If a conflict arises between a Clinical Payment and Coding Policy and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. "Plan documents" include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. Blue Cross and Blue Shield of Illinois may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSIL has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing Editor, American Medical Association, Current Procedural Terminology, CPT® Assistant, Healthcare Common Procedure Coding System, ICD-10 CM and PCS, National Drug Codes, Diagnosis Related Group guidelines, Centers for Medicare and Medicaid Services National Correct Coding Initiative Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

Diagnosis of Vaginitis

Policy Number: CPCPLAB059

Version 1.0

Approval Date: September 25, 2025

Plan Effective Date: January 1, 2026

Description

The Plan has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

Reimbursement Information:

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 **may be reimbursable**.

2. For individuals with signs and symptoms of vaginitis, direct probe DNA-based identification of *Gardnerella*, *Trichomonas,* and *Candida* (e.g., BD Affirm™ VPIII) **may be reimbursable.**

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 **may be reimbursable**.

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* **may be reimbursable**.

5. For individuals with sign and symptoms of bacterial vaginosis/BV, nucleic acid amplification test/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 **may be reimbursable.**

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) **may be reimbursable**.

7. For asymptomatic individuals, including asymptomatic pregnant individuals at an average or high risk for premature labor, screening for trichomoniasis and bacterial vaginosis **is not reimbursable.**

8. For all other situations not described above, NAAT testing for Candida (e.g., quantitative NAAT testing) **is not reimbursable.**

9. Testing for microorganisms involved in vaginal flora imbalance and/or infertility using molecular-based panel testing **is not reimbursable.**

10. All other tests for vaginitis (e.g., broad molecular panels designed to concurrently test for vaginitis and various other STIs) not addressed above **are not reimbursable.**

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.

Procedure Codes

The following is not an all-encompassing code list. The inclusion of a code does not guarantee it is a covered service or eligible for reimbursement.

Codes
81513, 81514, 81515. 82120, 83986, 87070, 87149, 87150, 87210, 87480, 87481, 87482, 87510, 87511, 87512, 87660, 87797, 87798, 87799, 87800, 87801, 87905, 0068U, 0330U, 0505U, 0557U, Q0111

References:

1) Sobel JD. Vulvovaginitis in healthy women. *Comprehensive therapy*. Jun-Jul 1999;25(6-7):335-46. doi:10.1007/BF02944280
2) Sobel JD. Vaginitis in adults: Initial evaluation. Updated November 6, 2023. https://www.uptodate.com/contents/vaginitis-in-adults-and-adolescents-initial-evaluation
3) Lamont RF, Sobel JD, Akins RA, et al. The vaginal microbiome: new information about genital tract flora using molecular based techniques. *BJOG : an international journal of obstetrics and gynaecology*. Apr 2011;118(5):533-49. doi:10.1111/j.1471-0528.2010.02840.x
4) Eschenbach DA, Davick PR, Williams BL, et al. Prevalence of hydrogen peroxide-producing Lactobacillus species in normal women and women with bacterial vaginosis. *Journal of clinical microbiology*. Feb 1989;27(2):251-6. doi:10.1128/jcm.27.2.251-256.1989
5) Ling Z, Kong J, Liu F, et al. Molecular analysis of the diversity of vaginal microbiota associated with bacterial vaginosis. *BMC genomics*. Sep 07 2010;11:488. doi:10.1186/1471-2164-11-488
6) Hill GB. The microbiology of bacterial vaginosis. *American journal of obstetrics and gynecology*. Aug 1993;169(2 Pt 2):450-4. doi:10.1016/0002-9378(93)90339-k
7) Sobel JD. Bacterial vaginosis: Clinical manifestations and diagnoses. Updated February 26, 2025. https://www.uptodate.com/contents/bacterial-vaginosis-clinical-manifestations-and-diagnosis

