Clinical UM Guideline

Subject:	Nucleic Acid Amplification Tests Using Algorithmic Analysis for the Diagnosis of Bacterial Vaginosis		
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Description

Bacterial vaginosis (BV) is a medical condition caused by an imbalance in the normal vaginal flora. Although Gardnerella vaginalis has been associated with BV, there is no single cause. Frequently BV does not produce symptoms, but in symptomatic individuals, the condition can often be diagnosed using clinical and microscopic tests.

This document addresses the use of nucleic acid amplification tests using algorithmic analysis to detect bacterial vaginosis, including assays that also detect Trichomonas vaginalis and/or Candida species. These multiplex assays use proprietary algorithms that are reported as either a positive or negative BV result (or high likelihood), or scoring system (for example, negative, positive, or intermediate) for the likelihood of BV.

Note: This document does not address stand-alone testing for trichomoniasis or vulvovaginal candidiasis.

Clinical Indications

Medically Necessary:

Nucleic acid amplification testing for bacterial vaginosis using algorithmic analysis without separate detection of Trichomonas vaginalis and/or Candida species, is considered **medically necessary** in symptomatic individuals and individuals with a history of recurrent infection when standard diagnostic testing (for example, Amsel criteria, Nugent score, and the Affirm VP III assay) is not available or the results of standard diagnostic testing are indeterminate.

Nucleic acid amplification testing for bacterial vaginosis using algorithmic analysis without separate detection of Trichomonas vaginalis and/or Candida species, is considered **medically necessary** in asymptomatic pregnant individuals with a history of preterm birth when standard diagnostic testing (for example, Amsel criteria, Nugent score, and the Affirm VP III assay) is not available or the results of standard diagnostic testing are indeterminate.

Not Medically Necessary:

Nucleic acid amplification testing for bacterial vaginosis using algorithmic analysis without separate detection of Trichomonas vaginalis and/or Candida species is considered **not medically necessary** when the medically necessary criteria above are not met.

Nucleic acid amplification testing for bacterial vaginosis using algorithmic analysis, with separate detection of Trichomonas vaginalis and/or Candida species, is considered **not medically necessary.**

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

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 Aptima® BV Assay, Hologic Inc
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 BD MAX™ Vaginal Panel, Becton Dickson and Company
81599	Unlisted multianalyte assay with algorithmic analysis [when specified as nucleic acid amplification testing for bacterial vaginosis using an algorithmic assay]

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or when the code describes a procedure designated in the Clinical Indications section as not medically necessary.

When services are also Not Medically Necessary:

CPT

0352U	Infectious disease (bacterial vaginosis and vaginitis), multiplex amplified probe technique, for detection of bacterial vaginosis-associated bacteria (BVAB-2, Atopobium vaginae, and Megasphera type 1), algorithm reported as detected or not detected and separate detection of Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, and trichomonas vaginalis, vaginal-fluid specimen, each result reported as detected or not detected Xpert® Xpress MVP, Cepheid®

ICD-10 Diagnosis

All diagnoses

Discussion/General Information

Bacterial Vaginosis

An optimum vaginal microbiome is comprised of more than 90 lactobacilli. Bacterial vaginosis (BV) occurs when there is a shift in vaginal flora to include a greater proportion of mixed anaerobic bacteria, such as the Gardnerella, Prevotella, and Atopobium species. Most often, BV does not produce symptoms. However, when they do occur, symptoms typically include off-white, thin, homogenous discharge, a vaginal "fishy" odor, or both (Muzny, 2020; USPSTF, 2020).

BV is the most common cause of vaginal symptoms and discharge in reproductive-age women in the United States. The overall prevalence of BV in North America in women of reproductive age is 27.4%, with an even higher prevalence in African American women (33.2%) and Hispanic women (30.7%) than in Caucasian (22.7%) or Asian women (11.1%). Nonpregnant women with BV are at an increased risk of various infections of the female reproductive tract, including pelvic inflammatory disease (PID) and postprocedural gynecologic infections, and have heightened susceptibility to sexually transmitted infections such as human immunodeficiency virus (HIV) and herpes simplex virus type 2. The prevalence of BV among pregnant women ranges from 5.8% to 19.3% but is higher in some races/ethnicities. BV during pregnancy has been associated with adverse obstetrical outcomes including early miscarriage, premature rupture of membranes, preterm labor, preterm delivery, low birth weight, and postpartum complications such as endometritis and wound infections (ACOG, 2020; Koumans, 2007; Muzny, 2020; USPSTF, 2020).

