**Letter of Medical Necessity Template for the BD MAX™ Vaginal Panel**

**PLEASE NOTE:** This letter is intended as an example for your consideration and may not include all the information necessary to support your appeal request. The requesting facility is entirely responsible for ensuring the accuracy, adequacy, and supportability of the information provided. You are responsible for providing true, accurate and complete information concerning the applicable diagnosis and procedure codes and the patient's medical record, and ensuring the medical necessity of the procedure.  
 **DISCLAIMER:** Health economic and reimbursement information provided by BD is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. BD encourages providers to submit accurate and appropriate claims for services. It is always the provider’s responsibility to determine medical necessity, the proper site for delivery of any services and to submit appropriate codes, charges, and modifiers for services that are rendered. BD recommends that you consult with your payers, reimbursement specialists and/or legal counsel regarding coding, coverage and reimbursement matters. BD does not promote the use of its products outside their FDA-cleared or FDA-market authorized labels.

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. Providers are responsible for making appropriate decisions related to coding and reimbursement submissions.

BD MAX™ Vaginal Panel is a registered trademark of BD (Becton, Dickinson and Company) or its affiliates. All other trademarks are the property of their respective owners.

**Instructions for completing the sample letter:**

1. Adopt to your facility’s letterhead and ensure it is signed by the laboratory/medical director.
2. Customize the appeals template based on the medical appropriateness of the BD MAX™ Vaginal Panel for your patient. Fields required for customization are **highlighted in yellow**.
3. It is important to provide the most complete and specific information to assist with the appeals process.
4. After you have customized the appeals letter, please make sure to delete any specific instructions for completion that are **highlighted** throughout the letter so the health plan does not misinterpret this as a form letter. Do not include this page with your submission.
5. If you have questions, please contact your BD representative.

[Current Date]

[Medical Director]

[Insurance Name]

[Insurance Address]

[Insurance City, State, Zip Code]

**Patient:** [Patient Name]

**Date of Birth:** [Patient Date of Birth]

**ID Number:** [XXXXX]

**Date of Service:** [XXXXXXX]

**Provider:** [Laboratory Director Name]

**Claim Number:** [XXXXX]

Dear [Medical Director]:

I am writing on behalf of my patient, [Patient Name], to request coverage for testing performed to diagnose the cause(s) of her vaginitis symptoms and determine the presence or absence of DNA from organisms associated with vulvovaginal candidiasis (VVC) and bacterial vaginosis (BV). This test was performed at our [Practice/Laboratory] [Practice/Laboratory Name] in [City, State]. This letter documents the medical necessity for VVC and BV testing by molecular methods and as such provides information about the patient’s medical history. Results from this test were used to guide appropriate medical care for the patient.

**Patient’s History and Symptoms:**

[Patient Name] is a [Age in Years] year old female who had a suspected diagnosis of vaginitis at the time of her visit with her physician as described by the following ICD-10 codes: ***[Direction: Use ICD-10 Codes listed on lab claim form]***

1. [Symptom #1 with ICD-10 code]
2. [Symptom #2 with ICD-10 code]
3. [Symptom #3 with ICD-10 code]
4. [Symptom #4 with ICD-10 code]

***[Direction: If possible add any additional details, such as if the patient had previously had any other testing that was inconclusive or if it is a recurrent condition.]***

**Rationale for Testing:**

We are committed to using diagnostic test methodologies that provide the most accurate information to guide appropriate clinical decision-making.

Pervasive inaccurate and inconsistent diagnosis of vaginitis and BV, due in part to variations in clinical practice, leaves 40% of the women seeking treatment undiagnosed at the initial visit.1 This can lead to continued symptoms, repeat visits, inappropriate treatment, poor antimicrobial stewardship, and unnecessary associated healthcare system costs.[[1]](#endnote-1),[[2]](#endnote-2) In addition to severely irritating symptoms that disrupt quality of life3, these infections have serious risks, including pre-term birth2,4 or low birth-weight babies4, late term miscarriage2, increased risk of STI transmission or acquisition such as HIV,2,4,5,6 and Pelvic Inflammatory Disease (PID)2, as well as increased risks associated with outpatient procedures and inpatient surgeries.2,4

Peer-reviewed published data concludes misdiagnosis of vaginal complaints when relying on clinical diagnosis based on traditional non-molecular diagnostic techniques is rather high with misjudgment of VVC and BV exceeding 60%.7 Although the Amsel criteria for BV and microscopy for VVC are traditional non-molecular methods, these methods do not enhance the diagnostic correctness of clinical diagnosis.[[3]](#endnote-3) While the Nugent Score is another non-molecular method considered for use as a diagnostic tool, this method is limited by its complexity, subjectivity and availability, and does not permit the identification of several bacterial morphotypes associated with BV.[[4]](#endnote-4),9 In addition, the Nugent Score is not standardized and does not permit the identification of several species, leading to misidentification.10Overall, traditional non-molecular methods tend to be subjective and lacking in sensitivity and specificity.7,11 These methods often are highly manual and require a special skillset and volume-related experience not available to all clinicians, resulting in incorrect diagnosis and poor subsequent treatment.7

**Evidence exists in support of improved diagnosis through molecular amplified diagnostic testing for VVC and BV.**

For VVC detection, studies show that multiplex PCR provides a rapid, simple, and reliable alternative to conventional methods to identify common clinical fungal isolates.12 Due to increasing prevalence of azole-resistant *Candida* species, it is critical to evaluate VVC at the species level in order to prescribe appropriate treatment. *Candida* species with inherent or acquired resistance to azole antifungal agents (e.g., *C. glabrata*, *C. krusei*) are frequently observed, with studies identifying these species in approximately 20% of all VVC cases.13