8) CDC. Vulvovaginal Candidiasis (VVC). Updated July 22, 2021. https://www.cdc.gov/std/treatment-guidelines/candidiasis.htm
9) Workowski KA, Bolan GA. Sexually transmitted diseases treatment guidelines, 2015. *MMWR Recommendations and reports : Morbidity and mortality weekly report Recommendations and reports*. 2015;64(Rr-03):1-137.
10) Sobel JD, Mitchell C. Candida vulvovaginitis: Clinical manifestations and diagnosis. Updated April 10, 2024. https://www.uptodate.com/contents/candida-vulvovaginitis-clinical-manifestations-and-diagnosis
11) Sobel JD, Mitchell C. Trichomoniasis: Clinical manifestations and diagnosis. Updated July 17, 2023. https://www.uptodate.com/contents/trichomoniasis-clinical-manifestations-and-diagnosis
12) Kissinger P. Epidemiology and treatment of trichomoniasis. *Current infectious disease reports*. Jun 2015;17(6):484. doi:10.1007/s11908-015-0484-7
13) CDC. Trichomoniasis. Updated September 21, 2022. https://www.cdc.gov/std/treatment-guidelines/trichomoniasis.htm
14) Paladine HL, Desai UA. Vaginitis: Diagnosis and Treatment. *Am Fam Physician*. 2018;97(5):321-329. https://www.aafp.org/afp/2018/0301/p321.html
15) Jones A. Bacterial Vaginosis: A Review of Treatment, Recurrence, and Disparities. *The Journal for Nurse Practitioners*. 2019/06/01/ 2019;15(6):420-423. doi:10.1016/j.nurpra.2019.03.010
16) Kairys N, Garg M. Bacterial Vaginosis. *StatPearls [Internet]*. StatPearls Publishing; 2024. https://www.ncbi.nlm.nih.gov/books/NBK459216/
17) Landers DV, Wiesenfeld HC, Heine RP, Krohn MA, Hillier SL. Predictive value of the clinical diagnosis of lower genital tract infection in women. *American journal of obstetrics and gynecology*. Apr 2004;190(4):1004-10. doi:10.1016/j.ajog.2004.02.015
18) Anderson MR, Klink K, Cohrssen A. Evaluation of vaginal complaints. *Jama*. Mar 17 2004;291(11):1368-79. doi:10.1001/jama.291.11.1368
19) Ellis I, Lerch MM, Whitcomb DC. Genetic testing for hereditary pancreatitis: guidelines for indications, counselling, consent and privacy issues. *Pancreatology : official journal of the International Association of Pancreatology (IAP) [et al]*. 2001;1(5):405-15. doi:10.1159/000055840
20) Brown H, Drexler M. Improving the Diagnosis of Vulvovaginitis: Perspectives to Align Practice, Guidelines, and Awareness. *Popul Health Manag*. Oct 2020;23(S1):S3-s12. doi:10.1089/pop.2020.0265
21) Diba K, Namaki A, Ayatolahi H, Hanifian H. Rapid identification of drug resistant Candida species causing recurrent vulvovaginal candidiasis. *Medical mycology journal*. 2012;53(3):193-8. doi:10.3314/mmj.53.193
22) Mahmoudi Rad M, Zafarghandi A, Amel Zabihi M, Tavallaee M, Mirdamadi Y. Identification of Candida species associated with vulvovaginal candidiasis by multiplex PCR. *Infectious diseases in obstetrics and gynecology*. 2012;2012:872169. doi:10.1155/2012/872169
23) Tabrizi SN, Pirotta MV, Rudland E, Garland SM. Detection of Candida species by PCR in self-collected vaginal swabs of women after taking antibiotics. *Mycoses*. 2006;49(6):523-4. doi:10.1111/j.1439-0507.2006.01312.x
24) Weissenbacher T, Witkin SS, Ledger WJ, et al. Relationship between clinical diagnosis of recurrent vulvovaginal candidiasis and detection of Candida species