It is important to note that many women (as high as 80%) with BV are asymptomatic. BV can resolve spontaneously and recurs frequently, with or without treatment. Treatment is recommended for symptomatic women and generally involves a course of antibiotic therapy. Antibiotic treatment results in a high rate of remission of symptoms, but recurrences are common within the first year after treatment. Recurrent BV can have a substantial psychosocial impact on women, affecting sexual relationships and quality of life. Although BV-associated bacteria

can be detected on male genitalia, treatment of male sex partners has not been beneficial in preventing the recurrence of BV (ACOG, 2020; Koumans, 2007; Muzny, 2020; USPSTF, 2020; Workowski, 2021).

Characteristics associated with an increased risk of BV include multiple male sexual partners, female sexual partners, having concurrent sexual partners, lack of condom use, douching and being herpes simplex virus type 2 seropositive. Consistent condom usage is associated with a decreased risk (ACOG, 2020; Koumans, 2007; Peebles, 2019; Workowski, 2021).

Diagnosis of BV

BV can be diagnosed using clinical criteria, point-of-care tests, laboratory tests and molecular assays. In the clinician's office, if microscopy is available, the cause of BV can often be determined by utilizing the Amsel criteria. To fulfill the Amsel criteria, an individual must have at least three of the following:

- Homogeneous, thin, grayish-white discharge that smoothly covers the vaginal walls.
- Vaginal pH greater than 4.5.
- Positive whiff-amine test (the presence of a fishy odor when a drop of 10 percent potassium hydroxide (KOH) is added to a fresh sample of vaginal discharge).
- Clue cells on saline wet mount (ACOG, 2020; Amsel 1983).

Gram stain with Nugent scoring is conducted in the laboratory setting and is considered the gold-standard for the diagnosis of BV. The Nugent scoring system assigns a value to different bacterial morphotypes identified on Gram stain of vaginal secretions. Scores valued at 0–3 are interpreted as normal flora; scores ranging from 4–6 are intermediate flora; and scores reported from 7–10 are interpreted as bacterial vaginosis flora. If an intermediate score is obtained, then Amsel criteria are used to dispute or accept the diagnosis of BV (Nugent, 1991). The identification of clue cells on microscopy compares well with Gram stain findings and are the most reliable indicator of BV (ACOG, 2020; Powell, 2014; Workowski, 2021). According to the collaborative guidelines from the European International Union Against Sexually Transmitted Infections (IUSTI) and the World Health Organization (WHO), the Hay-Ison criteria is an alternative method of scoring based on the findings on a Gram-stained smear. The Hay-Ison criteria are quicker and easier to use in clinical practice and do include non-BV-associated bacteria. The Hay-Ison criteria classifies vaginal specimens as follows:

- Grade 0: Only epithelial cells present, no lactobacilli (indicates recent antibiotics).
- Grade 1: Lactobacillus morphotypes predominate, (normal flora).
- Grade 2: Mixed flora, Lactobacilli and Gardnerella or Mobiluncus morphotypes present (indeterminate).
- Grade 3: Predominantly Gardnerella and/or Mobiluncus morphotypes; few or absent Lactobacilli.
- Grade 4: Gram-positive cocci only, no lactobacilli (AV flora), not related to BV (Sherrard, 2018).

Although Gram staining using Nugent scoring is considered the diagnostic standard and demonstrated higher interobserver and intraobserver reproducibility than Amsel's criteria, it is impractical (time consuming to perform), and its use is generally limited to the laboratory or research settings. Microscopy and the Amsel criteria are the preferred methods to diagnosis BV (ACOG, 2020; American Family Physician, 2018; Coleman, 2018). The clinical

value of nucleic acid amplification tests (NAATs) using algorithmic analysis to detect BV over standard diagnostic testing (for example, Amsel criteria, Nugent score, and the Affirm VP III assay) has not been established.

