Clinical Policy: Testing for Select Genitourinary Conditions

Reference Number: CP.MP.97 [Coding Implications](#Coding_Implications)

Last Review Date: 08/19

[Revision Log](#Revision_Log)

**See** [Important Reminder](#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 in members ≥ 13 years of age. This policy also defines unnecessary amplified DNA- (deoxyribonucleic acid) probe testing for genitourinary conditions.

## Policy/Criteria

1. It is the policy of health plans affiliated with Centene Corporation® that the following diagnostic tests for symptomatic women for the evaluation of vaginitis are **medically necessary** for members age ≥ 13:
	1. Microscopy with wet mount, KOH mount, and vaginal pH;
	2. Assay for sialidase activity;
	3. Direct DNA probe tests to detect the presence of *Candida and* *Gardnerella vaginalis.*
2. It is the policy of health plans affiliated with Centene Corporation that screening of asymptomatic pregnant women 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 pregnant women reduces these complications.9
3. It is the policy of health plans affiliated with Centene Corporation that unspecified amplified DNA-probe testing for genitourinary conditions for asymptomatic women during routine exams, contraceptive management care, or pregnancy care is considered **not medically necessary** for members ≥ 13 year of age as it has not been shown to improve clinical outcomes over direct DNA-probe testing.
4. It is the policy of health plans affiliated with Centene Corporation that unspecified amplified DNA-probe testing for the diagnostic evaluation of symptomatic women for the following genitourinary conditions is considered **not medically necessary** for members ≥ 13 of age as it has not been shown to improve clinical outcomes over direct DNA-probe testing:
	1. Acute vaginitis or vulvitis (≤ 4 episodes per year);
	2. 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:
				1. Pre-term labor;
				2. Ectopic pregnancy;
				3. High risk pregnancy.

## Background

The 3 diseases most frequently associated with vaginitis are BV, (caused by replacement of the vaginal flora by an overgrowth of anaerobic bacteria, including *Prevotella* sp., *Mobiluncus* sp., *Gardnerella vaginalis*, *Ureaplasma*, *Mycoplasma*, and numerous fastidious or uncultivated anaerobes), trichomoniasis (caused by *Trichomonas vaginalis*), and candidiasis (usually caused by *Candida albicans*). 3

Various diagnostic methods are available to identify the etiology of the signs and symptoms of vaginitis. The cause of vaginal symptoms might be determined by testing of pH, for the presence of amines by the use of a potassium hydroxide (KOH) test, and microscopic examination of fresh samples of the discharge. The pH of the vaginal secretions can be determined by narrow-range pH paper; an elevated pH (*i.e.,* >4.5) is common with BV or trichomonas. Because pH testing is not highly specific, the discharge should be further examined microscopically with both a saline and KOH solution. 3

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. The KOH specimen typically is used to identify the yeast or pseudohyphae of *Candida* species. However, the absence of trichomonads or pseudohyphae in KOH samples does not rule out these infections, because the sensitivity of microscopy is approximately 40-75%.4

In settings where pH paper, KOH, and microscopy are not available or are inconclusive, alternative, commercially available, point-of-care tests, such as commercially available direct DNA-probe tests, or clinical laboratory testing, can be used to diagnose vaginitis. The presence of objective signs of vulvar inflammation in the absence of vaginal pathogens after laboratory testing, along with a minimal amount of discharge, suggests the possibility of mechanical, chemical, allergic, or other noninfectious irritation of the vulva. 5

*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 (*e.g.,* *Prevotella* sp. and *Mobiluncus* sp.), *G. vaginalis*, *Ureaplasma*, *Mycoplasma*, and numerous fastidious or uncultivated anaerobes. BV is the most prevalent cause of vaginal discharge or malodor; however, in a nationally representative survey, most women with BV were asymptomatic. 3

BV can be diagnosed by the use of clinical criteria (*i.e.,* Amsel's Diagnostic Criteria) or Gram stain (considered the gold standard laboratory method for diagnosing BV). If a Gram stain is not available, clinical criteria can be used and require 3 of the following symptoms or signs:

* Homogeneous, thin, white discharge that smoothly coats the vaginal walls;
* Presence of clue cells on microscopic examination;
* pH of vaginal fluid >4.5;
* A fishy odor of vaginal discharge before or after addition of 10% KOH (*i.e.,* the whiff test). 8