by culture and polymerase chain reaction. *Archives of gynecology and obstetrics*. Feb 2009;279(2):125-9. doi:10.1007/s00404-008-0681-9
25) Giraldo P, von Nowaskonski A, Gomes FA, Linhares I, Neves NA, Witkin SS. Vaginal colonization by Candida in asymptomatic women with and without a history of recurrent vulvovaginal candidiasis. *Obstetrics and gynecology*. Mar 2000;95(3):413-6. doi:10.1016/s0029-7844(99)00577-3
26) Briselden AM, Hillier SL. Evaluation of affirm VP Microbial Identification Test for Gardnerella vaginalis and Trichomonas vaginalis. *Journal of clinical microbiology*. Jan 1994;32(1):148-52. doi:10.1128/jcm.32.1.148-152.1994
27) Page S. Bacterial Vaginosis and Symptomatic Vaginitis Test. https://www.ruclear.co.uk/testing/bacterial-vaginosis/
28) Hologic. Accurate Testing for Vaginitis. https://hologicwomenshealth.com/vaginitis/
29) Schwebke JR, Taylor SN, Ackerman R, et al. Clinical Validation of the Aptima Bacterial Vaginosis and Aptima Candida/Trichomonas Vaginitis Assays: Results from a Prospective Multicenter Clinical Study. *Journal of clinical microbiology*. Jan 28 2020;58(2)doi:10.1128/jcm.01643-19
30) FDA. 510(k) Substantial Equivalence Determination Decision Memorandum: Aptima BV Assay. https://www.accessdata.fda.gov/cdrh_docs/reviews/K190452.pdf
31) MDLabs. 166 Bacterial Vaginosis Panel by Real-Time PCR (with Lactobacillus Profiling by qPCR). https://www.mdlab.com/resources/testing-menu/?code=166
32) Fredricks DN, Fiedler TL, Thomas KK, Oakley BB, Marrazzo JM. Targeted PCR for detection of vaginal bacteria associated with bacterial vaginosis. *Journal of clinical microbiology*. Oct 2007;45(10):3270-6. doi:10.1128/JCM.01272-07
33) Quest. SureSwab® Advanced Bacterial Vaginosis (BV), TMA. https://testdirectory.questdiagnostics.com/test/test-detail/10016/sureswab-advanced-bacterial-vaginosis-bv-tma?q=sureswab&cc=MASTER
34) Sekisui Diagnostics. OSOM® BVBLUE® Test. https://sekisuidiagnostics.com/products-all/osom-bvblue-test/
35) Quest. SureSwab® Advanced Vaginitis, TMA. https://testdirectory.questdiagnostics.com/test/test-detail/10119/sureswab-advanced-vaginitis-tma?p=r&q=sureswab&cc=MASTER
36) Quest. SureSwab® Advanced Vaginitis Plus, TMA. https://testdirectory.questdiagnostics.com/test/test-detail/10120/sureswab-advanced-vaginitis-plus-tma?q=sureswab&cc=MASTER
37) FDA. Evaluation of Automatic Class III Designation for BD MAX Vaginal Panel. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160001.pdf
38) Amsel R, Totten PA, Spiegel CA, Chen KC, Eschenbach D, Holmes KK. Nonspecific vaginitis. Diagnostic criteria and microbial and epidemiologic associations. *The American journal of medicine*. Jan 1983;74(1):14-22. doi:10.1016/0002-9343(83)91112-9
39) Spiegel CA. Bacterial vaginosis. *Clinical microbiology reviews*. Oct 1991;4(4):485-502. doi:10.1128/CMR.4.4.485
40) Amegashie CP, Gilbert NM, Peipert JF, Allsworth JE, Lewis WG, Lewis AL. Relationship between nugent score and vaginal epithelial exfoliation. *PLoS One*. 2017;12(5):e0177797. doi:10.1371/journal.pone.0177797

