

If a conflict arises between a Clinical Payment and Coding Policy (“CPCP”) 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. BCBSNM may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSNM 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 (“HIPAA”) approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing (“UB”) Editor, American Medical Association (“AMA”), Current Procedural Terminology (“CPT®”), CPT® Assistant, Healthcare Common Procedure Coding System (“HCPCS”), ICD-10 CM and PCS, National Drug Codes (“NDC”), Diagnosis Related Group (“DRG”) guidelines, Centers for Medicare and Medicaid Services (“CMS”) National Correct Coding Initiative (“NCCI”) 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 Including Multi-target PCR Testing

Policy Number: CPCPLAB059

Version 1.0

Enterprise Clinical Payment and Coding Policy Committee Approval Date: July 17, 2023

Plan Effective Date: January 1, 2023

Description

BCBSNM 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 symptoms of vaginitis, testing of pH, testing for the presence of amines, saline wet mount, hydrogen peroxide (KOH) wet mount and microscopic examination of vaginal fluids **may be reimbursable**.
2. For individuals with symptoms of vaginitis, direct Probe DNA-based identification of *Gardnerella*, *Trichomonas*, and *Candida* (e.g., BD Affirm™ VP11) **may be reimbursable**.

3. For individuals with clinical 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 symptoms of vaginitis, measurement of sialidase activity in vaginal fluid for the diagnosis of bacterial vaginosis **may be reimbursable**.
5. For individuals with symptoms of vaginitis, nucleic Acid Amplification Test (NAAT) or Polymerase Chain Reaction (PCR)-based identification of *Trichomonas vaginalis* **may be reimbursable**.
6. For individuals with risk factors for *Trichomonas* (new or multiple partners; history of sexually transmitted infections [STIs], especially HIV; exchange of sex for payment; incarceration; or injection drug use) a screening for *Trichomonas* **may be reimbursable**.
7. For individuals with complicated vulvovaginal candidiasis (VVC), Polymerase Chain Reaction (PCR) based identification of *Candida* to confirm clinical diagnosis and identify non-*albicans* *Candida* **may be reimbursable**.
8. For individuals with 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**.
9. NAAT panel testing designed to detect more than one type of vaginitis (VVC, BV, and/or trichomoniasis; e.g., BC MAX™ Vaginal Panel, NuSwab® VG, Xpert® Xpress MVP) **is not reimbursable**.
10. 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**.
11. For individuals with symptoms of vaginitis, rapid identification of *Trichomonas* by enzyme immunoassay **is not reimbursable**.
12. Testing for microorganisms involved in vaginal flora imbalance and/or infertility using molecular-based panel testing **is not reimbursable**.
13. All other tests for vaginitis not addressed above **are not reimbursable**.

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, 82120, 83986, 87070, 87149, 87150, 87210, 87480, 87481, 87482, 87510, 87511, 87512, 87660, 87661, 87797, 87798, 87799, 87800, 87801, 87808, 87905, 0330U, 0352U, Q0111

References:

- Abbott, J. (1995). Clinical and microscopic diagnosis of vaginal yeast infection: a prospective analysis. *Ann Emerg Med*, 25(5), 587-591. <http://dx.doi.org/>
- ACOG. (2006). ACOG Practice Bulletin. Clinical management guidelines for obstetrician-gynecologists, Number 72, May 2006: Vaginitis. *Obstet Gynecol*, 107(5), 1195-1206. <http://dx.doi.org/>
- ACOG. (2017). College Publications. *Obstet Gynecol*, 129(6), 1147-1148. <https://doi.org/10.1097/aog.0000000000002107>
- ACOG. (2018). *Practice Bulletins*. American College of Obstetricians and Gynecologists. Retrieved 01/16/2019 from <https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Bulletins-List>
- ACOG. (2020). Vaginitis in Nonpregnant Patients: ACOG Practice Bulletin, Number 215. *Obstet Gynecol*, 135(1), e1-e17. <https://doi.org/10.1097/AOG.0000000000003604>
- Amegashie, C. P., Gilbert, N. M., Peipert, J. F., Allsworth, J. E., Lewis, W. G., & Lewis, A. L. (2017). Relationship between nugent score and vaginal epithelial exfoliation. *PLoS One*, 12(5), e0177797. <https://doi.org/10.1371/journal.pone.0177797>
- Amsel, R., Totten, P. A., Spiegel, C. A., Chen, K. C., Eschenbach, D., & Holmes, K. K. (1983). Nonspecific vaginitis. Diagnostic criteria and microbial and epidemiologic associations. *Am J Med*, 74(1), 14-22. <http://dx.doi.org/>
- Anand, K. V., Pimple, S. A., Mishra, G. A., Sahare, R. V., Pathuthara, S., Deodhar, K. K., & Shastri, S. S. (2020). Reliability of conventional Papanicolaou smear in diagnosing bacterial vaginosis among women with clinical genital infection. *South Asian J Cancer*, 9(1), 13-16. https://doi.org/10.4103/sajc.sajc_421_18
- Anderson, M. R., Klink, K., & Cohrssen, A. (2004). Evaluation of vaginal complaints. *Jama*, 291(11), 1368-1379. <https://doi.org/10.1001/jama.291.11.1368>
- Baron, E. J., Miller, J. M., Weinstein, M. P., Richter, S. S., Gilligan, P. H., Thomson, R. B., Jr., Bourbeau, P., Carroll, K. C., Kehl, S. C., Dunne, W. M., Robinson-Dunn, B., Schwartzman, J. D., Chapin, K. C., Snyder, J. W., Forbes, B. A., Patel, R., Rosenblatt, J. E., & Pritt, B. S. (2013). 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). *Clin Infect Dis*, 57(4), e22-e121. <https://doi.org/10.1093/cid/cit278>
- Bradshaw, C. S., Morton, A. N., Garland, S. M., Horvath, L. B., Kuzevska, I., & Fairley, C. K. (2005). Evaluation of a point-of-care test, BVBlue, and clinical and laboratory criteria for diagnosis of bacterial vaginosis. *J Clin Microbiol*, 43(3), 1304-1308. <https://doi.org/10.1128/jcm.43.3.1304-1308.2005>
- Briselden, A. M., & Hillier, S. L. (1994). Evaluation of affirm VP Microbial Identification Test for *Gardnerella vaginalis* and *Trichomonas vaginalis*. *J Clin Microbiol*, 32(1), 148-152. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC262986/>

- Brown, H., & Drexler, M. (2020). Improving the Diagnosis of Vulvovaginitis: Perspectives to Align Practice, Guidelines, and Awareness. *Popul Health Manag*, 23(S1), S3-s12. <https://doi.org/10.1089/pop.2020.0265>
- Cartwright, C. P., Lembke, B. D., Ramachandran, K., Body, B. A., Nye, M. B., Rivers, C. A., & Schwebke, J. R. (2012). Development and validation of a semiquantitative, multitarget PCR assay for diagnosis of bacterial vaginosis. *J Clin Microbiol*, 50(7), 2321-2329. <https://doi.org/10.1128/jcm.00506-12>
- Cartwright, C. P., Pherson, A. J., Harris, A. B., Clancey, M. S., & Nye, M. B. (2018). Multicenter study establishing the clinical validity of a nucleic-acid amplification-based assay for the diagnosis of bacterial vaginosis. *Diagn Microbiol Infect Dis*, 92(3), 173-178. <https://doi.org/10.1016/j.diagmicrobio.2018.05.022>
- CDC. (2021a). *Bacterial Vaginosis*. <https://www.cdc.gov/std/treatment-guidelines/bv.htm>
- CDC. (2021b). *Diseases Characterized by Vulvovaginal Itching, Burning, Irritation, Odor or Discharge*. <https://www.cdc.gov/std/treatment-guidelines/vaginal-discharge.htm>
- CDC. (2021c). *Trichomoniasis*. <https://www.cdc.gov/std/treatment-guidelines/trichomoniasis.htm>
- CDC. (2021d). *Vulvovaginal Candidiasis (VVC)*. <https://www.cdc.gov/std/treatment-guidelines/candidiasis.htm>
- Chatwani, A. J., Mehta, R., Hassan, S., Rahimi, S., Jeronis, S., & Dandolu, V. (2007). Rapid testing for vaginal yeast detection: a prospective study. *Am J Obstet Gynecol*, 196(4), 309.e301-304. <https://doi.org/10.1016/j.ajog.2006.11.025>
- Dan, M., Leshem, Y., & Yeshaya, A. (2010). Performance of a rapid yeast test in detecting *Candida* spp. in the vagina. *Diagn Microbiol Infect Dis*, 67(1), 52-55. <https://doi.org/10.1016/j.diagmicrobio.2009.12.010>
- Diagnostics, S. (2023). *OSOM® BVBLUE® Test*. <https://sekisuidiagnostics.com/products-all/osom-bvblue-test/>
- Diba, K., Namaki, A., Ayatollahi, H., & Hanifian, H. (2012). Rapid identification of drug resistant *Candida* species causing recurrent vulvovaginal candidiasis. *Med Mycol J*, 53(3), 193-198. <http://dx.doi.org/>
- Dumonceaux, T. J., Schellenberg, J., Goleski, V., Hill, J. E., Jaoko, W., Kimani, J., Money, D., Ball, T. B., Plummer, F. A., & Severini, A. (2009). Multiplex detection of bacteria associated with normal microbiota and with bacterial vaginosis in vaginal swabs by use of oligonucleotide-coupled fluorescent microspheres. *J Clin Microbiol*, 47(12), 4067-4077. <https://doi.org/10.1128/jcm.00112-09>
- Ellis, I., Lerch, M. M., & Whitcomb, D. C. (2001). Genetic testing for hereditary pancreatitis: guidelines for indications, counselling, consent and privacy issues. *Pancreatology*, 1(5), 405-415. <http://dx.doi.org/>
- Eschenbach, D. A., Davick, P. R., Williams, B. L., Klebanoff, S. J., Young-Smith, K., Critchlow, C. M., & Holmes, K. K. (1989). Prevalence of hydrogen peroxide-producing *Lactobacillus* species in

normal women and women with bacterial vaginosis. *J Clin Microbiol*, 27(2), 251-256.
<http://dx.doi.org/>

FDA. (2016). *EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR BD MAX Vaginal Panel*. U.S. Food and Drug Administration.
https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160001.pdf

FDA. (2019a). *510(k) Substantial Equivalence Determination Decision Memorandum: Aptima BV Assay*. https://www.accessdata.fda.gov/cdrh_docs/reviews/K190452.pdf

FDA. (2019b). *510(k) Substantial Equivalence Determination Decision Summary: BD MAX Vaginal Panel, BD MAX System*. https://www.accessdata.fda.gov/cdrh_docs/reviews/K191957.pdf

Fredricks, D. N., Fiedler, T. L., Thomas, K. K., Oakley, B. B., & Marrazzo, J. M. (2007). Targeted PCR for detection of vaginal bacteria associated with bacterial vaginosis. *J Clin Microbiol*, 45(10), 3270-3276. <https://doi.org/10.1128/JCM.01272-07>

Garrett, N., Mitchev, N., Osman, F., Naidoo, J., Dorward, J., Singh, R., Ngobese, H., Rompalo, A., Mlisana, K., & Mindel, A. (2019). Diagnostic accuracy of the Xpert CT/NG and OSOM Trichomonas Rapid assays for point-of-care STI testing among young women in South Africa: a cross-sectional study. *BMJ Open*, 9(2), e026888. <https://doi.org/10.1136/bmjopen-2018-026888>

Gaydos, C. A., Beqaj, S., Schwebke, J. R., Lebed, J., Smith, B., Davis, T. E., Fife, K. H., Nyirjesy, P., Spurrell, T., Furgerson, D., Coleman, J., Paradis, S., & Cooper, C. K. (2017). Clinical Validation of a Test for the Diagnosis of Vaginitis. *Obstet Gynecol*, 130(1), 181-189.
<https://doi.org/10.1097/aog.0000000000002090>

Giraldo, P., von Nowaskonski, A., Gomes, F. A., Linhares, I., Neves, N. A., & Witkin, S. S. (2000). Vaginal colonization by *Candida* in asymptomatic women with and without a history of recurrent vulvovaginal candidiasis. *Obstet Gynecol*, 95(3), 413-416.
<https://www.ncbi.nlm.nih.gov/pubmed/?term=10711554%5Buid%5D>

Hainer, B. L., & Gibson, M. V. (2011). Vaginitis: Diagnosis and Treatment. *American Family Physician*, 83(7), 807-815. </afp/2011/0401/p807.pdf>

Hilbert, D. W., Smith, W. L., Chadwick, S. G., Toner, G., Mordechai, E., Adelson, M. E., Aguin, T. J., Sobel, J. D., & Gyax, S. E. (2016). Development and Validation of a Highly Accurate Quantitative Real-Time PCR Assay for Diagnosis of Bacterial Vaginosis. *J Clin Microbiol*, 54(4), 1017-1024.
<https://doi.org/10.1128/jcm.03104-15>

Hill, G. B. (1993). The microbiology of bacterial vaginosis. *Am J Obstet Gynecol*, 169(2 Pt 2), 450-454. <http://dx.doi.org/>

Hologic. (2019). *FDA Clearance of Aptima BV and Aptima CV/TV Molecular Assays Ushers in New Era of Comprehensive and Objective Diagnostic Testing for Vaginitis*
<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>

Hologic. (2022). *Aptima® BV and CV/TV Assay*. Hologic, Inc. Retrieved 08/08/2022 from
<https://hologicwomenshealth.com/products/aptimabvandcvtvassay/>

- Hologic. (2023). *Aptima® BV and CV/TV Assay*.
<https://hologicwomenshealth.com/products/aptimabvandcvtvassay/>
- Hopwood, V., Evans, E. G., & Carney, J. A. (1985). Rapid diagnosis of vaginal candidosis by latex particle agglutination. *J Clin Pathol*, *38*(4), 455-458. <http://dx.doi.org/>
- Huppert, J. S., Mortensen, J. E., Reed, J. L., Kahn, J. A., Rich, K. D., Miller, W. C., & Hobbs, M. M. (2007). Rapid antigen testing compares favorably with transcription-mediated amplification assay for the detection of *Trichomonas vaginalis* in young women. *Clin Infect Dis*, *45*(2), 194-198. <https://doi.org/10.1086/518851>
- Jones, A. (2019). Bacterial Vaginosis: A Review of Treatment, Recurrence, and Disparities. *The Journal for Nurse Practitioners*, *15*(6), 420-423. <https://doi.org/https://doi.org/10.1016/j.nurpra.2019.03.010>
- Kairys, N., & Garg, M. (2020). *Bacterial Vaginosis*. StatPearls [Internet]. <https://www.ncbi.nlm.nih.gov/books/NBK459216/>
- Kissinger, P. (2015). Epidemiology and treatment of trichomoniasis. *Curr Infect Dis Rep*, *17*(6), 484. <https://doi.org/10.1007/s11908-015-0484-7>
- Kong, A. M., Jenkins, D., Troeger, K. A., Kim, G., & London, R. S. (2021). Diagnostic Testing of Vaginitis: Improving the Value of Care. *Population Health Management*, *24*(4), 515-524. <https://doi.org/10.1089/pop.2021.0143>
- Lamont, R. F., Sobel, J. D., Akins, R. A., Hassan, S. S., Chaiworapongsa, T., Kusanovic, J. P., & Romero, R. (2011). The vaginal microbiome: new information about genital tract flora using molecular based techniques. *Bjog*, *118*(5), 533-549. <https://doi.org/10.1111/j.1471-0528.2010.02840.x>
- Landers, D. V., Wiesenfeld, H. C., Heine, R. P., Krohn, M. A., & Hillier, S. L. (2004). Predictive value of the clinical diagnosis of lower genital tract infection in women. *Am J Obstet Gynecol*, *190*(4), 1004-1010. <https://doi.org/10.1016/j.ajog.2004.02.015>
- Ling, Z., Kong, J., Liu, F., Zhu, H., Chen, X., Wang, Y., Li, L., Nelson, K. E., Xia, Y., & Xiang, C. (2010). Molecular analysis of the diversity of vaginal microbiota associated with bacterial vaginosis. *BMC Genomics*, *11*, 488. <https://doi.org/10.1186/1471-2164-11-488>
- Lynch, T., Peirano, G., Lloyd, T., Read, R., Carter, J., Chu, A., Shaman, J. A., Jarvis, J. P., Diamond, E., Ijaz, U. Z., & Church, D. (2019). Molecular Diagnosis of Vaginitis: Comparing Quantitative PCR and Microbiome Profiling Approaches to Current Microscopy Scoring. *J Clin Microbiol*, *57*(9). <https://doi.org/10.1128/jcm.00300-19>
- Mahmoudi Rad, M., Zafarhandi, A., Amel Zabihi, M., Tavallaee, M., & Mirdamadi, Y. (2012). Identification of *Candida* species associated with vulvovaginal candidiasis by multiplex PCR. *Infect Dis Obstet Gynecol*, *2012*, 872169. <https://doi.org/10.1155/2012/872169>
- Marot-Leblond, A., Nail-Billaud, S., Pilon, F., Beucher, B., Poulain, D., & Robert, R. (2009). Efficient diagnosis of vulvovaginal candidiasis by use of a new rapid immunochromatography test. *J Clin Microbiol*, *47*(12), 3821-3825. <https://doi.org/10.1128/jcm.01168-09>

Matsui, H., Hanaki, H., Takahashi, K., Yokoyama, A., Nakae, T., Sunakawa, K., & Omura, S. (2009). Rapid detection of vaginal *Candida* species by newly developed immunochromatography. *Clin Vaccine Immunol*, 16(9), 1366-1368. <https://doi.org/10.1128/cvi.00204-09>

MDLabs. (2022). *166 Bacterial Vaginosis Panel by Real-Time PCR (with Lactobacillus Profiling by qPCR)*. <https://www.mdlab.com/resources/testing-menu/?code=166>

MedLabs. (2015). *AMPLISwab™ Women's Health*. MEDLABS DIAGNOSTICS. Retrieved 2/4/2021 from <http://www.medlabdx.com/AmpliSwab.html>

Menard, J. P., Fenollar, F., Henry, M., Bretelle, F., & Raoult, D. (2008). Molecular quantification of *Gardnerella vaginalis* and *Atopobium vaginae* loads to predict bacterial vaginosis. *Clin Infect Dis*, 47(1), 33-43. <https://doi.org/10.1086/588661>

Menard, J. P., Mazouni, C., Fenollar, F., Raoult, D., Boubli, L., & Bretelle, F. (2010). Diagnostic accuracy of quantitative real-time PCR assay versus clinical and Gram stain identification of bacterial vaginosis. *Eur J Clin Microbiol Infect Dis*, 29(12), 1547-1552. <https://doi.org/10.1007/s10096-010-1039-3>

Miller, J. M., Binnicker, M. J., Campbell, S., Carroll, K. C., Chapin, K. C., Gilligan, P. H., Gonzalez, M. D., Jerris, R. C., Kehl, S. C., Patel, R., Pritt, B. S., Richter, S. S., Robinson-Dunn, B., Schwartzman, J. D., Snyder, J. W., Telford, I. I. S., Theel, E. S., Thomson, J. R. B., Weinstein, M. P., & Yao, J. D. (2018). A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2018 Update by the Infectious Diseases Society of America and the American Society for Microbiology. *Clinical Infectious Diseases*, ciy381-ciy381. <https://doi.org/10.1093/cid/ciy381>

Myziuk, L., Romanowski, B., & Johnson, S. C. (2003). BVBlue test for diagnosis of bacterial vaginosis. *J Clin Microbiol*, 41(5), 1925-1928. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC154737/>

Owens, D. K., Davidson, K. W., Krist, A. H., Barry, M. J., Cabana, M., Caughey, A. B., Donahue, K., Doubeni, C. A., Epling, J. W., Jr., Kubik, M., Ogedegbe, G., Pbert, L., Silverstein, M., Simon, M. A., Tseng, C. W., & Wong, J. B. (2020). Screening for Bacterial Vaginosis in Pregnant Persons to Prevent Preterm Delivery: US Preventive Services Task Force Recommendation Statement. *Jama*, 323(13), 1286-1292. <https://doi.org/10.1001/jama.2020.2684>

Paladine, H. L., & Desai, U. A. (2018). Vaginitis: Diagnosis and Treatment. *Am Fam Physician*, 97(5), 321-329. <https://www.aafp.org/afp/2018/0301/p321.html>

Pappas, P. G., Kauffman, C. A., Andes, D. R., Clancy, C. J., Marr, K. A., Ostrosky-Zeichner, L., Reboli, A. C., Schuster, M. G., Vazquez, J. A., Walsh, T. J., Zaoutis, T. E., & Sobel, J. D. (2016). Clinical Practice Guideline for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America. *Clin Infect Dis*, 62(4), e1-50. <https://doi.org/10.1093/cid/civ933>

Quest. (2022a). *SureSwab® Advanced Bacterial Vaginosis (BV), TMA*. Quest Diagnostics, Inc. Retrieved 09/22/2022 from <https://testdirectory.questdiagnostics.com/test/test-detail/10016/sureswab-advanced-bacterial-vaginosis-bv-tma?q=sureswab&cc=MASTER>

Quest. (2022b). *SureSwab® Advanced Vaginitis Plus, TMA*. Quest Diagnostics, Inc. Retrieved 09/09/2022 from <https://testdirectory.questdiagnostics.com/test/test-detail/10120/sureswab-advanced-vaginitis-plus-tma?q=sureswab&cc=MASTER>

Quest. (2022c). *SureSwab® Advanced Vaginitis, TMA*. Quest Diagnostics, Inc. Retrieved 09/09/2022 from <https://testdirectory.questdiagnostics.com/test/test-detail/10119/sureswab-advanced-vaginitis-tma?p=r&q=sureswab&cc=MASTER>

Richter, S. S., Otiso, J., Goje, O. J., Vogel, S., Aebly, J., Keller, G., Van Heule, H., Wehn, D., Stephens, A. L., Zanotti, S., Johnson, T., Leal, S. M., & Procop, G. W. (2019). Prospective Evaluation of Molecular Assays for Diagnosis of Vaginitis. *J Clin Microbiol*, 58(1). <https://doi.org/10.1128/jcm.01264-19>

Schwebke, J. R., Gaydos, C. A., Nyirjesy, P., Paradis, S., Kodsí, S., & Cooper, C. K. (2018). Diagnostic Performance of a Molecular Test versus Clinician Assessment of Vaginitis. *J Clin Microbiol*, 56(6). <https://doi.org/10.1128/jcm.00252-18>

Schwebke, J. R., Taylor, S. N., Ackerman, R., Schlaberg, R., Quigley, N. B., Gaydos, C. A., Chavoustie, S. E., Nyirjesy, P., Remillard, C. V., Estes, P., McKinney, B., Getman, D. K., & Clark, C. (2020). Clinical Validation of the Aptima Bacterial Vaginosis and Aptima Candida/Trichomonas Vaginitis Assays: Results from a Prospective Multicenter Clinical Study. *J Clin Microbiol*, 58(2). <https://doi.org/10.1128/jcm.01643-19>

Sherrard, J. (2019). 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*, 30(4), 411-414. <https://doi.org/10.1177/0956462418815284>

Sobel, J. D. (1985). Epidemiology and pathogenesis of recurrent vulvovaginal candidiasis. *Am J Obstet Gynecol*, 152(7 Pt 2), 924-935. <http://dx.doi.org/>

Sobel, J. D. (1999). Vulvovaginitis in healthy women. *Compr Ther*, 25(6-7), 335-346. <http://dx.doi.org/>

Sobel, J. D. (2023a, 9/4/2020). *Bacterial vaginosis: Clinical manifestations and diagnoses*. Retrieved 1/29/2021 from <https://www.uptodate.com/contents/bacterial-vaginosis-clinical-manifestations-and-diagnosis>

Sobel, J. D. (2023b, 02/09/2022). *Candida vulvovaginitis: Clinical manifestations and diagnosis*. Retrieved 02/09/2022 from <https://www.uptodate.com/contents/candida-vulvovaginitis>

Sobel, J. D. (2023c, 05/16/2022). *Vaginal discharge (vaginitis): Initial evaluation*. <https://www.uptodate.com/contents/vaginal-discharge-vaginitis-initial-evaluation>

Sobel, J. D., & