

## Reimbursement Policy

### Diagnosis of Vaginitis

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#### I. Policy Description

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.<sup>1</sup> Other causes include vaginal atrophy in postmenopausal women, cervicitis, foreign body, irritants, and allergens.<sup>2</sup>

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.<sup>3-7</sup>

Vulvovaginal candidiasis (VVC) is usually caused by *Candida albicans* but can occasionally be caused by other *Candida* species.<sup>8</sup> It is the second most common cause of vaginitis symptoms (after BV) and accounts for approximately one-third of vaginitis cases.<sup>9,10</sup>

Trichomoniasis is caused by the flagellated protozoan *Trichomonas vaginalis*, which principally infects the squamous epithelium in the urogenital tract: vagina, urethra, and paraurethral glands.<sup>11,12</sup>

#### II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

- 1) For individuals with signs and symptoms of vaginitis, testing of pH, testing for the presence of amines, measurement of sialidase activity, saline wet mount, potassium hydroxide (KOH) wet mount, and microscopic examination of vaginal fluids **MEETS COVERAGE CRITERIA.**
- 2) For individuals with signs and symptoms of vaginitis, direct probe DNA-based identification of *Gardnerella*, *Trichomonas*, and *Candida* (e.g., BD Affirm™ VPIII) **MEETS COVERAGE CRITERIA.**

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- 3) For individuals with signs and symptoms of vaginitis but with negative findings on wet-mount preparations and a normal pH test, vaginal cultures for *Candida* species for the diagnosis of vulvovaginal candidiasis **MEET COVERAGE CRITERIA.**

For individuals with signs and symptoms of vaginitis, nucleic acid amplification testing (NAAT) or polymerase chain reaction (PCR)-based identification of *Trichomonas vaginalis* **MEETS COVERAGE CRITERIA.**

- 4) For individuals with risk factors for trichomoniasis (new or multiple partners; history of sexually transmitted infections (STIs), especially HIV; exchange of sex for payment; incarceration; injection drug use), screening for *Trichomonas* **MEETS COVERAGE CRITERIA.**
- 5) For individuals with complicated vulvovaginal candidiasis (VVC), polymerase chain reaction (PCR) based identification of *Candida* to confirm clinical diagnosis and identify non-albicans *Candida* **MEETS COVERAGE CRITERIA.**
- 6) For individuals with signs and symptoms of bacterial vaginosis (BV), NAAT specific to the diagnosis of BV (e.g., Aptima® BV; OneSwab® BV Panel PCR with Lactobacillus Profiling by qPCR; SureSwab® Advanced BV, TMA) and single or multitarget PCR testing for the diagnosis of BV **MEETS COVERAGE CRITERIA.**
- 7) For individuals with signs and symptoms of vaginitis, NAAT panel testing designed to detect more than one type of vaginitis (VVC, BV, and/or trichomoniasis; e.g., BD MAX™ Vaginal Panel, NuSwab® VG, Xpert® Xpress MVP) **MEETS COVERAGE CRITERIA.**
- 8) For asymptomatic individuals, including asymptomatic pregnant individuals at an average or high risk for premature labor, screening for trichomoniasis and bacterial vaginosis **DOES NOT MEET COVERAGE CRITERIA.**

*The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.*

- 9) For individuals with symptoms of vaginitis, rapid identification of *Trichomonas* by enzyme immunoassay **DOES NOT MEET COVERAGE CRITERIA.**
- 10) Testing for microorganisms involved in vaginal flora imbalance and/or infertility using molecular-based panel testing **DOES NOT MEET COVERAGE CRITERIA.**
- 11) All other tests for vaginitis not addressed above **DO NOT MEET COVERAGE CRITERIA.**

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### III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website <https://www.cms.gov/medicare-coverage-database/search.aspx> . For the most up-to-date Medicaid policies and coverage, please visit the applicable state Medicaid website.

#### Food and Drug Administration

On October 28, 2016, the FDA approved an automatic class III designation for the BD MAX™ Vaginal Panel.<sup>38</sup> Following the initial approval, an additional 510(k) Substantial Equivalence Determination Decision Summary was released on October 21, 2019, with the following note: “Routine post market surveillance activities informed BD of an unanticipated high rate of nonreportable result rate for the BD MAX Vaginal Panel. Through investigations, BD identified four design modifications intended to improve the tolerance of the BD MAX Vaginal Panel without significantly impacting the validated clinical and analytical performance. . . One of the four design modifications was determined to be significant with the potential to affect the safety or effectiveness of the device and is the focus of this submission. The cumulative changes require minor modifications to the labeling.”<sup>82</sup>

