Clinical Policy: Testing for Select Genitourinary Conditions

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Effective Date: 06/16
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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 in members ≥ 13 years of age. This policy also defines unnecessary amplified DNA- (deoxyribonucleic acid) probe testing for genitourinary conditions.

Policy/Criteria

I. It is the policy of Coordinated Care® that the following diagnostic tests for symptomatic women for the evaluation of vaginitis are **medically necessary** for members age ≥ 13:
   A. Microscopy with wet mount, KOH mount, and vaginal pH;
   B. Assay for sialidase activity;
   C. Direct or amplified DNA probe tests to detect the presence of *Candida, Gardnerella vaginalis* and *Trichomoniasis vaginalis.*

II. It is the policy of Coordinated Care 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]

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

IV. It is the policy of Coordinated Care 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 years of age as it has not been shown to improve clinical outcomes over direct DNA-probe testing:
   A. Acute vaginitis or vulvitis (≤ 4 episodes per year);
   B. Gynecologic and obstetric conditions triggered by etiologies other than complicated vaginitis inducing mechanisms as listed in 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.

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]

Trichomoniasis
Trichomoniasis is caused by the protozoan *Trichomonas vaginalis*. Some women have symptoms characterized by a diffuse, malodorous, yellow-green vaginal discharge with vulvar irritation. However, many women have minimal or no symptoms. Because of the high prevalence of trichomoniasis in clinical and nonclinical settings, testing for *T. vaginalis* should be performed in women seeking care for vaginal discharge. 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 sexually transmitted infections [STIs], exchange sex for payment, and use injection drugs). [3]

Diagnosis of vaginal trichomoniasis is usually performed by microscopy of vaginal secretions, but this method has a sensitivity of only approximately 60% - 70% and requires immediate evaluation of wet preparation slide for optimal results. U.S. Food and Drug Administration (FDA)-cleared tests for trichomoniasis in women include OSOM Trichomonas Rapid Test (Genzyme Diagnostics, Cambridge, Massachusetts), an immunochromatographic capillary flow dipstick technology, and the Affirm VP III (Becton Dickenson, San Jose, California), a nucleic acid probe test that evaluates for *T. vaginalis*, *G. vaginalis*, and *C. albicans*. Each of these tests are performed on vaginal secretions, with a sensitivity > 82% and a specificity > 97% for the OSOM Trichomonas Rapid Test, and a sensitivity of > 63% and specificity > 99% for the Affirm VPIII test. The results of the OSOM Trichomonas Rapid Test are available in approximately 10 minutes, whereas results of the Affirm VP III are available within 45 minutes. Although these tests tend to be more sensitive than those requiring vaginal wet preparation, false positives might occur, especially in populations with a low prevalence of disease. [3]

Nucleic acid amplification tests (NAAT) detect RNA (ribonucleic acid) by transcription-mediated amplification polymerase chain reaction (PCR) or reverse transcriptase, are highly sensitive and specific, and have become the accepted gold standard for the diagnosis of Trichomonas vaginalis. Test limitations include the need for instrumentation and laboratory analysis. If NAAT is not available for trichomonas, rapid antigen tests or DNA probe tests can be used as an alternative.[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 the 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
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 2018, 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 per this policy

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
87481	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique
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
87660	Infectious agent detection by nucleic acid (DNA or RNA); Trichomonas 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 specified 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 4. Procedure codes considered not medically necessary when billed with an ICD-10-CM code listed in Table 5 below.

CPT Codes	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
N89.8	Other specified noninflammatory disorders of vagina
N89.9	Noninflammatory disorder of vagina, unspecified
N90.89	Other specified noninflammatory disorders of vulva and perineum
N90.9	Noninflammatory disorder of vulva and perineum, unspecified
N91.0 – N91.5	Absent, scanty and rare menstruation
N92.0	Excessive, frequent and irregular menstruation
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	Primary dysmenorrhea
N94.5	Secondary dysmenorrhea
N94.6	Dysmenorrhea, unspecified
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

ICD-10-CM Code	Description
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 Normql
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
Z33.1	Pregnant state, incidental
Z34.00 – Z34.03	Encounter for supervision of normal first pregnancy
Z34.80 – Z34.83	Encounter for supervision of other normal pregnancy
Z34.90 – Z34.93	Encounter for supervision of normal pregnancy, unspecified
Z36.0-Z36.5	Encounter for antenatal screening of mother
Z36.81-Z36.9	Encounter for other antenatal screening
Z38.00 – Z38.01	Single liveborn infant, born in hospital
Z38.30 – Z38.31	Twin liveborn infant, born in hospital
Z38.61 – Z38.69	Other multiple liveborn infant, born in hospital
Z39.0 – Z39.2	Encounter for maternal postpartum care and examination
Z3A.00 – Z3A.49	Weeks of gestation
Z97.5	Presence of (intrauterine) contraceptive device

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
Changed CPT codes 87481 and 87511 to medically necessary when billed with a corresponding diagnosis code in Table 2.	11/17	
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. Removed ICD-9-CM V22 pregnancy code set and replaced with ICD-10-CM pregnancy code set. Added ICD-10 CM code N89.8 as a code that supports medical necessity.	12/17	09/17
Section I, removed "based on the following indications." Background updated with no clinical implications. References reviewed and updated.	10/18	08/18

References

1. Current Procedural Terminology (CPT®), 2016. Updated 2017.
2. ICD-10-CM Official Code Set, 2016. Updated 2017.
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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.

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