For BV detection, published data concludes that “quantitative determination of the presence of *G. vaginalis*, *A. vaginae*, *Eggerthella*, *Prevotella*, BVAB-2 and *Megasphaera* type-1 as well as the depletion of *Lactobacillus* [is] highly accurate for BV diagnosis. Measurements of abundance of normal and BV microbiota relative to total bacteria in vaginal fluid may provide more accurate BV diagnosis, and be used for test of cure, rather than qualitative detection or absolute counts of BV related microorganisms.”8This conclusion, along with the characterization of BV by both the CDC and ACOG as a polymicrobial condition, supports the use of nucleic acid amplification test (NAAT) technology for detection of BV, and points to the additional need for consideration of the ratio of normal (*Lactobacilli*) flora.

There is a body of evidence that indicates the use of NAAT testing for detection of VVC and BV improves accuracy and objectivity versus non-molecular methods. Because physicians follow guidelines to make treatment decisions for vaginitis and vaginosis based on diagnosis, improving diagnostic accuracy allows physicians to more accurately treat their patients.

I am requesting that [Patient Name] be approved for VVC and BV testing using a PCR-based methodology (Test Code XXXX; CPT Code XXXX) offered by our [Practice/Laboratory] [Practice/Laboratory Name], ***[Direction: list only test component that was denied – VVC and/or BV]*** This test is performed using the FDA-market authorized test for vaginitis, the BD MAX™ Vaginal Panel. The analytical and clinical data was evaluated by the FDA and the test was 510(k) market authorized in 2016. This test “can accurately diagnose most common bacterial, fungal, and protozoan causes of vaginitis. Women and their clinicians seeking accurate diagnosis and appropriate selection of efficacious treatment for symptoms of vaginitis might benefit from this molecular test.”14 The BD MAX™ Vaginal Panel offers an objective testing method with significantly greater sensitivity than traditional methods, which often rely on subjective diagnostic criteria (e.g., Amsel criteria).15 Physicians choose to order this test from our laboratory due to its validated performance and ability to provide them with accurate diagnostic information to guide treatment of their patients.

Testing for VVC and BV ***[Direction: list only test component that was denied – VVC and/or BV]*** using PCR-based technology is medically necessary to obtain an accurate diagnosis for this patient and supports the ordering physician’s ability to make an appropriate treatment decision regarding the use of antifungals and antibiotics for clinical patient management. I hope you will support this letter of medical necessity for [Patient Name]. Please feel free to contact me at [Phone Number] if you have additional questions.

Sincerely,

[Laboratory Director Name], MD

NPI #: [Lab NPI #]

Contact information:

[Lab Name]

[Address]

[City], [State] [Zip]

Contact Phone No.: [Phone Number]

1. Carr P. Cost-Effectiveness of Diagnostic Strategies for Vaginitis. JGIM. 2005. [↑](#endnote-ref-1)
2. Hainer BL, Gibson MV. Vaginitis: diagnosis and treatment. *A Fam Phys.* 2011; 83: 807‐815.

   3Powell K. Vaginal thrush: quality of life and treatments. *Br J Nurs* 2010; 19: 1106‐1111.

   4Sherrard J, Donders G, White D. 2. Editor: Jensen JS. 2011 European (IUSTI/WHO) Guideline on the Management of Vaginal Discharge.

   5Powell AM, Nyirjesy P. Recurrent vulvovaginitis. Best Pract Res Clin Obstet and Gynaecol 2014; 28: 967‐976.

   6Lamont RF, Sobel JD, Akins RA, Hassan SS, Chaiworapongsa T, Kusanovic JP, Romero R. The vaginal microbiome: New information about genital tract flora using molecular based techniques. BJOG 2011;118: 533–549. [↑](#endnote-ref-2)
3. 7Schwiertz A, T. D. Throwing the dice for the diagnosis of vaginal complaints? Annals of Clinical Microbiology and Antimicrobials, 5:4.2006 [↑](#endnote-ref-3)
4. 8Shipitsyna E, Roos A, Datcu R, Hallén A, Fredlund H, et al. (2013) Composition of the Vaginal Microbiota in Women of Reproductive Age – Sensitive and Specific Molecular Diagnosis of Bacterial Vaginosis Is Possible? PLoS ONE 8(4): e60670. doi: 10.1371/journal.pone.0060670

   9Modak et al. J Infect Dev Ctries 2011; 5(5):353-360 10Menard et al. Molecular Quantification of Gardnerella vaginalis and Atopobium vaginae Loads to Predict Bacterial Vaginosis. CID 47: 33‐43; 2008.

   11Chow, L. Vaginitis Diagnosis: An Opportunity to Improve Patient Care, Dark Daily Report, 2010.

   12Luo G, Mitchell TG. Rapid identification of pathogenic fungi directly from cultures by using multiplex PCR. J Clin Microbiol 2002;40(8):2860–2865.  
   13Goncalves, B (2016) Vulvovaginal candidiasis: Epidemiology, microbiology and risk factors. Crit Rev Microbiol. 42(6):905-27.

   14Gaydos et al. Obstet Gynecol. 2017 Jul;130(1):181-189. doi: 10.1097/AOG.0000000000002090.  
   15Schwebke, J. R., Gaydos, C. A., Nyirjesy, P., Paradis, S., Kodsi, S., & Cooper, C. K. (2018). Diagnostic Performance of a Molecular Test versus Clinician Assessment of Vaginitis. Journal of Clinical Microbiology, 56(6), e00252–18. [↑](#endnote-ref-4)