Several professional, medical societies or governmental organizations have published guidelines on the diagnosis, treatment, and screening of BV. At the time of this review, no professional or medical societies recommend the use of NAAT to diagnose BV above standard diagnostic testing (Amsel clinical criteria or Gram stain with Nugent scoring).

In their discussion on the DNA testing for the diagnosis of BV, the American Family Physician concluded:

> Some data show that newer laboratory tests such as DNA and antigen testing for bacterial vaginosis and vulvovaginal candidiasis, or vaginal fluid sialidase testing for bacterial vaginosis, may have similar or better sensitivity and specificity compared with office-based testing. However, more comparisons with diagnostic standard testing (i.e., Gram stain for bacterial vaginosis and culture for vulvovaginal candidiasis) are needed (American Family Physician, 2018).

The IUSTI/WHO Guidelines Group recommends that the current best method to diagnose BV in women is microscopy using the Hay-Ison Criteria (Sherrard, 2018).

The American College of Obstetricians and Gynecologists (ACOG) recommends that Amsel clinical criteria or Gram stain with Nugent scoring be used for the diagnosis of BV and clarifies the most appropriate setting for each:

> In research settings, Gram stain with Nugent scoring is considered the criterion standard for diagnosing bacterial vaginosis; however, it is impractical for most clinical practitioners and, therefore, Amsel criteria typically are used for the diagnosis of bacterial vaginosis. Overdiagnosis of bacterial vaginosis is common and clinical correlation is necessary to avoid overtreatment of a condition that is usually asymptomatic (ACOG, 2020).

ACOG also states:

> Polymerase chain reaction (PCR) has been used in research settings for the detection of G vaginalis as well as a variety of organisms associated with bacterial vaginosis; however, until recently, its use as a clinical diagnostic test for bacterial vaginosis was still investigational. 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. This multiplex PCR panel also can detect other common causes of vaginitis, such as trichomoniasis and candidiasis. Although the clinical

> utility of PCR testing for the diagnosis of bacterial vaginosis is still being evaluated, this single-swab multiplex test may be a promising alternative to microscopy (ACOG, 2020).

In their guidelines on Sexually Transmitted Infections Treatment Guidelines, the Centers for Disease Control and Prevention (CDC) state:

> BV NAATs should be used among symptomatic women only (e.g., women with vaginal discharge, odor, or itch) because their accuracy is not well defined for asymptomatic women. Despite the availability of BV NAATs, traditional methods of BV diagnosis, including the Amsel criteria, Nugent score, and the Affirm VP III assay, remain useful for diagnosing symptomatic BV because of their lower cost and ability to provide a rapid diagnosis" (Workowski 2021).

Clinicians routinely evaluate and treat individuals (both pregnant and nonpregnant) when they are symptomatic for BV. Treatment of BV is recommended for all symptomatic pregnant women because symptomatic BV has been linked to adverse pregnancy outcomes, including premature rupture of membranes, preterm birth, intra-amniotic infection, and postpartum endometritis. Recognized benefits of therapy among affected women are relief of vaginal symptoms and signs of infection. Other potential benefits of treatment include reduction in the risk for acquiring N. gonorrhoeae, C. trachomatis, Trichomonas vaginalis (T. vaginalis), M. genitalium, HIV, HPV, and HSV-2 (USPSTF, 2020; Workowski, 2021).

At the time of this review, several professional or medical societies including, but not limited to ACOG, CDC and WHO support the use of standard diagnostic testing (Amsel clinical criteria or Gram stain with Nugent scoring) to diagnose BV. While none of these organizations currently recommend that NAATs be used to diagnose BV, the CDC acknowledges that NAATs may be considered an important and necessary alternative when microscopy-based diagnostics is not available (Workowski, 2021). An accurate vaginitis diagnosis can be hampered by several factors within the physician's practice. These include, but are not necessarily limited to, subjective and possibly imprecise clinician point-of-care (POC) in-office evaluations; diagnosis based only on an evaluation of the individual's symptoms; and a lack of tools and equipment, such as pH paper, KOH, and microscopy, which are needed to conduct a full workup (Nyirjesy, 2020). NAATs using algorithmic analysis may an acceptable diagnostic option to diagnose BV when standard diagnostic testing is not available.

