

## Clinical Policy: Testing for Select Genitourinary Conditions

Reference Number: CP.MP.97

Date of Last Revision: 03/22

Revision Log

See <u>Important Reminder</u> 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 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<sup>®</sup> that the following diagnostic tests for symptomatic women for the evaluation of vaginitis are **medically necessary** for members/enrollees age  $\geq 13$ :
  - 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 preterm 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.<sup>2</sup>
- 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 ( $\leq 4$  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:

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- 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.<sup>3</sup> The infections most frequently associated with vaginitis are bacterial vaginosis (BV), trichomoniasis, and vulvovaginal candidiasis (VVC).<sup>1</sup> Various diagnostic methods are available to identify the etiology of the signs and symptoms of vaginitis.<sup>1</sup>

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.<sup>1</sup> 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.<sup>1</sup> 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.<sup>1</sup>

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. 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. <sup>1,4</sup> BV is the most prevalent cause of vaginal discharge or malodor; however, in a nationally representative survey, most women with BV were asymptomatic. <sup>1,3-4</sup>

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. 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.<sup>1</sup> 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.<sup>1</sup> 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.<sup>1</sup> Additionally, there is no clinical utility for diagnosing BV with cervical pap tests due to their low sensitivity and specificity.<sup>1</sup>

#### 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.<sup>3,5-6</sup> 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.<sup>1</sup>

A diagnosis of Candida vaginitis is suggested clinically by the presence of external dysuria and vulvar pruritus, pain, swelling, and redness.<sup>5</sup> Signs include vulvar edema, fissures, excoriations, or thick, curdy vaginal discharge.<sup>5</sup> 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.<sup>5,7</sup> Candida vaginitis is associated with a normal vaginal pH (<4.5), so pH testing is not a useful diagnostic tool.<sup>3</sup> 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.<sup>5</sup> 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. 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.<sup>5</sup> 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.<sup>1</sup>

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.<sup>1</sup>



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.<sup>8</sup> However, this population is likely to manifest other acquired immune deficiency syndrome –related sentinel conditions.<sup>8</sup> HIV testing of women only for the indication of RVVC is not justified, given that this condition is common in women without HIV.<sup>1,3</sup>

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.<sup>1,11</sup> 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. <sup>11</sup> 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. 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.

## Centers for Disease Control and Prevention (CDC)<sup>1</sup>

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)<sup>2</sup>

The USPFTF does not recommend screening for bacterial vaginosis in pregnant women at low risk for preterm delivery.<sup>2</sup> 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)<sup>4</sup>

ACOG recommends the use of Amsel clinical criteria or Gram stain with Nugent scoring for the diagnosis of bacterial vaginosis.<sup>4</sup> 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;

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• 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.<sup>11</sup>

### **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®* | Description  |
|-------|--|
| Codes |  |
| 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       | Description   |
|-----------------|---|
| Code            |   |
| 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   | Description  |
|-------|--|
| Codes |  |
| 0330U | Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, |
|       | identification of 27 organisms, amplified probe technique, vaginal swab          |



| 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 |
| 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   | Description   |
|-------|---|
| Codes |   |
| 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   | Description   |
|-------|---|
| Codes |   |
| 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.

| CPT code 87481 per |  |
|--------------------|--|
| 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<br>Date | Approval<br>Date |
|--|------------------|------------------|
| Policy developed, reviewed by specialist.                                    | 06/16            | 06/16            |
| Added age restriction of $\geq 13$ , with supporting background information. | 08/16            |                  |
| Removed trichomonas from 1.A. section listing criteria for direct DNA        | 06/17            | 06/17            |
| 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.                                |                  |                  |
| Added CPT 87798 – not otherwise specified amplified DNA probe as             | 08/17            | 09/17            |
| 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-               | 12/17            |                  |
| 10-CM pregnancy code set.  |                  |                  |
| Section I, removed "based on the following indications".                     | 08/18            | 08/18            |
| Background updated with no clinical implications.                            |                  |                  |
| References reviewed and updated.   |                  |                  |
| Removed criteria in I. regarding amplified DNA probe testing for             | 07/19            |                  |
| trichomonas, as the amplified probe for trichomonas does not require         |                  |                  |
| specific symptoms to be present.   |                  |                  |
| Annual review completed. Specialty review completed. Removed                 | 08/19            | 08/19            |
| 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.  |                  |                  |
| Minor rewording in I.A. with no impact on meaning. Table 5: Added            | 07/20            | 08/20            |
| 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.   | <u> </u>         |                  |



| Reviews, Revisions, and Approvals  | Revision<br>Date | Approval<br>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            |
| Added 0330U to the not medically necessary CPT code table 3.   | 08/22            |                  |

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### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible



for the medical advice and treatment of member/enrollees. This clinical policy is not intended to recommend treatment for member/enrollees. Member/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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**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 <u>prior to</u> applying the criteria set forth in this clinical policy. Refer to the CMS website at <a href="http://www.cms.gov">http://www.cms.gov</a> for additional information.

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