Clinical Policy: Testing for Select Genitourinary Conditions

Reference Number: CP.MP.97 Coding Implications
Date of Last Revison: 05/25 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 unspecified amplified DNA 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 health plans affiliated with Centene Corporation® 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 health plans affiliated with Centene Corporation that screening of birthing individuals for bacterial vaginosis (BV) without symptoms associated with BV to reduce the incidence of pre-term 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 health plans affiliated with Centene Corporation 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. Targeted nucleic acid amplification testing (NAAT) panels for vaginitis/vaginosis, with six targets or less: SureSwab (81513) and BD MAX Vaginal Panel (CPT 81514).

IV. It is the policy of health plans affiliated with Centene Corporation 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 are 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 the following:
   a. Pre-term labor;
   b. Ectopic pregnancy;
   c. High risk pregnancy.

V. It is the policy of health plans affiliated with Centene Corporation that current scientific literature does not support the use of expanded multiplex NAAT tests with seven or greater targets such as, but not limited to, Bridge Women's Health Infectious Disease Detection panel (CPT 0330U) or Xpert Xpress MVP (CPT 81515) 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 trichomonads or clue cells (i.e., epithelial cells with borders obscured by bacteria), which are characteristics 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 pseudohyphae, of *Candida* species. Testing sensitivity is approximately 50% through microscopic examination, so the absence of trichomonads 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 BV, 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.[25]

Sensitivity of clinical and nucleic acid amplification testing (NAAT) for detecting coinfections among women with vaginitis:[25]

Coinfection	Sensitivity, % (95% CI)	
	Clinical testing	NAAT
BV + VVC	17.8 (13.0–24.0)	73.5 (66.7–79.3)

Coinfection	Sensitivity, % (95% CI)	
	Clinical testing	NAAT
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)
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 by determining the Nugent score or Hay/Ison grade through a vaginal Gram stain, which is considered the gold standard laboratory method for diagnosing BV.[1,3,13] If a Gram stain is not available, clinical criteria by Amsel 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 BV Blue test have acceptable performance characteristics compared with Gram stain.[1] The BV Blue 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 (VVC)
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.[1,3,5] None of these symptoms is specific for VVC. An estimated 75% of individuals will have at least one 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.[1,5] Signs include vulvar edema, fissures, excoriations, or thick, curdy vaginal discharge.[1,5] 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 pseudohyphae, or when a culture or other test yields a yeast species.[1,5,6] *Candida* vaginitis is associated with a normal vaginal pH (<4.5), so pH testing is not a useful diagnostic tool.[1,3] 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.[1,5] 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.[1] For those with negative wet mounts who are symptomatic, vaginal cultures for *Candida* should be considered.[1] 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.[1] 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.[27]

Complicated or recurrent vulvovaginal candidiasis (RVVC) is usually defined as three or more episodes of symptomatic VVC in one year and affects <5% of women. 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 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 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 the absence of HIV.[1,3]

Nucleic acid amplifications tests (NAATs) can diagnose bacterial vaginosis (BV), *Candida,* and cervicitis with sensitivities and specificities of >90 percent. The traditional gold standard tests have been culture (for candida species) and microscopy with Nugent score, followed by Amsel criteria for indeterminate tests, for BV. However, NAATs have become an established alternative to both as NAATs have similar or better test sensitivity and specificity.[3] An advanced single-swab panel test that combines multiplex PCR and DNA probe technology can also diagnose BV 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. This multiplex PCR panel can also detect other common causes of vaginitis, such as trichomoniasis and candidiasis.[4]

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

The CDC recommends the gram stain as the gold standard for diagnosis of bacterial vaginosis and recommends the use of Amsel's criteria if a gram stain is not available.

U.S. Preventive Services Task Force (USPSTF)[2]
The USPSTF does not recommend screening for bacterial vaginosis in birthing individuals at low risk for preterm delivery. 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.[2]

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. In a symptomatic patient, diagnosis of vulvovaginal candidiasis requires one of the following two findings:

- visualization of spores, pseudohyphae, or hyphae on wet mount microscopy;
- 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.[4]

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.

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

CPT®* Codes	Description
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
82120	Amines, vaginal fluid, qualitative
87510	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, direct probe technique

CPT®* Codes	Description
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

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	Infections 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 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

CPT Codes	Description
81515	Infectious disease, bacterial vaginosis and vaginitis, real-time PCR amplification of DNA markers for Atopobium vaginae, Atopobium species, Megasphaera type 1, and Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), utilizing vaginal-fluid specimens, algorithm reported as positive or negative for high likelihood of bacterial vaginosis, includes separate detection of Trichomonas vaginalis and Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, when reported

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 codes 87480, 87481 and 87798 per this policy.