Screening Asymptomatic Pregnant Women at Risk for Preterm Labor/Delivery

With regards to testing for BV in asymptomatic pregnant women, multiple studies have reported an association between preterm labor/delivery and BV (Hillier, 1995; Laxmi, 2012; Koumans, 2001; Nelson, 2009). However, the cause of preterm delivery is likely multifactorial. According to USPSTF:

> Numerous risk factors are associated with an increased risk for preterm birth. History of a prior preterm delivery is associated with a 2.5-fold higher odds for preterm delivery in

subsequent pregnancies. While bacterial vaginosis during pregnancy is associated with a 2-fold higher odds for preterm delivery, it is not clear that bacterial vaginosis is a cause of preterm delivery. Other additional risk factors for preterm delivery include, but are not limited to, cervical insufficiency, multifetal gestation, young or advanced maternal age, low maternal body mass index (<20, calculated as weight in kilograms divided by height in meters squared), genitourinary infections, HIV infection, and other maternal medical conditions.

The association of these additional risk factors with preterm delivery is small to moderate, and factors can act in isolation or in combination. Preterm birth rates also vary by race/ethnicity in the US; recent data report preterm birth rates of 8.6% among Asian women, 11.8% among Native Hawaiian/Other Pacific Islander women, 9.7% among Hispanic women, 11.5% among American Indian/Alaska Native women, 14.1% among black women, and 9.1% among white women. Among women with a prior preterm delivery, the rate of recurrent preterm delivery in African American women is 4 times higher than the rate of recurrent preterm delivery in white women. Even when these risk factors are present, it is unclear whether screening and treating asymptomatic bacterial vaginosis in pregnant persons at increased risk for preterm delivery prevents preterm delivery (USPSTF, 2020).

At the time of this review, no professional medical organization was identified that supported routine screening for BV in asymptomatic pregnant persons (both those at high risk and those at low risk) to reduce the likelihood of preterm birth. In their 2021 guidelines, (Workowski, 2021), the CDC reported that the treatment of asymptomatic BV among pregnant women at high risk for preterm delivery has been evaluated by several studies and produced mixed results: one demonstrated harm (Odendaal, 2002), two reported no benefit (Carey, 2000, Vermeulen, 1999), and four revealed benefit (Hauth, 1995; Morales, 1994; McDonald, 1997; Ugwumadu, 2003). In a similar fashion, the USPSTF recommends against screening for BV in pregnant persons who are not at increased risk for preterm delivery (pregnant persons with no history of previous preterm delivery or other risk factors for preterm delivery). Additionally, the USPSTF concluded that the current evidence is insufficient to assess the balance of benefits and harms of screening for BV in pregnant persons who are at increased risk for preterm delivery (USPSTF, 2020).

Although the routine screening and treating of asymptomatic pregnant women for BV remains controversial because the available data do not show a consistent benefit to this approach, screening for BV in asymptomatic pregnant individuals who have a history of a previous preterm delivery may result in improved health outcomes for this population of individuals. NAAT provides the most sensitive and medically appropriate modality for BV screening in this population, especially when standard diagnostic testing is not available, or the results of the latter are indeterminate.

Nucleic acid Amplification Tests (NAATs) Using Algorithmic Analysis

Nucleic acid amplification tests (NAATs), such as polymerase chain reaction (PCR) are being investigated as an alternative means to detect of Gardnerella vaginalis as well as a variety of organisms associated with BV in the

clinical setting and when microscopy is unavailable. The limit of detection (LOD) of a NAAT ranges from 10 organisms to $3x10^4$ organisms per ml, depending on the target being examined. These assays are based on identification of specific bacterial nucleic acids and have high sensitivity and specificity for BV (i.e., G. vaginalis, BVAB2, A. vaginae, or Megasphaera type 1) and certain lactobacilli (i.e, Lactobacillus crispatus, Lactobacillus gasseri and Lactobacillus jensenii). Because DNA amplification can be observed in real-time, the need for postamplification analysis is eliminated and chances for sample contamination are diminished. These tests can be performed on either clinician- or self-collected vaginal specimens with results available in less than 24 hours, depending on the availability of the molecular diagnostic platform (Coleman, 2018; Workowski, 2021).

