BD MAX™ Vaginal Panel

Reimbursement and market access toolkit

BD

About this toolkit

BD is committed to providing coverage and support to physician offices, hospitals and laboratories that utilize the BD MAX™ Vaginal Panel. As part of this commitment, we have created this toolkit that provides coding guidance, claim submission and appeal process overview, a letter of medical necessity template as well as information on how to access reimbursement support services.

BD MAX™ Vaginal Panel 2023 Coding Reference Guide*

Current Procedural Terminology (CPT®) that may be applicable to the BD MAX™ Vaginal Panel include:		
CPT Code	Description	Medicare National Average
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 Baceria-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	$262.99

Reminder: Vaginal panels made by other manufacturers test for bacterial vaginosis (BV), vulvovaginal candidiasis (VVC) and *Trichomonas vaginalis* (TV). Only those panels that test for a specific combination of markers, such as BD MAX™ Vaginal Panel, may be eligible for reimbursement when billed with CPT® Code 81514. Please see the following Vaginal Panel Assay Overview for more detailed information.

Vaginal Panel Assay Overview

		BD MAX™ Vaginal Panel[1]	Hologic Aptima® BV and CV/TV Assays[2,3]	Cepheid Xpert® Xpress MVP[4]
Bacterial Vaginosis (BV)	*Gardnerella vaginalis*	✓	✓	X
	Lactobacillus spp.	✓ *L. crispatus* and *L. jensenii*	✓ *L. crispatus* and *L. jensenii*, *L. gasseri*	X
	Atopobium vaginae	✓	✓	✓*
	BVAB-2	✓	X	✓
	Megasphaera-1	✓	X	✓
	Reported as	**BV**	**BV**	**BV**
	Reportable results	**POS NEG**	**POS NEG**	**POS NEG**
Vulvovaginal candidiasis (VVC) / Trichomonas vaginalis (TV)	*Candida albicans*	✓	✓	✓
	Candida tropicalis	✓	✓	✓
	Candida parapsilosis	✓	✓	✓
	Candida dubliniensis	✓	✓	✓
	Candida glabrata	✓	✓	✓
	Candida krusei	✓	X	✓
	Trichomonas vaginalis	✓	✓	✓
	Reported as	*Candida* group *C. glabrata* *C. krusei* *T. vaginalis*	*Candida* species group *C. glabrata* *T. vaginalis*	*Candida* spp. *C. glabrata / C. krusei* *T. vaginalis*
	Reportable results	**POS NEG**	**POS NEG**	**DETECTED NOT DETECTED**
Recommended CPT® Code 81514		✓	X	X

1. BD MAX™ Vaginal Panel [Latest Version]
2. Hologic Aptima® BV Assay [Latest Version]
3. Hologic Aptima® CV/TV Assay [Latest Version]
4. Cepheid Xpert® Xpress MVP 510(k) Substantial Equivalence Determination Decision Summary

The Guide to Appealing Claims provides an overview of the appeal process and guidance on how to appeal a denial.

1. Understand the reason for denial

Review the explanation of benefits for the denial reason(s). The most common reasons for denials include:

- Use of incorrect CPT/HCPCS code(s)
- Considered experimental/investigational
- Not medically necessary
- Incorrect number of units billed
- Transposed, missing, or truncated policy numbers
- No prior authorization on file
- Missing prior authorization number on claim
- Patient's insurance mandates the use of a specialty pharmacy

2. Appeal the claim

If appeal information is not included within the denial letter, contact the payer to obtain their appeals process. Elements to consider in your inquiry include:

- Your ability to submit the appeal via fax or electronically (online)
- Address and phone number for appeals department
- Payer-specific timeline and process for responding to appeal requests
- Payer-specific appeals form that must be completed
- Name and phone number of your provider representative
- Name and address of their medical director

3. Monitor the claim

Check with payer to confirm that they have received your request and to determine status of decision. Notify the patient of instances where your office may need his or her involvement Often, the patient, too, can submit an appeal to the payer.

- Understand the denial reason
- Continue to follow up with payer on status of decision

For more information on reimbursement support services, please see back page.

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

This letter of medical necessity is a template that should be customized by the requesting facility with details specific to the patient and appeals situation. It can be used in the following ways:

1. It can be included with the initial claim submission to provide information to the payer regarding patient-specific and test-specific information.
2. It can be used as an appeal if the initial claim is denied.

Instructions for completing the 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 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.
5. If you have questions, please contact your BD representative.

Please note: This letter is intended as an example and may not include all the information necessary to support your appeal request. The requesting facility is responsible for ensuring the accuracy, adequacy, and supportability of the information provided. The requesting facility must provide 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.

Letter of Medical Necessity for the BD MAX™ Vaginal Panel

[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 bacterial vaginosis (BV), vulvovaginal candidiasis (VVC) and *trichomonas vaginalis* (TV). The test was performed at **[Practice/Laboratory]** **[Practice/Laboratory Name]** in **[City, State]**. This letter documents the medical necessity for BV, VVC and TV testing by molecular methods and 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 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.[1,2] In addition to severely irritating symptoms that disrupt quality of life[3], these infections have serious risks, including pre-term birth[2,4] or low birth-weight babies[4], late term

miscarriage[2], 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 did not enhance the diagnostic correctness of clinical diagnosis.[3] Although 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.[4,9] In addition, the Nugent Score is not standardized and does not permit the identification of several species, leading to misidentification.[10] Overall, traditional non-molecular methods tend to be subjective and lacking in sensitivity and specificity.[3,11] [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.[3]

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

For VVC detection, studies show that multiplex polymerase chain reaction (PCR) tests provide a rapid, simple, and reliable alternative to conventional methods to identify common clinical fungal isolates.[12] For BV detection, published data concludes that "quantitative determination of the presence of *G. vaginalis, A. vaginae, Eggerthella, Prevotella,* BVAB2 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."[4] This conclusion 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.

