Corporate Medical Policy

Diagnosis of Vaginitis including Multi-target PCR Testing AHS – M2057

“Notification”

File Name: diagnosis_of_vaginitis_including_multi_target_pcr_testing

Origination: 01/01/2019

Last CAP Review: n/a

Next CAP Review: 01/01/2020

Last Review: 4/2019

Policy effective July 16, 2019

Description of Procedure or Service

Definition

Vaginitis is defined as inflammation of the vagina with symptoms of discharge, itching and discomfort often due to a disruption of the vaginal microflora. The most common infections are bacterial vaginosis, *Candida* vulvovaginitis, and trichomoniasis (J. D. Sobel, 1999). Other causes include vaginal atrophy in postmenopausal women, cervicitis, foreign body, irritants and allergens (J. Sobel, 2017a).

Bacterial vaginosis (BV) is characterized by a shift in microbial species from the normally dominant hydrogen-peroxide producing *Lactobacillus* species to *Gardnerella vaginalis* and anaerobic commensals (Eschenbach et al., 1989; Hill, 1993; Lamont et al., 2011; Ling et al., 2010; J. Sobel, 2017b).

Vulvovaginal candidiasis (VVC) is characterized by *Candida* species. It is the second most common cause of vaginitis symptoms (after BV) and accounts for approximately one-third of vaginitis cases (J. Sobel, 2017c; Workowski & Bolan, 2015).

Trichomoniasis is caused by the flagellated protozoan *Trichomonas vaginalis*, which principally infects the squamous epithelium in the urogenital tract: vagina, urethra, and paraurethral glands (Kissinger, 2015; J. Sobel, 2017d).

Related Policies:

Cervical Cancer Screening
Diagnostic Testing of Sexually Transmitted Infections
Identification of Microorganisms Using Nucleic Acid Probes
Pathogen Panel Testing

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for diagnosis of vaginitis including multi-target PCR testing when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application
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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When diagnosis of vaginitis including multi-target PCR testing is covered

Testing of pH, testing for the presence of amines, saline wet mount, hydrogen peroxide (KOH) wet mount and microscopic examination of vaginal fluids is considered medically necessary in patients with symptoms of vaginitis.

Direct Probe DNA-based identification of Gardnerella, Trichomonas, and Candida is considered medically necessary in patients with symptoms of vaginitis.

Vaginal culture Candida species is considered medically necessary for the diagnosis of vulvovaginal candidiasis in patients with clinical signs and symptoms of vaginitis and negative findings on wet-mount preparations and a normal pH test.

Measurement of sialidase activity in vaginal fluid is considered medically necessary for the diagnosis of bacterial vaginosis in women with symptoms of vaginitis.

Nucleic Acid Amplification Test (NAAT) or Polymerase Chain Reaction (PCR)-based identification of Trichomonas vaginalis is considered medically necessary in patients with symptoms of vaginitis.

Screening for Trichomonas is considered medically necessary for women with risk factors including: new or multiple partners; history of sexually transmitted diseases (STDs); exchange of sex for payment; or injection drug use.

When diagnosis of vaginitis including multi-target PCR testing is not covered

Polymerase Chain Reaction (PCR) based identification of Candida is considered not medically necessary for any indication.

Screening for trichomoniasis and bacterial vaginosis is considered not medically necessary in asymptomatic patients, including asymptomatic pregnant patients at average or high risk for premature labor.

Rapid identification of Trichomonas by enzyme immunoassay is considered investigational in patients with symptoms of vaginitis.

PCR testing and Multitarget polymerase chain reaction (PCR) testing for diagnosis of bacterial vaginosis is considered investigational.

Using molecular-based panel testing, including, but not limited to testing such as SmartJane™, to test for microorganisms involved in vaginal flora imbalance and/or infertility is considered investigational.