Detection of 3 of these criteria has been correlated with results by Gram stain. Other tests, including a DNA probe-based test for high concentrations of *G. vaginalis* (Affirm VP III, Becton Dickinson, Sparks, Maryland), and the OSOM BVBlue test have acceptable performance characteristics compared with Gram stain. 3 The BVBlue test is a colorimetric test for enzymes (sialidase) produced by BV organisms. Culture of *G. vaginalis* is not recommended as a diagnostic tool, because 50% of women in the general population will culture positively for *G. vaginalis*. Use of the proline-aminopeptidase test card (Pip Activity TestCard) is no longer recommended because of low sensitivity and specificity. 8

*Vulvovaginal Candidiasis*

Vulvovaginal candidiasis (VVC) usually is 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. None of these symptoms is specific for VVC. An estimated 75% of women will have at least 1 episode of VVC, and 40%–45% will have 2 or more episodes within their lifetime. On the basis of clinical presentation, microbiology, host factors, and response to therapy, VVC can be classified as either uncomplicated or complicated. 3

A diagnosis of *Candida* vaginitis is suggested clinically by the presence of external dysuria and vulvar pruritus, pain, swelling, and redness. Signs include vulvar edema, fissures, excoriations, or thick, curdy vaginal discharge. The diagnosis can be made in a woman who has signs and symptoms of vaginitis when either 1) a wet preparation (saline, 10% KOH) or Gram stain of vaginal discharge demonstrates yeasts, hyphae, or pseudohyphae or 2) a culture or other test yields a yeast species. *Candida* vaginitis is associated with a normal vaginal pH (<4.5), and therefore, pH testing is not a useful diagnostic tool. 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. Examination of a wet mount with KOH preparation should be performed for all women with symptoms or signs of VVC, and women with a positive result should receive treatment. For women with negative wet mounts who are symptomatic, vaginal cultures for *Candida* should be considered. If the wet mount is negative and *Candida* cultures cannot be done, empiric treatment can be considered for symptomatic women with any sign of VVC on examination. Identifying *Candida* by culture in the absence of symptoms or signs is not an indication for treatment because approximately 10%-20% of women harbor *Candida* species and other yeasts in the vagina. VVC can occur concomitantly with STIs. Most healthy women with uncomplicated VVC have no identifiable precipitating factors. 3

Complicated or recurrent vulvovaginal candidiasis (RVVC) is usually defined as 4 or more episodes of symptomatic VVC in 1 year, and affects a small percentage of women (<5%). The pathogenesis of RVVC is poorly understood, and most women with RVVC have no apparent predisposing or underlying conditions. Vaginal cultures should be obtained from patients with RVVC to confirm the clinical diagnosis and to identify unusual species (including nonalbicans species), particularly *Candida glabrata*. Although *C. glabrata* and other nonalbicans *Candida* species are observed in 10%-20% of patients with RVVC, *C. glabrata* does not form pseudohyphae or hyphae and is not easily recognized on microscopy. 3

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

DNA-probe tests have been developed to directly detect the presence of *Candida*, *Trichomonas* and *G. vaginalis*. 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*. DNA probes amplified by PCR testing can also detect these pathogens. 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.

*Pediatric Patients*

Girls less than 13 years of age tend to have a different etiology for vaginitis than do older girls, due to the lack of estrogenization of the vagina, and the consequential alkalinity and vaginal atrophy.5 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..5 6

*Centers for Disease Control and Prevention*

Screening for T. vaginalis in women can be considered in those at high risk for infection (i.e., women who have new or multiple partners, have a history of STIs, exchange sex for payment, and use injection drugs). 3

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

*U.S. Preventive Services Task Force*

This organization does not recommend screening for bacterial vaginosis in pregnant women at low-risk for pre-term delivery. 9

**Coding Implications**

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

| **CPT®\* Codes**  | **Description** |
| --- | --- |
| 82120 | Amines, vaginal fluid, qualitative |
| 83986 | pH; body fluid, not otherwise specified |
| 87210 | Smear, primary source with interpretation; wet mount for infectious agents (eg, saline, India ink, KOH preps) |
| 87480 | Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique |
| 87510 | Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, direct probe technique |
| 87905 | Infectious agent enzymatic activity other than virus (eg, sialidase activity in vaginal fluid) |