I am requesting that **[Patient Name]** be approved for BV, VVC and TV testing using a PCR-based methodology (Test Code XXXX; CPT Code XXXXX) offered by our **[Practice/Laboratory] [Practice/Laboratory Name]**. This test is performed using the FDA-cleared test for the three most common infectious causes of vaginitis, the BD MAX™ Vaginal Panel. The analytical and clinical data was evaluated by the FDA and the test was cleared 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."[13] 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 BV, VVC and TV 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]

References: 1. Carr P. Cost-Effectiveness of Diagnostic Strategies for Vaginitis. *JGIM*. 2005 Sep;20(9):793-9. **2.** Hainer BL, Gibson MV. Vaginitis: diagnosis and treatment. *A Fam Phys.* 2011;83:807–815. **3.** Powell K. Vaginal thrush: quality of life and treatments. *Br J Nurs* 2010;19:1106–1111. **4.** Sherrard J, Wilson J, Donders G, Mendling W, Jensen JS. 2018 European (IUSTI/WHO) International Union against sexually transmitted infections (IUSTI) World Health Organisation (WHO) guideline on the management of vaginal discharge. *Int J STD AIDS*. 2018 Nov;29(13):1258–1272. doi: 10.1177/0956462418785451. Epub 2018 Jul 27. PMID: 30049258. **5.** Powell AM, Nyirjesy P. Recurrent vulvovaginitis. *Best Pract Res Clin Obstet and Gynaecol* 2014;28:967–976. **6.** Lamont RF, Sobel JD, Akins RA, et al. The vaginal microbiome: New information about genital tract flora using molecular based techniques. *BJOG* 2011;118:533–549. **7.** Schwiertz A, Taras D, Rusch K, et al. Throwing the dice for the diagnosis of vaginal complaints? *Annals of Clinical Microbiology and Antimicrobials,* 2006;5:4. **8.** Shipitsyna E, Roos A, Datcu R, Hallén A, Fredlund H, et al. Composition of the Vaginal Microbiota in Women of Reproductive Age – Sensitive and Specific Molecular Diagnosis of Bacterial Vaginosis Is Possible? *PLoS ONE* 2013;8:4. e60670. doi: 10.1371/journal.pone.0060670. **9.** Modak et al. *J Infect Dev Ctries* 2011;5(5):353–360. **10.** Menard et al. Molecular Quantification of Gardnerella vaginalis and Atopobium vaginae Loads to Predict Bacterial Vaginosis. *Clinical Infectious Disease* 2008;47:33-43. **11.** Chow, L. Vaginitis Diagnosis: An Opportunity to Improve Patient Care, *Dark Daily Report*, 2010. **12.** Luo G, Mitchell TG. Rapid identification of pathogenic fungi directly from cultures by using microbiol. 2002;40(8):2860–2865. **13.** Gaydos et al. Clinical Validation of a Test for the Diagnosis of Vaginitis. *Obstet Gynecol.* 2017;130(1):181-189..1097/AOG.0000000000002090.

BD MAX™ Vaginal Panel Reimbursement Support Services

Reimbursement support is our commitment to physicians and facilities in their use of BD products

A third-party team* of credentialed professional medical coders is ready to assist with your reimbursement needs including:

- Coding and coverage questions
- Appeals support for denied claims

Providing physicians' offices, hospitals, and laboratories with comprehensive support. Reimbursement Support Services includes:

Reimbursement Hotline**

Answer questions on correct coding practices, insurance coverage, policy guidelines and required documentation.

Appeals Assistance***

Provide personalized appeals support for denied patient Please refer to **Contact us** for more information on how to access this service.

*JDL Access, LLC is the third party vendor that provides the BD MAX™ Vaginal Panel Reimbursement Support Services for BD customers.

**This line receives recorded voicemail messages only and will not be answered by a live representative. Voicemail messages will be responded to by phone within 24-48 hours. E-mail is highly encouraged. Do not share patient protected health information (PHI) under any circumstances.

***A signed Business Associate Agreement (BAA) is required prior to receipt of protected health information (PHI). Under the U.S. Health Insurance Portability and Accountability Act (HIPAA) of 1996, a HIPAA business associate agreement (BAA) is a mandatory contract between a HIPAA-covered entity and a HIPAA business associate (BA) and is required whenever a contractor provides functions, activities, or services involving the use and/or disclosure of PHI. This contract protects the personal health information in accordance with HIPAA guidelines.

Limitations apply.

This document has been prepared for providers using BD products and is intended for informational purposes only, not as guidance or instructions. It does not represent a guarantee, promise, or statement by BD concerning guarantee of payment or levels of reimbursement. It is not intended to increase or maximize reimbursement. The decision as to how to complete a claim form, including the codes chosen and amounts to bill, is exclusively the responsibility of the provider. Coding selection is at the discretion of the provider. It is advised to contact your local payor directly for coding guidance and requirements when reporting codes for BD products.

Contact us:

For reimbursement questions:
reimbursement@bd.com

1.800.637.4065

For appeals assistance:
https://bdassistance.mytrial.me/EnrollmentRequest

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