

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

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.³⁻⁷

Vulvovaginal candidiasis (VVC) is usually caused by *Candida albicans* but can occasionally be caused by other *Candida* species.⁸ It is the second most common cause of vaginitis symptoms (after BV) and accounts for approximately one-third of vaginitis cases.^{9,10} For guidance on testing for *Candida* as the cause of onychomycosis, please see AHS-M2172-Onychomycosis Testing.

Trichomoniasis is caused by the flagellated protozoan *Trichomonas vaginalis*, which principally infects the squamous epithelium in the urogenital tract: vagina, urethra, and paraurethral glands.^{11,12} This policy only addresses testing for *T. vaginalis* in vaginitis panels. For guidance on single organism amplified probe testing for *T. vaginalis*, please see AHS-G2157-Diagnostic Testing of Common Sexually Transmitted Infections.

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.**

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- 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.**
- 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.**
- 4) For individuals with complicated vulvovaginal candidiasis (VVC), qualitative polymerase chain reaction (PCR) based identification of *Candida* to confirm clinical diagnosis and identify non-albicans *Candida* **MEETS COVERAGE CRITERIA.**
- 5) 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.**
- 6) For individuals with signs and symptoms of vaginitis, NAAT panel testing (no more than one test every seven days; see Note 1) 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.**
- 7) 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.**
- 8) For all other situations not described above, NAAT testing for *Candida* (e.g., quantitative NAAT testing) **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) Testing for microorganisms involved in vaginal flora imbalance and/or infertility using molecular-based panel testing **DOES NOT MEET COVERAGE CRITERIA.**
- 10) All other tests for vaginitis (e.g., broad molecular panels designed to concurrently test for vaginitis and various other STIs) not addressed above **DO NOT MEET COVERAGE CRITERIA.**

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NOTES:

Note 1: Per CDC recommendations,¹³ the longest minimum treatment for an organism included on the allowed vaginitis panels is a seven day course of antibiotics to treat trichomoniasis. NAAT panel testing for all three types of vaginitis should not be repeated before a minimum treatment window has passed. When symptoms persist despite treatment, individual organism testing may be performed within this window.

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

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.

On October 28, 2016, the FDA approved an automatic class III designation for the BD MAX™ Vaginal Panel.³⁷ 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.”⁸²

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 (TMA) for detection and quantitation of ribosomal RNA from bacteria associated with BV, including *Lactobacillus* (*L. gasseri*, *L. crispatus*, and *L. jensenii*), *Gardnerella vaginalis*, and *Atopobium*

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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.”³⁰

IV. Applicable CPT/HCPCS Procedure Codes

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
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
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
87210	Smear, primary source with interpretation; wet mount for infectious agents (e.g., saline, India ink, KOH preps)
87480	Infectious agent detection by nucleic acid (DNA or RNA); <i>Candida</i> species, direct probe technique
87481	Infectious agent detection by nucleic acid (DNA or RNA); <i>Candida</i> species, amplified probe technique

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CPT	Code Description
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
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
87801	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique
87905	Infectious agent enzymatic activity other than virus (e.g., sialidase activity in vaginal fluid)
0068U	Candida species panel (C. albicans, C. glabrata, C. parapsilosis, C. krusei, C. tropicalis, and C. auris), amplified probe technique with qualitative report of the presence or absence of each species Proprietary test: MYCODART-PCR™ Dual Amplification Real Time PCR Panel for 6 Candida species Lab/Manufacturer: RealTime Laboratories, Inc/MycoDART, Inc
0505U	Infectious disease (vaginal infection), identification of 32 pathogenic organisms, swab, real-time PCR, reported as positive or negative for each organism Proprietary test: Vaginal Infection Testing Lab/Manufacturer: NxGen MDx LLC
0557U	Infectious disease (bacterial vaginosis and vaginitis), real-time amplification of DNA markers for Atopobium vaginae, Gardnerella vaginalis, Megasphaera types 1 and 2, bacterial vaginosis associated bacteria-2 and -3 (BVAB-2, BVAB-3), Mobiluncus species, Trichomonas vaginalis, Neisseria gonorrhoeae, Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. glabrata, C. krusei), Herpes simplex viruses 1 and 2, vaginal fluid, reported as detected or not detected for each organism

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CPT	Code Description
	Proprietary test: HealthTrackRx Vaginitis Lab/Manufacturer: HealthTrackRx, Thermo Fisher Scientific
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.

V. Evidence-based Scientific References

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VI. Revision History

Revision Date	Summary of Changes
09/04/2025	Reviewed and Updated: Updated the background, guidelines and recommendations, and evidence-based scientific references. Literature review did not necessitate any modifications to coverage criteria. The following updates were made for clarity and consistency: Individual organism testing for <i>T. vaginalis</i> moved to G2157. Results in removal of CC4, CC5, and CC10. Former CC6, now CC4, added “qualitative” to define the correct type of NAAT testing to be used to screen for <i>Candida</i> infection. Now reads: “4) For individuals with complicated vulvovaginal candidiasis (VVC), qualitative polymerase chain reaction (PCR) based identification of <i>Candida</i> to confirm clinical diagnosis and identify non-<i>albicans</i> <i>Candida</i> MEETS COVERAGE CRITERIA.” Former CC8, now CC6, added “(no more than one test every seven days; see Note 1)”, now reads: “6) For individuals with signs and symptoms of vaginitis, NAAT panel testing (no more than one test every seven days; see Note 1) 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.” New CC8: “8) For all other situations not described above, NAAT testing for <i>Candida</i> (e.g., quantitative NAAT testing) DOES NOT MEET COVERAGE CRITERIA.” Former CC12, now CC10, edited for clarity. Now reads: “10) All other tests for vaginitis (e.g., broad molecular panels designed to concurrently test for vaginitis and various other STIs) not addressed above DO NOT MEET COVERAGE CRITERIA.)

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	New Note 1: “Note 1: Per CDC recommendations, the longest minimum treatment for an organism included on the allowed vaginitis panels is a seven day course of antibiotics to treat trichomoniasis. NAAT panel testing for all three types of vaginitis should not be repeated before a minimum treatment window has passed. When symptoms persist despite treatment, individual organism testing may be performed within this window.” Added CPT code 0068U Removed CPT code 87661, 87808
06/04/2025	Off-Cycle Coding Modification: Added CPT code 0557U (effective date 7/1/2025)