**Table 2. ICD-10-CM diagnosis codes that support medical necessity per this policy**

| **ICD-10-CM Code** | **Description** |
| --- | --- |
| A59.01 | Trichomonal vulvovaginitis |
| B37.3 | Candidiasis of vulva and vagina |
| F11.10 - F11.19 | Opioid abuse [injection drug use] |
| F11.20 – F11.29 | Opioid dependence [injection drug use] |
| F14.10 – F14.19 | Cocaine abuse [injection drug use] |
| F14.20 – F14.29 | Cocaine dependence [injection drug use] |
| F15.10 – F15.19 | Other stimulant abuse [injection drug use] |
| F15.20 – F15.29 | Other stimulant dependence [injection drug use] |
| F18.10 – F18.19 | Inhalant abuse |
| F18.20 – F18.29 | Inhalant dependence |
| F19.10 – F19.19 | Other psychoactive substance abuse |
| F19.20 – F19.29 | Other psychoactive substance dependence |
| L29.2, L29.3 | Pruritus of genitals |
| N76.0 – N76.3 | Vaginitis and vulvitis |
| N77.1 | Vaginitis, vulvitis, and vulvovaginitis in diseases classified elsewhere |
| N89.8 | Other specific noninflammatory disorders of vagina |
| O23.511– O23.93 | Infection of genitourinary tract in pregnancy |
| Z11.2\* | Encounter for screening for other bacterial diseases |
| Z11.8\* | Encounter for screening for other infectious and parasitic diseases (Trichomonas) |
| Z13.89\* | Encounter for screening for other genitourinary disorders  |
| Z72.51 – Z72.53 | High risk sexual behavior [exchange of sex for payment, new or multiple partners] |
| Z86.19 | Personal history of other infectious and parasitic diseases [history of STDs] |

\*ICD-10 codes Z11.2, Z11.8, and Z11.89 should be used with one of the drug abuse or dependence codes in the F series above.

**Table 3. CPT codes considered not medically necessary unless an exception is noted in this policy.**

| **CPTCodes**  | **Description** |
| --- | --- |
| 87481 | Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique |
| 87511 | Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, amplified probe technique |