Several CLIA-certified laboratories provide PCR assays including, but not limited to NAATs, to identify bacteria associated with BV. However, at the time of this review, only two NAATs that employ algorithmic analysis for the diagnosis of BV in symptomatic women had received marketing clearance from the United States Food and Drug Administration (FDA): BD Max™ Vaginal Panel, and Aptima® BV Assay.

Aptima BV Assay

The Aptima BV assay (Hologic, San Diego CA) is an in vitro NAAT that utilizes real time transcription-mediated amplification (TMA) for identification and quantitation of ribosomal RNA from bacteria associated with BV, including Lactobacillus (L. gasseri, L. crispatus, and L. jensenii), Gardnerella vaginalis, and Atopobium vaginae. The assay provides a qualitative result for BV and does not report results for individual organisms. The assay is intended to aid in the diagnosis of BV on the automated Panther system using patient-collected or clinician-collected vaginal swab specimens from females with a clinical presentation consistent with vaginitis and/or vaginosis. The Aptima BV Assay was cleared for marketing by the U.S. Food and Drug Administration (K190452) with the BD Max as the predicate device. The Aptima BV assay reported sensitivity and specificity ranging from 95.0% to 97.3% and 85.8% to 89.6%, respectively (using either clinician-collected or patient-collected vaginal swabs) (US FDA 510[K]a); Schwebke 2020).

As mentioned above, nucleic acid amplification testing using algorithmic analysis may be considered an acceptable diagnostic option to diagnose BV when standard diagnostic testing is not available.

BD Max Vaginal Panel

In October 2016, the FDA granted class II designation and marketing authorization for the BD Max Vaginal Panel (Becton, Dickinson, Sparks, MD). The BD MAX Vaginal Panel is carried out on the BD MAX system (a bench-top molecular diagnostics workstation). The panel is an automated assay that utilizes real-time PCR for the amplification of specific DNA targets from bacteria associated with BV including Lactobacillus (L. crispatus, and L. jensenii), Lactobacillus (L. gasseri, L. crispatus, and L. jensenii), Atopobium vaginae, Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), Megasphaera-1, Candida (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata, Candida krusei, and T. vaginalis. The panel reports a positive or negative result for BV based on a quantitative algorithm that ascertains the ratio of vaginal bacteria (i.e., the assay detects BV as a

syndrome, rather than identification based on the presence or absence of specific bacterial species alone). The panel also provides results for Candida group species (C. group), as well as two separate results for C. glabrata and C. krusei, and TV. The BD MAX received FDA marketing clearance (K191957) for the diagnosis of vaginitis in symptomatic women. According to information provided in the FDA Substantial Equivalence Determination Decision Summary for the BD MAX Vaginal Panel, when compared to the reference of a combined Nugent score and Amsel's criteria, the test demonstrated 90.5% sensitivity (95% confidence interval [CI], 88.3% to 92.2%), 85.8% specificity (95% CI, 83% to 88.3%), 89% PPV (95% CI, 87.1 to 90.7), and 87.7% NPV (95% CI, 85.4 to 89.8) for BV (US FDA 510[K]b). The BD Max panel also includes an extension that incudes testing for select causes of vaginitis (*T. vaginalis and Candidiasis species*) (Workowski, 2021).

Historically, wet-mount microscopy has been used as the preferred diagnostic test for T. vaginalis among women, but it has low sensitivity (44%–68%) compared with culture. Culture has a sensitivity of 44%–75% and specificity of < 100%. More recently, researchers have begun exploring the use of more highly sensitive and specific molecular diagnostic options (including NAATs) that can provide accurate results in less time. Several professional, medical societies or governmental organizations including but not limited to ACOG, CDC, the Infectious Diseases Society of America (IDSA) and International Union Against Sexually Transmitted Infections/World Health Organization (IUSTI/WHO), have issued guidance and determined that NAATs are superior to wet mount microscopy and culture and are the preferred test to detect T. vaginalis. However, NAAT testing to detect T. vaginalis can be conducted using stand-alone tests and does not require concurrent assessment of BV (for example, the BD MAX Vaginal Panel). Therefore, nucleic acid amplification testing using algorithmic analysis, with separate detection of T. vaginalis is not required for the diagnosis of BV.

