

Clinical Policy: Testing for Select Genitourinary Conditions

Reference Number: LA.CP.MP.97 Date of Last Revision: 5/23 Coding Implications 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. 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 potassium hydroxide [KOH]) in members/enrollees \geq 13 years of age. This policy also defines unspecified amplified DNA probe testing for genitourinary conditions.

Policy/Criteria

- I. It is the policy of Louisiana Healthcare Connections that the following diagnostic tests for symptomatic individuals for the evaluation of vaginitis are medically necessary for members/enrollees ≥ 13 years of age:
 - 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 Louisiana Healthcare Connections that screening of asymptomatic birthing individuals for bacterial vaginosis (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 Louisiana Healthcare Connections 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/enrollees ≥ 13 year of age as it has not been shown to improve clinical outcomes over direct DNA-probe testing.
- IV. It is the policy of Louisiana Healthcare Connections that unspecified amplified DNA-probe testing for the diagnostic evaluation of symptomatic individuals for the following genitourinary conditions is considered **not medically necessary** for members/enrollees ≥ 13 of age as it has not been shown to improve clinical outcomes over direct DNA-probe testing:
 - A. Acute vaginitis or vulvitis (\leq four episodes per year);
 - B. Gynecologic and obstetric conditions triggered by etiologies other than complicated vaginitis inducing mechanisms as listed in Table 5, 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 Louisiana Healthcare Connections that current literature does not support the use of multiplex/multitarget amplified DNA-probe testing/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

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 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 individuals with BV were asymptomatic.^{1,3,4}

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.^{1,13} 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

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 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.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 veasts, hyphae, or pseudohyphae or when a 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 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 four or more episodes of symptomatic VVC in one 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 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.⁸ However, this population is likely to manifest other acquired immune deficiency syndrome–related sentinel conditions.⁸ 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}

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 vaginosisassociated bacterial species ("bad bacteria") in a patient-collected or physician-collected singleswab sample and has demonstrated comparable diagnostic sensitivity and specificity to Nugent scoring and Amsel criteria.¹¹ This multiplex PCR panel can also 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.⁴

Pediatric Patients

Individuals less than 13 years of age tend to have a different etiology for vaginitis than older individuals 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 (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 USPFTF does not recommend screening for bacterial vaginosis in birthing individuals at low risk for preterm 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:

• 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. 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.^{4,11}

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 and may not support medical necessity. 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 ^{®*}	Description
Codes	
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
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
87482	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, quantification
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

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



CPT ^{®*}	Description
Codes	
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
87905	Infectious agent enzymatic activity other than virus (eg, sialidase activity in vaginal fluid)

Table 2. ICD-10-CM diagnosis codes that support medical necessity for codes in table 1

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

Table 3. CPT codes considered not medically necessary

СРТ	Description
Codes	
0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel,
	identification of 27 organisms, amplified probe technique, vaginal swab
0352U	Infectious disease (bacterial vaginosis and vaginitis), multiplex amplified probe
	technique, for detection of bacterial vaginosis-associated bacteria (BVAB-2,
	Atopobium vaginae, and Megasphera type 1), algorithm reported as detected or not
	detected and separate detection of Candida species (C. albicans, C. tropicalis, C.
	parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, and trichomonas
	vaginalis, vaginal-fluid specimen, each result reported as detected or not detected

Table 4. CPT codes considered not medically necessary when billed with an ICD-10-CMcode listed in Table 7 below.

CPT Codes	Description
0353U	Infectious agent detection by nucleic acid (DNA), Chlamydia trachomatis and Neisseria gonorrhoeae, multiplex amplified probe technique, urine, vaginal, pharyngeal, or rectal, each pathogen reported as detected or not detected



Table 5. ICD-10-CM diagnosis codes considered not medically necessary when billed with	h
CPT codes 0353U	

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
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
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 through	Absent, scanty and rare menstruation
N91.5	
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	Dysmenorrhea
N94.6	
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
O09.10 through O09.13	Supervision of pregnancy with history of ectopic pregnancy
009.A0 through 009.A3	Supervision of pregnancy with history of molar pregnancy
009.211 through 009.219	Supervision of pregnancy with history of pre-term labor
009.291 through 009.299	Supervision of pregnancy with other poor reproductive or obstetric history



ICD-10-CM Code	Description
O09.30 through	Supervision of pregnancy with insufficient antenatal care
009.33	Supervision of pregnancy with insufficient antenatal care
O09.40 through	Supervision of pregnancy with grand multiparity
009.43	
O09.511 through	Supervision of elderly primigravida
009.519	
O09.521 through	Supervision of elderly multigravida
009.529	
O09.611 through	Supervision of young primigravida
009.619	
O09.621 through	Supervision of young multigravida
009.629	
O09.70 through	Supervision of high risk pregnancy due to social problems
009.73	
O09.811 through	Supervision of pregnancy resulting from assisted reproductive technology
009.819	
O09.821 through	Supervision of pregnancy with history of in utero procedure during
009.829	previous pregnancy
O09.891 through	Supervision of other high risk pregnancies
O09.899	
O09.90 through	Supervision of high risk pregnancy, unspecified
009.93	
O23.511 through	Infection of genitourinary tract in pregnancy
023.93	
Z00.00	Encounter for general adult medical examination without abnormal
700.0	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 through	Encounter for initial prescription of contraceptives
Z30.019	I I I I I I I I I I I I I I I I I I I
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	Encounter for surveillance of contraceptives
Z30.9	r and r and r and r and r
Z32.00	Encounter for pregnancy test, result unknown
Z33.1	Pregnant state, incidental
Z34.00 through	Encounter for supervision of normal first pregnancy
Z34.03	



ICD-10-CM Code	Description
Z34.80 through	Encounter for supervision of other normal pregnancy
Z34.83	
Z34.90 through	Encounter for supervision of normal pregnancy, unspecified
Z34.93	
Z36.0 through	Encounter for antenatal screening of mother
Z36.5	
Z36.81 through	Encounter for other antenatal screening
Z36.9	
Z38.00 through	Single liveborn infant, born in hospital
Z38.01	
Z38.30 through	Twin liveborn infant, born in hospital
Z38.31	
Z38.61 through	Other multiple liveborn infant, born in hospital
Z38.69	
Z39.0 through	Encounter for maternal postpartum care and examination
Z39.2	
Z3A.00 through	Weeks of gestation of pregnancy
Z3A.49	
Z72.51 through	High risk sexual behavior
Z72.53	
Z86.19	Personal history of other infectious and parasitic diseases [history of STDs]
Z97.5	Presence of (intrauterine) contraceptive device

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Converted corporate to local policy.	08/15/2020	
Noted in the description that the policy does not apply to the diagnosis	1/2022	
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 - 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. Specialist review.		



Reviews, Revisions, and Approvals	Revision Date	Approval Date
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. Added "and may not support mecial necessity" to Coding Implications section	5/22	8/13/22
Added 0330U to the not medically necessary CPT code table 3	9/22	
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.	09/22	2/27/23
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. Added CPT codes 87481 and 87482 for Candida species. Moved codes 81513, 81514, 87511, 87841, 87798 from the "not medically necessary" table as they are covered on LDH FS. References reviewed and updated. External specialist reviewed.	3/23	7/24/23

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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. LHCC 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.

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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.

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