Clinical Policy: Testing for Select Genitourinary Conditions

Reference Number: CP.MP.97 Coding Implications
Date of Last Revison: 03/22 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 (excluding *Trichomonas vaginalis*, vaginal pH testing, and microscopic examination with saline and KOH) in members/enrollees ≥ 13 years of age. This policy also defines unspecified amplified DNA-probe testing for genitourinary conditions.

Policy/Criteria

I. 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/enrollees age ≥ 13:
   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 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.[2]

III. 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/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 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/enrollees ≥ 13 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.

V. It is the policy of health plans affiliated with Centene Corporation that current literature does not support the use of multiplex/multitarget 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 women with BV were asymptomatic.[1,3-4]

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

- 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).

Detection of three of these criteria has been correlated with results by Gram stain.[1] 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] 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 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.[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 a woman 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.[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 women with symptoms or signs of VVC, and women with a positive result should receive treatment.[7] For women 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 women 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%-20% of women harbor *Candida* species and other yeasts in the vagina. VVC can occur concomitantly with sexually transmitted infections. Most healthy women with uncomplicated VVC have no identifiable precipitating factors.[1]

Complicated or recurrent vulvovaginal candidiasis (RVVC) is usually defined as 4 or more episodes of symptomatic VVC in 1 year and affects a small percentage of women (<5%). The pathogenesis of RVVC is poorly understood, and most 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 such as nonalbicans species and 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.[1]

VVC occurs more frequently and has greater persistence, but not greater severity, in HIV-(human immunodeficiency virus) infected women 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 women only for the indication of RVVC is not justified, given that this condition is common in women without 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 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.[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.

Pediatric Patients
Females less than 13 years of age tend to have a different etiology for vaginitis than older females 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 pregnant women 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 pregnant persons 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.[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. 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
82120	Amines, vaginal fluid, qualitative
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 for codes in table 1

ICD-10-CM Code	Description
B37.3	Candidiasis of vulva and vagina
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
Z72.51 – 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
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
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.

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
N89.9	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

ICD-10-CM Code	Description
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
O09.521- O09.529	Supervision of elderly multigravida
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
Z36.0-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

ICD-10-CM Code	Description
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

Table 6. CPT codes considered not medically necessary when billed with an ICD-10-CM code listed in Table 7 below.

CPT Codes	Description
87481	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique

Table 7. ICD-10-CM diagnosis codes considered not medically necessary when billed with CPT code 87481 per this policy.

ICD-10-CM Code	Description
B37.3	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 – 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

ICD-10-CM Code	Description
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
O09.521- O09.529	Supervision of elderly multigravida
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
O23.511– O23.93	Infection of genitourinary tract in pregnancy
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
Z36.0-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

ICD-10-CM Code	Description
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
Z72.51 – Z72.53	High risk sexual behavior
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
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
Minor rewording in I.A. with no impact on meaning. Table 5: Added ICD 10 codes: O09.521- O09.529. Removed code Z36.3 as code is already included in the range Z36.0-Z36.5 noted in the policy. References reviewed and updated.	07/20	08/20

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Corrected typo in the coding note below Table 2 to indicate that Z13.89 should be billed with the F-series codes, and not Z11.89 (not a valid code).	09/20	
Added criteria V. Multiplex PCR panel testing as investigational and updated background accordingly. Added 2021 CPT codes 81513 and 81514 codes to Table 3 as not medically necessary. Replaced "member" with "member/enrollee" in all instances.	12/20	1/21
Noted in the description that the policy does not apply to the diagnosis of Trichomonas vaginalis, vaginal pH testing, and wet mount microscope tests, and updated background accordingly. 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.	07/21	07/21
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

References

1. Workowski KA, Bachmann LH, Chan PA, et al. Sexually Transmitted Infections Treatment Guidelines, 2021. *MMWR Recomm Rep*. 2021;70(4):1-187. Published 2021 Jul 23. doi:10.15585/mmwr.rr7004a1
2. US Preventive Services Task Force, Owens DK, Davidson KW, et al. Screening for Bacterial Vaginosis in Pregnant Persons to Prevent Preterm Delivery: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2020;323(13):1286-1292. doi:10.1001/jama.2020.2684
3. Sobel JD. Approach to females with symptoms of vaginitis. UpToDate. www.uptodate.com. Published May 25, 2021. Accessed February 18, 2022.
4. Vaginitis in Nonpregnant Patients: ACOG Practice Bulletin, Number 215. *Obstet Gynecol*. 2020;135(1):e1-e17. doi:10.1097/AOG.0000000000003604
5. Kaufman CA. Overview of candida infections. UpToDate. www.uptodate.com. Published May 26, 2021. Accessed February 15, 2022.
6. Laufer MR, Emans SJ. Overview of vulvovaginal complaints in the prepubertal child. UpTodate. www.uptodate.com. Published November 23, 2021. Accessed February 24, 2022.

7. Schwebke JR, Taylor SN, Ackerman R, et al. Clinical Validation of the Aptima Bacterial Vaginosis and Aptima *Candida/Trichomonas* Vaginitis Assays: Results from a Prospective Multicenter Clinical Study. *J Clin Microbiol*. 2020;58(2):e01643-19. Published 2020 Jan 28. doi:10.1128/JCM.01643-19
8. Aberg JA, Cespedes MS. HIV and women. UpToDate. www.uptodate.com. Published September 21, 2021. Accessed February 25, 2022.
9. Ferris DG, Hendrich J, Payne PM, et al. Office laboratory diagnosis of vaginitis. Clinician-performed tests compared with a rapid nucleic acid hybridization test. *J Fam Pract*. 1995;41(6):575-581.
10. Van Der Pol B. Clinical and Laboratory Testing for Trichomonas vaginalis Infection. *J Clin Microbiol*. 2016;54(1):7-12. doi:10.1128/JCM.02025-15
11. Sobel JD, Mitchell C. Trichomoniasis. UpToDate. www.uptodate.com. Published February 09, 2022. Accessed February 23, 2022.

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.