41) Menard JP, Fenollar F, Henry M, Bretelle F, Raoult D. Molecular quantification of Gardnerella vaginalis and Atopobium vaginae loads to predict bacterial vaginosis. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*. Jul 01 2008;47(1):33-43. doi:10.1086/588661
42) Cartwright CP, Lembke BD, Ramachandran K, et al. Development and validation of a semiquantitative, multitarget PCR assay for diagnosis of bacterial vaginosis. *Journal of clinical microbiology*. Jul 2012;50(7):2321-9. doi:10.1128/jcm.00506-12
43) Menard JP, Mazouni C, Fenollar F, Raoult D, Boubli L, Bretelle F. Diagnostic accuracy of quantitative real-time PCR assay versus clinical and Gram stain identification of bacterial vaginosis. *European journal of clinical microbiology & infectious diseases : official publication of the European Society of Clinical Microbiology*. Dec 2010;29(12):1547-52. doi:10.1007/s10096-010-1039-3
44) Dumonceaux TJ, Schellenberg J, Goleski V, et al. Multiplex detection of bacteria associated with normal microbiota and with bacterial vaginosis in vaginal swabs by use of oligonucleotide-coupled fluorescent microspheres. *Journal of clinical microbiology*. Dec 2009;47(12):4067-77. doi:10.1128/jcm.00112-09
45) Baron EJ, Miller JM, Weinstein MP, et al. A guide to utilization of the microbiology laboratory for diagnosis of infectious diseases: 2013 recommendations by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM)(a). *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*. Aug 2013;57(4):e22-e121. doi:10.1093/cid/cit278
46) Huppert JS, Mortensen JE, Reed JL, et al. Rapid antigen testing compares favorably with transcription-mediated amplification assay for the detection of Trichomonas vaginalis in young women. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*. Jul 15 2007;45(2):194-8. doi:10.1086/518851
47) Sobel JD, Subramanian C, Foxman B, Fairfax M, Gygax SE. Mixed vaginitis-more than coinfection and with therapeutic implications. *Current infectious disease reports*. Apr 2013;15(2):104-8. doi:10.1007/s11908-013-0325-5
48) Sobel JD. Epidemiology and pathogenesis of recurrent vulvovaginal candidiasis. *American journal of obstetrics and gynecology*. Aug 01 1985;152(7 Pt 2):924-35. doi:10.1016/s0002-9378(85)80003-x
49) Dan M, Leshem Y, Yeshaya A. Performance of a rapid yeast test in detecting Candida spp. in the vagina. *Diagnostic microbiology and infectious disease*. May 2010;67(1):52-5. doi:10.1016/j.diagmicrobio.2009.12.010
50) Chatwani AJ, Mehta R, Hassan S, Rahimi S, Jeronis S, Dandolu V. Rapid testing for vaginal yeast detection: a prospective study. *American journal of obstetrics and gynecology*. Apr 2007;196(4):309.e1-4. doi:10.1016/j.ajog.2006.11.025
51) Marot-Leblond A, Nail-Billaud S, Pilon F, Beucher B, Poulain D, Robert R. Efficient diagnosis of vulvovaginal candidiasis by use of a new rapid immunochromatography test. *Journal of clinical microbiology*. Dec 2009;47(12):3821-5. doi:10.1128/jcm.01168-09
52) Hopwood V, Evans EG, Carney JA. Rapid diagnosis of vaginal candidosis by latex particle agglutination. *Journal of clinical pathology*. Apr 1985;38(4):455-8. doi:10.1136/jcp.38.4.455