The BD MAX Vaginal Panel also can also be used to identify Candida group species (C. group), as well as two separate results for C. glabrata and C. krusei. In symptomatic individuals, the diagnosis of vulvovaginal candidiasis (VVC), caused by Candida albicans or by other Candida species or yeasts, requires either of the following two findings: 1) visualization of spores, pseudohyphae, or hyphae on wet-mount microscopy or 2) vaginal fungal culture or commercial diagnostic test results positive for Candida species. Diagnosis can be made using microscopy with KOH prep, Gram stain, or, if necessary, culture of vaginal discharge. While Gram stains and KOH preps reveal budding yeasts, Candida glabrata does not form hyphae and may thereby escape microscopic detection. Culture is not necessary if microscopy reveals yeast but should be obtained in: 1) Individuals with clinical features of VVC, who have normal vaginal pH and negative microscopy. 2) Individuals with complicated disease (persistent or recurrent symptoms) because these women may have a nonalbicans strain of Candida that is resistant to azoles (Workowski, 2021).

In their discussion of a NAAT panel employing an algorithmic analysis that can be used to detect BV, trichomoniasis and candidiasis (Gaydos, 2017), ACOG concluded:

> Polymerase chain reaction testing for Candida species offers results within a few hours compared with culture and has comparable sensitivity and specificity (97.7% and 93.2%, respectively).

However, these PCR tests often are considerably more expensive than fungal culture (ACOG, 2020).

Nucleic acid amplification using an algorithmic assay to detect bacterial vaginosis does not require concurrent assessment of candida.

Summary

Nucleic acid amplification tests (NAATs), such as PCR, can detect 10 organisms to $3x10^4$ organisms per ml in a sample. These tests permit quantitation of select bacteria and are work sufficiently well for clinical-collected or patient-collected vaginal samples. These real-time PCRs utilize DNA amplification which can be observed in real-time and eliminate the need for postamplification analysis and minimize the chances for contamination.

NAAT is an important and necessary alternative to microscopy-based diagnostics for all individuals with symptomatic BV. While clinicians have various options to consider when diagnosing BV (for example, the Amsel clinical criteria, Gram stain with Nugent scoring), the use of traditional microscopy-based diagnostics is declining in usage and many offices do not have access to and/or do not use in-office tools. Alternative diagnostic tools are critical to appropriately treating individuals suffering from the symptoms of BV and accommodating clinicians that do not diagnosis or treat BV due to lack of access to microscopy-based resources. Recurrent or persistent BV is not uncommon in treated individuals. Nucleic acid amplification testing using an algorithmic analysis without separate detection of Trichomonas vaginalis and/or Candida species may be considered an acceptable diagnostic option to diagnose BV in symptomatic individuals as well as individuals with a history of recurrent infection when standard diagnostic testing is not available

Several peer-reviewed studies have reported an association between preterm labor/delivery and BV. However, routine screening of asymptomatic pregnant women for BV remains controversial because the available data do not consistently demonstrate benefits with this approach. However, there may be benefits to early screening for BV in asymptomatic pregnant individuals who have a history of a previous preterm delivery. NAAT provides the most sensitive and medically appropriate modality for BV screening in this population, especially when standard diagnostic testing is not available, or the results of the latter are indeterminate. Identifying and characterizing the specific features of the subgroup of individuals who might respond favorably to screening protocols is an active area of investigation.

While NAATs are considered the preferred diagnostic tool for the diagnosis of T. vaginalis in symptomatic women, NAAT testing to detect T. vaginalis can be conducted using stand-alone tests and does not require concurrent assessment of BV. Similarly, the diagnosis of Candida can be made using stand-alone tests and does not require concurrent assessment of BV.

Definitions

Morphotype: A group of bacterial strains within a single species that can be distinguished from other such strains because of morphological characteristics.

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Government Agency, Medical Society, and Other Authoritative Publications:

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
New	08/11/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.