Policy Guidelines

Background

The squamous epithelium of the vagina in premenopausal women is rich in glycogen, a substrate for lactobacilli, which create an acidic vaginal environment (pH 4.0 to 4.5). This acidity helps maintain the normal vaginal flora and inhibits growth of pathogenic organisms. Disruption of the normal ecosystem by menstrual cycle, sexual activity, contraceptive, pregnancy, foreign bodies, estrogen level, sexually transmitted diseases, and use of hygienic products or antibiotics can lead development of vaginitis. Bacterial vaginosis, vulvovaginal candidiasis, and trichomoniasis are the three most common infections responsible for vaginitis. Other causes include: vaginal atrophy in postmenopausal women, cervicitis, foreign body, irritants and allergens(J. Sobel, 2017a).
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Laboratory documentation of the etiology of vaginitis is important before initiating therapy, given the nonspecific nature considerable overlap of the symptoms (Anderson, Klink, & Cohrssen, 2004; Ellis, Lerch, & Whitcomb, 2001; Landers, Wiesenfeld, Heine, Krohn, & Hillier, 2004) Diagnostic testing enables targeted treatment, increases therapeutic compliance, and increases the likelihood of partner notification (J. Sobel, 2017a; Workowski & Bolan, 2015).

Measurement of vaginal pH is the primary initial finding that drives the diagnostic. The pH of the normal vaginal secretions in premenopausal women with relatively high estrogen levels is 4.0 to 4.5. The pH of normal vaginal secretions in premenarchal and postmenopausal women in whom estrogen levels are low is ≥4.7. An elevated pH in a premenopausal woman suggests infections such as BV (pH>4.5) or trichomoniasis (pH 5 to 6), and helps to exclude Candida vulvovaginitis (pH 4 to 4.5). Vaginal pH may also be altered by lubricating gels, semen, douches, intravaginal medications and in pregnant women, leakage of amniotic fluid. (Anderson et al., 2004; J. Sobel, 2017a)

Microscopic examination of normal vaginal discharge reveals a predominance of squamous epithelial cells, rare polymorphonuclear leukocytes (PMNs), and Lactobacillus species. The primary goal of the examination is to look for candidal buds or hyphae, motile trichomonads, epithelial cells studded with adherent coccobacilli (clue cells), and increased numbers of PMNs.(J. Sobel, 2017a)

Analytical Validity
The microscopic evaluation of BV is usually based on Amsel criteria (Amsel et al., 1983). If clinical criteria are used to define infection, then reported sensitivity ranges from 62 to 100 percent (Spiegel, 1991). Using Gram's stain as the standard for diagnosing BV, the sensitivity of Amsel criteria for diagnosis of BV is over 90 percent and specificity is 77 percent (Landers et al., 2004). Because BV represents complex changes in the vaginal flora, vaginal culture has no role in diagnosis. If microscopy is not available, commercial diagnostic testing methods (eg, rapid antigen and nucleic acid amplification tests) are used for confirming the clinical suspicion of BV. PCR-based assays to quantify BV associated bacteria (Cartwright et al., 2012; Menard, Fenollar, Henry, Bretelle, & Raoult, 2008) have good sensitivity and specificity compared with standard clinical tests (Dumonceaux et al., 2009; Menard et al., 2010). However, they are expensive and of limited utility (J. Sobel, 2017b).

Trichomoniasis can be diagnosed by the presence of motile trichomonads on wet mount, but they are identified in only 60 to 70 percent of culture-confirmed cases. Culture on Diamond's medium was considered the gold standard method for diagnosing T. vaginalis infection (Workowski & Bolan, 2015) however, nucleic acid amplification tests (Baron et al., 2013) have become the accepted gold standard for the diagnosis of T. vaginalis. One study found the sensitivities for T. vaginalis using wet mount, culture, rapid antigen testing, and transcription-mediated amplification testing were 65, 96, 90, and 98 percent, respectively(Huppert et al., 2007). Coexistence of T. vaginalis and BV pathogens is common, with coinfection rates of 60 to 80 percent(J. Sobel, 2017d; J. D. Sobel, Subramanian, Foxman, Fairfax, & Gygax, 2013)

Microscopy is negative in up to 50 percent of patients with culture confirmed VVC (J. D. Sobel, 1985). There are no reliable point of care tests for Candida available in the United States (Abbott, 1995; Chatwani et al., 2007; Dan, Leshem, & Yeshaya, 2010; Hopwood, Evans, & Carney, 1985; Marot-Leblond et al., 2009; Matsui et al., 2009), a culture must be obtained. Polymerase chain reaction (PCR) methods have high sensitivity and specificity and a shorter turn-around time than culture(Diba, Namaki, Ayatolah, & Hanifian, 2012; Mahmoudi Rad, Zafarghandi, Amel Zabihi, Tavallaei, & Mirdamadi, 2012; Tabrizi, Pirotta, Rudland, & Garland, 2006; Weissenbacher et al., 2009), but are costly and offer no proven benefit over culture in symptomatic women (J. Sobel, 2017c).