53) Matsui H, Hanaki H, Takahashi K, et al. Rapid detection of vaginal Candida species by newly developed immunochromatography. *Clinical and vaccine immunology : CVI*. Sep 2009;16(9):1366-8. doi:10.1128/cvi.00204-09
54) Abbott J. Clinical and microscopic diagnosis of vaginal yeast infection: a prospective analysis. *Annals of emergency medicine*. May 1995;25(5):587-91. doi:10.1016/s0196-0644(95)70168-0
55) Lynch T, Peirano G, Lloyd T, et al. Molecular Diagnosis of Vaginitis: Comparing Quantitative PCR and Microbiome Profiling Approaches to Current Microscopy Scoring. *Journal of clinical microbiology*. Sep 2019;57(9)doi:10.1128/jcm.00300-19
56) Cartwright CP, Pherson AJ, Harris AB, Clancey MS, Nye MB. Multicenter study establishing the clinical validity of a nucleic-acid amplification-based assay for the diagnosis of bacterial vaginosis. *Diagnostic microbiology and infectious disease*. Nov 2018;92(3):173-178. doi:10.1016/j.diagmicrobio.2018.05.022
57) Gaydos CA, Beqaj S, Schwebke JR, et al. Clinical Validation of a Test for the Diagnosis of Vaginitis. *Obstetrics and gynecology*. Jul 2017;130(1):181-189. doi:10.1097/aog.0000000000002090
58) Schwebke JR, Gaydos CA, Nyirjesy P, Paradis S, Kodsi S, Cooper CK. Diagnostic Performance of a Molecular Test versus Clinician Assessment of Vaginitis. *Journal of clinical microbiology*. Jun 2018;56(6)doi:10.1128/jcm.00252-18
59) Sherrard J. Evaluation of the BD MAX Vaginal Panel for the detection of vaginal infections in a sexual health service in the UK. *Int J STD AIDS*. Mar 2019;30(4):411-414. doi:10.1177/0956462418815284
60) Sumeksri P, Koprasert C, Panichkul S. BVBLUE test for diagnosis of bacterial vaginosis in pregnant women attending antenatal care at Phramongkutklao Hospital. *J Med Assoc Thai*. Nov 2005;88 Suppl 3:S7-13.
61) Myziuk L, Romanowski B, Johnson SC. BVBlue test for diagnosis of bacterial vaginosis. *Journal of clinical microbiology*. May 2003;41(5):1925-8. doi:10.1128/JCM.41.5.1925-1928.2003
62) Bradshaw CS, Morton AN, Garland SM, Horvath LB, Kuzevska I, Fairley CK. Evaluation of a point-of-care test, BVBlue, and clinical and laboratory criteria for diagnosis of bacterial vaginosis. *Journal of clinical microbiology*. Mar 2005;43(3):1304-8. doi:10.1128/jcm.43.3.1304-1308.2005
63) Anand KV, Pimple SA, Mishra GA, et al. Reliability of conventional Papanicolaou smear in diagnosing bacterial vaginosis among women with clinical genital infection. *South Asian J Cancer*. Jan-Mar 2020;9(1):13-16. doi:10.4103/sajc.sajc_421_18
64) Hilbert DW, Smith WL, Chadwick SG, et al. Development and Validation of a Highly Accurate Quantitative Real-Time PCR Assay for Diagnosis of Bacterial Vaginosis. *Journal of clinical microbiology*. Apr 2016;54(4):1017-24. doi:10.1128/jcm.03104-15
65) Hologic. Aptima® BV and CV/TV Assay. https://hologicwomenshealth.com/products/aptimabvandcvtvassay/
66) FDA Clearance of Aptima BV and Aptima CV/TV Molecular Assays Ushers in New Era of Comprehensive and Objective Diagnostic Testing for Vaginitis. 2019. https://investors.hologic.com/press-releases/press-release-details/2019/FDA-Clearance-of-Aptima-BV-and-Aptima-CVTV-Molecular-Assays-Ushers-in-New-Era-of-Comprehensive-and-Objective-Diagnostic-Testing-for-Vaginitis/default.aspx

