberg JA, Cespedes MS. HIV, and women. UpToDate. www.uptodate.com. Updated March 18, 2024. Accessed April 29, 2024.
8. Ferris DG, Hendrich J, Payne PM, et al. Office laboratory diagnosis of vaginitis. clinician-performed tests compared with a rapid nucleic acid hybridization test. J Fam Pract. 1995;41(6):575 to 581.
9. Van Der Pol B. Clinical and laboratory testing for trichomonas vaginalis infection. J Clin Microbiol. 2016;54(1):7 to 12. doi:10.1128/JCM.02025-15
10. Sobel JD, Mitchell C. Trichomoniasis: clinical manifestations and diagnosis. UpToDate. www.uptodate.com. Updated July 17, 2023. Accessed April 29, 2024.
11. Sobel JD, Mitchell C. Bacterial vaginosis: clinical manifestations and diagnosis. UpToDate. www.uptodate.com. Updated December 7, 2024. Accessed April 29, 2024.
12. Brown H, Drexler M. Improving the Diagnosis of Vulvovaginitis: Perspectives to Align Practice, Guidelines, and Awareness. Popul Health Manag. 2020;23(S1):S3 to S12. doi:10.1089/pop.2020.0265
13. Willems HME, Ahmed SS, Liu J, Xu Z, Peters BM. Vulvovaginal Candidiasis: A Current Understanding and Burning Questions. J Fungi (Basel). 2020;6(1):27. Published 2020 Feb 25. doi:10.3390/jof6010027
14. Nyirjesy P, Banker WM, Bonus TM. Physician Awareness and Adherence to Clinical Practice Guidelines in the Diagnosis of Vaginitis Patients: A Retrospective Chart Review. Popul Health Manag. 2020;23(S1):S13 to S21. doi:10.1089/pop.2020.0258
15. Yano J, Sobel JD, Nyirjesy P, et al. Current patient perspectives of vulvovaginal candidiasis: incidence, symptoms, management, and post-treatment outcomes. BMC Womens Health. 2019;19(1):48. Published 2019 Mar 29. doi:10.1186/s12905-019-0748-8
16. Sobel JD, Mitchell C. Bacterial vaginosis: Clinical manifestations and diagnosis. UpToDate. www.uptodate.com. Updated December 7, 2023. Accessed April 29, 2024.
17. Marnach ML, Wygant JN, Casey PM. Evaluation and Management of Vaginitis. Mayo Clin Proc. 2022;97(2):347-358. doi:10.1016/j.mayocp.2021.09.022
18. Schwebke JR, Gaydos CA, Nyirjesy P, Paradis S, Kodsi S, Cooper CK. Diagnostic Performance of a Molecular Test versus Clinician Assessment of Vaginitis. J Clin Microbiol. 2018;56(6):e00252-18. Published 2018 May 25. doi:10.1128/JCM.00252-18
19. Local coverage article: Response to Comments: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (A59007). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Published March 3, 2022. Accessed April 29, 2024.
20. Jones, A. Bacterial Vaginosis: A Review of Treatment, Recurrence, and Disparities. The Journal for Nurse Practitioners, 2019;15(6):420-423. doi:10.1016/j.nurpra.2019.03.010
21. Tang C, Zafar Gondal A, Damian M. Delayed Puberty. In: StatPearls. Treasure Island (FL): StatPearls Publishing; July 31, 2023. https://www.ncbi.nlm.nih.gov/books/NBK544322/. Accessed April 29, 2024.

22. Danby CS, Althouse AD, Hillier SL, Wiesenfeld HC. Nucleic Acid Amplification Testing Compared With Cultures, Gram Stain, and Microscopy in the Diagnosis of Vaginitis. J Low Genit Tract Dis. 2021;25(1):76-80. doi:10.1097/LGT.0000000000000576
23. Cartwright CP, Lembke BD, Ramachandran K, et al. Comparison of nucleic acid amplification assays with BD affirm VPIII for diagnosis of vaginitis in symptomatic women. J Clin Microbiol. 2013;51(11):3694-3699. doi:10.1128/JCM.01537-13
24. Kong AM, Jenkins D, Troeger KA, Kim G, London RS. Diagnostic Testing of Vaginitis: Improving the Value of Care. Popul Health Manag. 2021;24(4):515-524. doi:10.1089/pop.2021.0143
25. Quest Diagnostics. Vaginitis: Laboratory Testing for Diagnosis and Management. https://testdirectory.questdiagnostics.com/test/test-guides/CF_Vaginitis/vaginitis-laboratory-testing-for-diagnosis-and-management. Accessed April 29, 2024.

North Carolina Guidance

Eligibility Requirements

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
b. Provider(s) shall verify each Medicaid 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.

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/

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 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:

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

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.