On May 23, 2019, the FDA approved the use of the Aptima® BV Assay for the detection and identification of bacterial vaginosis. According to the FDA, “the Aptima BV assay is an in vitro nucleic acid amplification test that utilizes real time transcription-mediated amplification<sup>28</sup> for detection and quantitation of ribosomal RNA from bacteria associated with bacterial vaginosis (BV), including *Lactobacillus* (*L. gasseri*, *L. crispatus*, and *L. jensenii*), *Gardnerella vaginalis*, and *Atopobium vaginae*. The assay reports 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 clinician-collected and patient-collected vaginal swab specimens from females with a clinical presentation consistent with vaginitis and/or vaginosis.”<sup>31</sup>

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). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

### IV. Applicable CPT/HCPCS Procedure Codes

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| CPT   | Code Description  |
|-------|---|
| 81513 | Infectious disease, bacterial vaginosis, quantitative real-time amplification of RNA markers for <i>Atopobium vaginae</i> , <i>Gardnerella vaginalis</i> , and <i>Lactobacillus</i> species, utilizing vaginal-fluid specimens, algorithm reported as a positive or negative result for bacterial vaginosis<br>Proprietary test: Aptima® BV Assay<br>Lab/Manufacturer: Hologic, Inc   |
| 81514 | Infectious disease, bacterial vaginosis and vaginitis, quantitative real-time amplification of DNA markers for <i>Gardnerella vaginalis</i> , <i>Atopobium vaginae</i> , <i>Megasphaera</i> type 1, Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), and <i>Lactobacillus</i> species ( <i>L. crispatus</i> and <i>L. jensenii</i> ), utilizing vaginal-fluid specimens, algorithm reported as a positive or negative for high likelihood of bacterial vaginosis, includes separate detection of <i>Trichomonas vaginalis</i> and/or <i>Candida</i> species ( <i>C. albicans</i> , <i>C. tropicalis</i> , <i>C. parapsilosis</i> , <i>C. dubliniensis</i> ), <i>Candida glabrata</i> , <i>Candida krusei</i> , when reported (Do not report 81514 in conjunction with 87480, 87481, 87482, 87510, 87511, 87512, 87660, 87661)<br>Proprietary test: BD MAX™ Vaginal Panel<br>Lab/Manufacturer: Becton Dickson and Company |
| 81515 | Infectious disease, bacterial vaginosis and vaginitis, real-time PCR amplification of DNA markers for <i>Atopobium vaginae</i> , <i>Atopobium</i> species, <i>Megasphaera</i> type 1, and Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), utilizing vaginal-fluid specimens, algorithm reported as positive or negative for high likelihood of bacterial vaginosis, includes separate detection of <i>Trichomonas vaginalis</i> and <i>Candida</i> species ( <i>C. albicans</i> , <i>C. tropicalis</i> , <i>C. parapsilosis</i> , <i>C. dubliniensis</i> ), <i>Candida glabrata</i> / <i>Candida krusei</i> , when reported   |
| 82120 | Amines, vaginal fluid, qualitative  |
| 83986 | pH; body fluid, not otherwise specified   |
| 87070 | Culture, bacterial; any other source except urine, blood or stool, aerobic, with isolation and presumptive identification of isolates   |
| 87149 | Culture, typing; identification by nucleic acid (DNA or RNA) probe, direct probe technique, per culture or isolate, each organism probed  |
| 87150 | Culture, typing; identification by nucleic acid (DNA or RNA) probe, amplified probe technique, per culture or isolate, each organism probed   |

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| CPT   | Code Description   |
|-------|--|
| 87210 | Smear, primary source with interpretation; wet mount for infectious agents (eg, saline, India ink, KOH preps)              |
| 87480 | Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique                           |
| 87481 | Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique                        |
| 87482 | Infectious agent detection by nucleic acid (DNA or RNA); Candida species, quantification                                   |
| 87510 | Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, direct probe technique                     |
| 87511 | Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, amplified probe technique                  |
| 87512 | Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, quantification                             |
| 87660 | Infectious agent detection by nucleic acid (DNA or RNA); Trichomonas vaginalis, direct probe technique                     |
| 87661 | Infectious agent detection by nucleic acid (DNA or RNA); Trichomonas vaginalis, amplified probe technique                  |
| 87797 | Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; direct probe technique, each organism    |
| 87798 | Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism |
| 87799 | Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; quantification, each organism            |
| 87800 | Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; direct probe(s) technique                     |

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| CPT   | Code Description  |
|-------|---|
| 87801 | Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique   |
| 87808 | Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; <i>Trichomonas vaginalis</i>  |
| 87905 | Infectious agent enzymatic activity other than virus (eg, sialidase activity in vaginal fluid)  |
| 0330U | Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab<br>Proprietary test: Bridge Women's Health Infectious Disease Detection Test<br>Lab/Manufacturer: Bridge Diagnostics/ThermoFisher and Hologic Test Kit on Panther Instrument |
| 0505U | Infectious disease (vaginal infection), identification of 32 pathogenic organisms, swab, real-time PCR, reported as positive or negative for each organism<br><br>Proprietary test: Vaginal Infection Testing<br><br>Lab/Manufacturer: NxGen MDx LLC  |
| Q0111 | Wet mounts, including preparations of vaginal, cervical or skin specimens   |

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*Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.*

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