Clinical Validity and Utility
As previously stated, microscopy rather than bacterial culture, is the standard of care for diagnosing BV, and commercially available tests are available in the absence of microscopy but are not widely used. A study of 176 women using the Affirm VP III test reported comparable results to wet mount examination with no false positives and only three false negatives for T. vaginalis, and three false
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positives and four false negatives for G. vaginalis (Briselden & Hillier, 1994). This test “takes less than one hour to perform and is the best option when findings on physical examination suggest BV… but microscopy cannot be performed to look for clue cells (Sobel, 2018b).”

The OSOM BVBlue chromogenic diagnostic point-of-care test is a CLIA-waived test with a reported 10 minute read time. One study of 173 pregnant women reported a sensitivity and specificity of 94% and 96% respectively, as compared to Gram stain score (Sumeksri, Koprasert, & Panichkul, 2005). These results were comparable to the previously reported values of 91.7% sensitivity and 97.8% specificity in an earlier, smaller study of non-menstruating women (n=57) (Myziuk, Romanowski, & Johnson, 2003). A larger study (n=288 women) reported a sensitivity of 88% and specificity of 91% as compared to the Amstel criteria. The authors of this report concluded that women who “are not in settings where the conventional diagnostic methods are either practical or possible… would greatly benefit from access to rapid and reliable point-of-care tests to improve the diagnosis and management of BV (Bradshaw et al., 2005).”

The FDA approved the use of the BD MAX Vaginal Panel as “an automated qualitative in vitro diagnostic test for the direct detection of DNA targets from bacteria associated with bacterial vaginosis (qualitative results reported based on detection and quantitation of targeted organism markers), Candida species associated with vulvovaginal candidiasis, and Trichomonas vaginalis from vaginal swabs in patients who are symptomatic for vaginitis/vaginosis. The test utilizes real-time polymerase chain reaction (PCR) for the amplification of specific DNA targets and utilizes fluorogenic target-specific hybridization probes to detect and differentiate DNA (FDA, 2016)…” A 2017 cross-sectional, multi-site study into the clinical validation of this system (n=1740 symptomatic women) reported a sensitivity and specificity of 90.9% and 94.1%, respectively, for Candida group and 90.5% sensitivity and 85.8% specificity for bacterial vaginosis. For C. glabrata specifically, the assay had only 75.9% sensitivity but 99.7% specificity. For trichomoniasis, the sensitivity and specificity were 93.1% and 99.3%, respectively (Gaydos et al., 2017). These researchers also compared the results of this test to clinician assessment. Again, to qualify for the study, the women must have at least one symptom of BV. Using Amsel’s criteria, the investigational test sensitivity was 92.7% as compared to the 75.6% sensitivity of the clinician assessment. The authors conclude, “The investigational test showed significantly higher sensitivity for detecting vaginitis, involving more than one cause, than did clinician diagnosis. Taken together, these results suggest that a molecular investigational test can facilitate accurate detection of vaginitis (Schwebke et al., 2018)”. It should be noted, however, that these studies only included symptomatic women, and, therefore, the possible clinical nonspecificity (i.e. instances where an asymptomatic woman would test positive) is not addressed.

SureSwab®(Quest Diagnostics, Inc.) is a multi-target PCR test using RT-PCR to screen for a number of microorganisms involved in vaginal flora imbalances, including B. vaginalis, T. vaginalis, C. albicans, C. glabrata, C. tropicalis, and C. parapsilosis, from a vaginal swab. The swab can be collected either by a physician or the patient (Quest, 2018a). Similarly, Quest Diagnostics also offers the SureSwab® Vaginosis/Vaginitis Plus test, which tests for the presence of Chlamydia trachomatis and Neisseria gonorrhoeae in addition to the microorganisms of the SureSwab® test (Quest, 2018b). The test is based on the unique set of primers synthesized by a CDC research team to identify Candida that purports to diagnose vulvovaginal candidiasis while ruling out other genital infections (CDC, 2016). The CDC research group, led by Dr. C.J. Morrison, developed the DNA probes to identify medically important Candida species by the internal transcribed spacer 2 region of ribosomal DNA. The specific hybridization was measured by a sample-to-background ratio of 58.7, 53.2, 46.9, 59.9, and 54.7 for C. albicans, C. tropicalis, C. glabrata, C. parapsilosis, and C. krusei, respectively. The negative control sample-to-background ratio was 0.9 (Das, Brown, Kellar, Holloway, & Morrison, 2006).