ICD-10-CM Code	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 and 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

ICD-10-CM Code	Description
O09.00 through O09.03	Supervision of pregnancy with history of infertility
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

ICD-10-CM Code	Description
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
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 of pregnancy
Z97.5	Presence of (intrauterine) contraceptive device

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed, reviewed by specialist.	06/16	06/16
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. Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." References reviewed, reformatted and updated. 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 through F11.19, F11.20 through F11.29, F14.10 through F14.19, F14.20 through F14.29, F15.10 through F15.19, F15.20 through F15.29, F18.10 through F18.19, F18.20 through F18.29,	07/21	07/21

Reviews, Revisions, and Approvals	Revision Date	Approval Date
F19.10 through F19.19, F19.20 through F19.29, Z11.2, Z11.8, Z13.89. Specialist review.		
Annual review. "Investigational" verbiage replaced in criteria V. with descriptive language. Updated description and background with no impact on criteria. Moved code 87481 from Table 3, "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.	03/22	03/22
Added 0330U to the not medically necessary CPT code table 3.	08/22	
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.	10/22	
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. External specialist reviewed.	03/23	03/23
Description, Policy, and Background updated to increase age at which criteria restrictions apply to ≥ 16 years of age and note added in description for Trichomonas vaginalis, vaginal pH testing, and KOH. Policy/Criteria updated to include specified amplified DNA probe testing (NAAT) as medically necessary. Updated criteria I. to include amplified DNA probe testing (NAAT) for symptomatic members/enrollees ≥ 16 years of age. Updated criteria III. for specific testing not medically necessary in asymptomatic individuals during routine exams, contraceptive management care, or pregnancy care to include unspecified amplified DNA probe testing, amplified DNA probe Candida testing, and SureSwab (81513), BD MAX Vaginal Panel (81514), and Xpert Xpress MVP (0352U) nucleic acid amplification testing (NAAT) panels for vaginitis. Updated criteria V. to include 0330U as not medically necessary. Background updated to include Megasphaera phylotype 1 and 2, BV-associated bacteria (BVAB)1, 2, and 3 which allows for payment for CPT codes 81513 and 81514 and Sensitivity of Clinical and Nucleic Acid Amplification Testing (NAAT) table. Background information related to pediatric patients updated to address puberty and increase in age to ≥ 16 years of age. 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, O23.1 through O23.13, O23.2 through O23.23, and O23.3 through O23.43 to Table 2 (ICD-10-CM diagnosis codes that support medical necessity). Table 5 updated to include screening codes Z11.2 and Z13.9 as not	09/23	09/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
medically necessary. CPT Code 0353U removed from Table 6 and Table 7 header as gonorrhea and chlamydia are not in scope for this policy. Table 7 updated to remove codes B37.31, B37.32, L29.2, L29.3, N76.0 through N76.3, N77.1, N89.8, O23.511through 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. Internal specialist reviewed.		
Annual review. Added applicable CPT codes to policy statement III. In I.C., removed requirement for amplified or direct probe testing to be for Candida or Gardnerella, and instead specified that testing is for microorganisms likely to cause vaginitis. In III.B., added direct probe testing for candida in addition to the already-listed amplified probe candida testing. Added direct and amplified probe testing for Candida to policy statement IV. Removed section IV.A. criteria related to unspecified amplified probe testing for acute vaginitis and vulvitis. Minor rewording in new indication IV.A. for clarity. Removed "for members/enrollees ≥ 16 of age" from description and policy statements I., III., and IV. Added ICD-10 codes N94.10, N94.11, N94.19, and R30.0 to Table 2, ICD-10 codes that support medical necessity for CPT codes in Table 1. Deleted tables previously noted as IV and V. Added CPT code 87480 and 87798 to new Table 4 (CPT codes considered not medically necessary when billed with ICD-10-CM code listed in Table 5) and in the description of Table 5 (ICD-10-CM diagnosis codes considered not medically necessary when billed with CPT codes 87480, 87481 and 87798 per this policy). Updated description and background with no clinical significance. References reviewed and updated. Internal specialist reviewed.	06/24	06/24
Annual review. In III.C., specified that targeted NAAT panels of six pathogen targets or less are medically necessary and removed Xpert Xpress MVP and associated deleted code 0352U. Modified V. to specify that it addresses expanded multiplex NAAT testing of seven targets or more, including Xpert Xpress MVP (81515). Updated background and description with no clinical significance. Reviewed codes and descriptions. Added CPT code 81515 to Table 3, CPT codes considered not medically necesary. Removed deleted code 0352U from Table 1, CPT codes considered medically necessary when billed with a diagnosis code in Table 2. Corrected 6/24 revision log to say, "added CPT code 87480 and 87798 to new Table 4 (CPT codes considered *not* medically necessary…" and not, "added CPT code 87480 and 87798 to new Table 4 (CPT codes considered medically necessary…" References reviewed and updated. External specialist reviewed.	05/25	

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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 member/enrollees. This clinical policy is not intended to recommend treatment for member/enrollees. Member/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, member/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, member/enrollees and their representatives agree to be bound by such terms and conditions by providing services to member/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid member/enrollees, 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.

Note: For Medicare member/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.