**Table 4. CPT codes considered not medically necessary when billed with an ICD-10-CM code listed in Table 5 below.**

| **CPTCodes**  | **Description** |
| --- | --- |
| 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 Code** | **Description** |
| --- | --- |
| N39.0 | Urinary tract infection, site not specified |
| N72 | Inflammatory disease of cervix uteri |
| N76.0 | Acute vaginitis |
| N76.2 | Acute vulvitis |
| N89.9 | Noninflammatory disorder of vagina, unspecified |
| N90.89 | Other specified noninflammatory disorders of vulva and perineum |
| N90.9 | Noninflammatory disorder of vulva and perineum, unspecified |
| N91.0 – N91.5 | Absent, scanty and rare menstruation |
| N92.0 | Excessive, frequent menstruation with regular cycle |
| N93.0 | Postcoital and contact bleeding |
| N93.8 | Other specified abnormal uterine and vaginal bleeding |
| N93.9 | Abnormal uterine and vaginal bleeding, unspecified |
| N94.3 | Premenstrual tension syndrome |
| N94.4 – N94.6 | Dysmenorrhea  |
| N94.89 | Other specified conditions associated with female genital organs and menstrual cycle |
| N94.9 | Unspecified condition associated with female genital organs and menstrual cycle |
| O09.00-O09.03 | Supervision of pregnancy with history of infertility |
| O09.10-O09.13 | Supervision of pregnancy with history of ectopic pregnancy |
| O09.A0-O09.A3 | Supervision of pregnancy with history of molar pregnancy |
| O09.211-O09.219 | Supervision of pregnancy with history of pre-term labor |
| O09.291-O09.299 | Supervision of pregnancy with other poor reproductive or obstetric history |
| O09.30-O09.33 | Supervision of pregnancy with insufficient antenatal care |
| O09.40-O09.43 | Supervision of pregnancy with grand multiparity |
| O09.511-O09.519 | Supervision of elderly primigravida |
| O09.611-O09.619 | Supervision of young primigravida |
| O09.621-O09.629 | Supervision of young multigravida |
| O09.70-O09.73 | Supervision of high risk pregnancy due to social problems |
| O09.811-O09.819 | Supervision of pregnancy resulting from assisted reproductive technology |
| O09.821-O09.829 | Supervision of pregnancy with history of in utero procedure during previous pregnancy |
| O09.891-O09.899 | Supervision of other high risk pregnancies |
| O09.90-O09.93 | Supervision of high risk pregnancy, unspecified  |
| Z00.00 | Encounter for general adult medical examination without abnormal findings |
| Z00.8 | Encounter for other general examination |
| Z01.419 | Encounter for gynecological examination (general) (routine) without abnormal findings |
| Z11.3 | Encounter for screening for infections with a predominantly sexual mode of transmission |
| Z11.51 | Encounter for screening for human papillomavirus (HPV) |
| Z22.330 | Carrier of Group B streptococcus |
| Z23 | Encounter for immunization |
| Z30.011 – Z30.019 | Encounter for initial prescription of contraceptives |
| Z30.02 | Counseling and instruction in natural family planning to avoid pregnancy |
| Z30.09 | Encounter for other general counseling and advice on contraception |
| Z30.40 – Z30.9 | Encounter for surveillance of contraceptives |
| Z32.00 | Encounter for pregnancy test, result unknown |
| Z33.1 | Pregnant state, incidental |
| Z34.00 – Z34.03 | Encounter for supervision of normal first pregnancy |
| Z34.80 – Z34.83 | Encounter for supervision of other normal pregnancy |
| Z34.90 – Z34.93 | Encounter for supervision of normal pregnancy, unspecified |
| Z36.3 | Encounter for antenatal screening for malformations  |
| Z36.0-Z36.5 | Encounter for antenatal screening of mother |
| Z36.81-Z36.9 | Encounter for other antenatal screening |
| Z38.00 – Z38.01 | Single liveborn infant, born in hospital |
| Z38.30 – Z38.31 | Twin liveborn infant, born in hospital |
| Z38.61 – Z38.69 | Other multiple liveborn infant, born in hospital |
| Z39.0 – Z39.2 | Encounter for maternal postpartum care and examination |
| Z3A.00 – Z3A.49 | Weeks of gestation |
| Z97.5 | Presence of (intrauterine) contraceptive device |

| Reviews, Revisions, and Approvals | Date | Approval Date |
| --- | --- | --- |
| Policy developed, reviewed by specialist. | 06/16 | 06/16 |
| Added age restriction of ≥ 13, with supporting background information. | 08/16 |  |
| Removed trichomonas from 1.A. section listing criteria for direct DNA probe. Added to ‘background information’ under bacterial vaginosis that the use of the proline-aminopeptidase test card (Pip Activity TestCard) is no longer recommended because of low sensitivity and specificity. Removed CPT code for detection of trichomonas- 87661 from the not medically necessary code tables.  | 06/17 | 06/17 |
| Added CPT 87798 – not otherwise specified amplified DNA probe as not medically necessary when performed for indications listed in the policy related to GU conditions, asymptomatic women, and asymptomatic women during pregnancy. Slight rewording of criteria with no clinical implications.Renamed to “Testing for Select Genitourinary Conditions.”Reviewed by external OB/Gyn.  | 08/17 | 09/17 |
| Removed ICD-9-CM V22 pregnancy code set and replaced with ICD-10-CM pregnancy code set. | 12/17 |  |
| Section I, removed “based on the following indications”.Background updated with no clinical implications.References reviewed and updated. | 08/18 | 08/18 |
| Removed criteria in I. regarding amplified DNA probe testing for trichomonas, as the amplified probe for trichomonas does not require specific symptoms to be present. | 07/19 |  |
| Annual review completed. Specialty review completed. Removed direct probe for trichomonas vaginalis from the policy (CPT 87660) to allow trichomonas testing to be performed without symptoms. Added ICD-10 N89.8 as medically necessary for testing. Background removed related to trichomonas vaginalis. | 08/19 | 08/19 |

### References

1. Current Procedural Terminology (CPT®), 2016. Updated 2019
2. ICD-10-CM Official Code Set, 2016. Updated 2019
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11. Van Der Pol B. Clinical and Laboratory Testing for Trichomonas Vaginalis Infection. J Clin Microbiology. V.54 (1); 2016 Jan

**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.

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