The multiplex PCR assay SmartJane™ measures a specimen’s vaginal flora (such as Lactobacillus iners or Treponema pallidum). The test proposes that the results can provide a health snapshot of the environment tested based on the levels of microorganisms detected. The procedure for the test requires the user to self-sample by collecting a vaginal swab and send the sample back to Ubiome where it is analyzed by their labs. The labs use Precision Sequencing technology to extract DNA from the microorganisms in the sample and Illumina Next-Generation to sequence the targeted genes. Then,
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Phylogenetic algorithms are used to analyze and organize the DNA from those microorganisms. Finally, a clinical report detailing the levels of the targeted microorganisms is sent to the user and medical provider (Ubiome, 2018). The report contains measurements of its targeted microorganisms, whether those measurements are within the normal reference ranges for certain conditions, and whether certain high danger pathogens are present. The manufacturers state that on average SmartJane™ has a sensitivity and specificity for the species of microorganism of 99.4% and 100.0%, respectively. SmartJane™ tests for 19 different HPV strains and common pathological agents involved in sexually transmitted infections in addition to more than 20 different microorganisms involved in bacterial vaginosis, including G. vaginalis (Ubiome, 2017).

Even though studies have shown that PCR methods have a higher specificity and sensitivity than culture and shorter turn-around time in identifying Candida (Diba et al., 2012; Mahmoudi Rad et al., 2012; Tabrizi et al., 2006; Weissenbacher et al., 2009), their use may be adding to clinical nonspecificity. Tabrizi and colleagues reported that PCR “detected four additional Candida albicans, three Candida parapsilosis and one Candida tropicalis when compared with culture. All but one case additionally detected by PCR were found in patients with no VVC symptoms (Tabrizi et al., 2006).” These data support the earlier findings by Giraldo et al. where, unlike culture testing, “Candida was identified by PCR in a similar proportion of patients with previous recurrent vulvovaginal candidiasis (30%) and in controls (28.8%)” (Giraldo et al., 2000).” Taken together, these studies indicate that, even though PCR is more sensitive than culture, it may be identifying cases of Candida in asymptomatic women that may be clinically irrelevant.

Applicable State and Federal Regulations

A search of the term “vaginitis” on the FDA Device database on 01/16/2019 yielded 137 records. Additionally, many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA ‘88). As an LDT, the U. S. Food and Drug Administration has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use.

Guidelines and Recommendations

Centers for Disease Control and Prevention (CDC)

The CDC published recommendations for the evaluation of diseases characterized by vaginal discharge in the 2015 Sexually Transmitted Diseases Treatment Guidelines (CDC, 2015a). They state, “Various diagnostic methods are available to identify the etiology of an abnormal vaginal discharge…In the clinician’s office, the cause of vaginal symptoms might be determined by pH, a potassium hydroxide (KOH) test, and microscopic examination of fresh samples of the discharge” and “In settings where pH paper, KOH, and microscopy are not available, alternative commercially available point-of-care tests or clinical laboratory testing can be used to diagnose vaginitis (CDC, 2015a).”