67) Richter SS, Otiso J, Goje OJ, et al. Prospective Evaluation of Molecular Assays for Diagnosis of Vaginitis. *Journal of clinical microbiology*. Dec 23 2019;58(1)doi:10.1128/jcm.01264-19
68) Kong AM, Jenkins D, Troeger KA, Kim G, London RS. Diagnostic Testing of Vaginitis: Improving the Value of Care. *Population Health Management*. 2021/08/01 2021;24(4):515-524. doi:10.1089/pop.2021.0143
69) Evans A, Fragala MS, Upadhyay P, French A, Goldberg SE, Reddy J. Utilization of Syndromic Vaginitis Diagnostic Testing Reduces 6-Month Follow-Up Outpatient Service Healthcare Costs-A Real-World Data Analysis. *Healthcare (Basel)*. Nov 5 2024;12(22)doi:10.3390/healthcare12222204
70) CDC. Diseases Characterized by Vulvovaginal Itching, Burning, Irritation, Odor or Discharge. Updated July 22, 2021. https://www.cdc.gov/std/treatment-guidelines/vaginal-discharge.htm
71) CDC. Bacterial Vaginosis. Updated July 22, 2021. https://www.cdc.gov/std/treatment-guidelines/bv.htm
72) USPSTF. Bacterial Vaginosis in Pregnant Persons to Prevent Preterm Delivery: Screening. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/bacterial-vaginosis-in-pregnancy-to-prevent-preterm-delivery-screening
73) Hainer BL, Gibson MV. Vaginitis: Diagnosis and Treatment. *American Family Physician*. 2011;83(7):807-815. https://www.aafp.org/pubs/afp/issues/2011/0401/p807.pdf
74) Owens DK, Davidson KW, Krist AH, et al. Screening for Bacterial Vaginosis in Pregnant Persons to Prevent Preterm Delivery: US Preventive Services Task Force Recommendation Statement. *Jama*. Apr 7 2020;323(13):1286-1292. doi:10.1001/jama.2020.2684
75) ACOG. Vaginitis in Nonpregnant Patients: ACOG Practice Bulletin, Number 215. *Obstetrics and gynecology*. Jan 2020;135(1):e1-e17. doi:10.1097/AOG.0000000000003604
76) Pappas PG, Kauffman CA, Andes DR, et al. Clinical Practice Guideline for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*. Feb 15 2016;62(4):e1-50. doi:10.1093/cid/civ933
77) Miller JM, Binnicker MJ, Campbell S, et al. Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2024 Update by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM) ∗. *Clinical Infectious Diseases*. 2024;doi:10.1093/cid/ciae104
78) Yudin MH, Money DM. No. 211-Screening and Management of Bacterial Vaginosis in Pregnancy. *J Obstet Gynaecol Can*. Aug 2017;39(8):e184-e191. doi:10.1016/j.jogc.2017.04.018
79) van Schalkwyk J, Yudin MH. Vulvovaginitis: screening for and management of trichomoniasis, vulvovaginal candidiasis, and bacterial vaginosis. *J Obstet Gynaecol Can*. Mar 2015;37(3):266-274. doi:10.1016/s1701-2163(15)30316-9
80) Australian STI Management Guidelines for Use in Primary Care. Bacterial vaginosis. 2024. https://sti.guidelines.org.au/sexually-transmissible-infections/bacterial-vaginosis/

81) Cornely OA, Sprute R, Bassetti M, et al. Global guideline for the diagnosis and management of candidiasis: an initiative of the ECMM in cooperation with ISHAM and ASM. *The Lancet Infectious Diseases*. 2025;25(5):e280-e293. doi:10.1016/S1473-3099(24)00749-7
82) FDA. 510(k) Substantial Equivalence Determination Decision Summary: BD MAX Vaginal Panel, BD MAX System. https://www.accessdata.fda.gov/cdrh_docs/reviews/K191957.pdf

Policy Update History:

Approval Date	Effective Date; Summary of Changes
09/25/2025	01/01/2026: New policy