For the evaluation of BV they recommend: “BV can be diagnosed by the use of clinical criteria (i.e., Amsel’s Diagnostic Criteria) (Amsel et al., 1983) or Gram stain” and state that “Other tests, including Affirm VP III (Becton Dickinson, Sparks, MD), a DNA hybridization probe test for high concentrations of G. vaginalis, and the OSOM BV Blue test (Sekisui Diagnostics, Framingham, MA), which detects vaginal fluid sialidase activity, have acceptable performance characteristics compared with Gram stain. Although a prolineaminopeptidase card test is available for the detection of elevated pH and trimethylamine, it has low sensitivity and specificity and therefore is not recommended. PCR has been used in research settings for the detection of a variety of organisms associated with BV, but evaluation of its clinical utility is still underway. Detection of specific organisms might be predictive of BV by PCR (Cartwright et al., 2012; Fredricks, Fiedler, Thomas, Oakley, & Marrazzo, 2007). Additional validation is needed before these tests can be recommended to diagnose BV. Culture of G. vaginalis is not recommended as a diagnostic tool because it is not specific. Cervical Pap tests have no clinical utility for the diagnosis of BV because of their low sensitivity and specificity.” They also found that “evidence is insufficient to recommend routine screening for BV in asymptomatic pregnant women at...
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high or low risk for preterm delivery for the prevention of preterm birth (CDC, 2015a)”, which is in compliance with the 2008 USPSTF recommendations (USPSTF, 2008).

For the evaluation of vulvovaginal candidiasis, they recommend: “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 be treated. For those with negative wet mounts but existing signs or symptoms, vaginal cultures for Candida should be considered…PCR testing for yeast is not FDA-cleared; culture for yeast remains the gold standard for diagnosis (CDC, 2015c).” They do not address DNA hybridization probe tests.

For the evaluation of Trichomoniasis they recommend: “Diagnostic testing for T. vaginalis should be performed in women seeking care for vaginal discharge… The use of highly sensitive and specific tests is recommended for detecting T. vaginalis. Among women, NAAT is highly sensitive, often detecting three to five times more T. vaginalis infections than wet-mount microscopy, a method with poor sensitivity (51%-65%) (CDC, 2015b; Hollman, Coupey, Fox, & Herold, 2010; Roth et al., 2011).”

Regarding point of care testing, they state that “Other FDA-cleared tests to detect T. vaginalis in vaginal secretions include the OSOM Trichomonas Rapid Test (Sekisui Diagnostics, Framingham, MA), an antigen-detection test using immunochromatographic capillary flow dipstick technology that can be performed at the point of care, and the Affirm VP III (Becton Dickinson, Sparks, MD), a DNA hybridization probe test that evaluates for T. vaginalis, G. vaginalis, and Candida albicans. The results of the OSOM Trichomonas Rapid Test are available in approximately 10 minutes, with sensitivity 82%-95% and specificity 97%-100% (Campbell, Woods, Lloyd, Elsayed, & Church, 2008; Huppert et al., 2007). Self-testing might become an option, as a study of 209 young women aged 14-22 years found that >99% could correctly perform and interpret her own self-test using the OSOM assay, with a high correlation with clinician interpretation (96% agreement, κ = 0.87) (Huppert et al., 2010). The results of the Affirm VP III are available within 45 minutes. Sensitivity and specificity are 63% and 99.9%, respectively, compared with culture and TMA; sensitivity might be higher among women who are symptomatic (Andrea & Chapin, 2011; Brown, Fuller, Jasper, Davis, & Wright, 2004; CDC, 2015b).”

American Academy of Family Physicians

The AAFP published an article (Hainer & Gibson, 2011) on the diagnosis of vaginitis which states that: “Physicians traditionally diagnose vaginitis using the combination of symptoms, physical examination, pH of vaginal fluid, microscopy, and the whiff test. When combined, these tests have a sensitivity and specificity of 81 and 70 percent, respectively, for BV; 84 and 85 percent for vulvovaginal candidiasis; and 85 and 100 percent for trichomoniasis when compared with the DNA probe standard…A cost-effectiveness analysis of diagnostic strategies for vaginitis undiagnosed by pelvic examination, wet-mount preparation, and related office tests showed that the least expensive strategy was to perform yeast culture, gonorrhea and chlamydia probes at the initial visit, and Gram stain and Trichomonas culture only when the vaginal pH exceeded 4.9. Other strategies cost more and increased duration of symptoms by up to 1.3 days (Hainer & Gibson, 2011).”

U.S. Preventive Services Task Force Recommendations

The USPSTF published recommendations (USPSTF, 2008) on screening for BV in pregnancy which state: “The USPSTF recommends against screening for BV in asymptomatic pregnant women at low risk for preterm delivery”. And “The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for BV in asymptomatic pregnant women at high risk for preterm delivery.”

American College of Obstetrics and Gynecology

ACOG published recommendations (ACOG, 2006) for the evaluation of vaginitis in 2006, and reaffirmed in 2017 (ACOG, 2017, 2018), which state: “Evaluation of women with vaginitis should include a focused history about the entire spectrum of vaginal symptoms, including change in
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discharge, vaginal malodor, itching, irritation, burning, swelling, dyspareunia, and dysuria.” “During speculum examination, samples should be obtained for vaginal pH, amine (“whiff”) test, and saline (wet mount) and 10% potassium hydroxide (KOH) microscopy. The pH and amine testing can be performed either through direct measurement or by colorimetric testing.” With a Level B recommendation, they state, “Microscopy is the first line for diagnosing vulvovaginal candidiasis and trichomoniasis. In selected patients, culture for yeast and T. vaginalis should be obtained in addition to standard office-based testing.” Additionally, they state, “A vaginal Gram stain for Nugent scoring of the bacterial flora may help to identify patients with BV. Other currently available ancillary tests for diagnosing vaginal infections include rapid tests for enzyme activity from BV-associated organisms, Trichomonas vaginalis antigen, and point-of-care testing for DNA of G. vaginalis, T. vaginalis, and Candida species; however, the role of these tests in the proper management of patients with vaginitis is unclear. Depending on risk factors, DNA amplification tests can be obtained for Neisseria gonorrhoeae and Chlamydia trachomatis (ACOG, 2006).”

IDSA Clinical Practice Guidelines

IDSA has published an updated clinical guideline (Pappas et al., 2016) for the management of candidiasis in which they recommend diagnosing vulvovaginal candidiasis before proceeding with empiric antifungal therapy. The usual diagnosis is clinical based on signs and symptoms of vaginitis such as pruritus, irritation, vaginal soreness, vulvar edema, erythema and many others. Clinical signs and symptoms are nonspecific and could be attributed to other causes than vulvovaginal candidiasis. Therefore, authors recommend confirming clinical diagnosis by a wet-mount preparation with saline and 10% KOH to demonstrate the presence of yeast and a normal pH. In cases where signs and symptoms are suggestive of vulvovaginal candidiasis, but microscopic findings and pH are negative, culture testing confirms the diagnosis according to published guidelines. Concerning the use of PCR, they discuss the possible use in diagnosing invasive candidiasis even though they state, “Cultures of blood or other samples collected under sterile conditions have long been considered diagnostic gold standards for invasive candidiasis…The role of PCR in testing samples other than blood is not established (Pappas et al., 2016).”

In the 2018 IDSA A guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases, the IDSA states, “For vaginosis (altered vaginal flora) a Gram stain and recently available microbiome-based assays are more specific than culture and probe testing for Gardnerella vaginalis alone… A number of point-of-care tests can be performed from a vaginal discharge specimen while the patient is in the healthcare setting. Although point-of-care tests are popular, the sensitivity and specificity for making a specific diagnosis vary widely and these assays, while rapid, are often diagnostically poor (Miller et al., 2018).” They do note that the FDA has approved the use of the Max Vaginal Panel by Becton Dickinson in symptomatic females. They note, “preliminary data show greater specificity of this approach compared to methods that identify only G. vaginalis, as well as consistency in both reproducible as well as standardized results (Miller et al., 2018).”

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

**Applicable service codes:**

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BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources


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Policy Implementation/Update Information

<table>
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<th>Date</th>
<th>Description</th>
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<td>1/1/19</td>
<td>New policy developed. BCBSNC will provide coverage for diagnosis of vaginitis including multi-target PCR testing when it is determined to be medically necessary because the medical criteria and guidelines are met. Medical Director review 1/1/2019. Policy noticed 1/1/2019 for effective date 4/1/2019. (an)</td>
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<td>5/14/19</td>
<td>Reviewed by Avalon 1st Quarter 2019 CAB. “Using molecular-based panel testing, including, but not limited to testing such as SmartJane™, to test for microorganisms involved in vaginal flora imbalance and/or infertility is considered investigational” was added to list of NonCovered indications. Policy Guidelines updated. Codes 87905 and 0068U added to Billing/Coding section. References added. Medical Director review 4/2019. <strong>Policy noticed 5/14/2019 for effective date 7/16/2019.</strong> (an)</td>
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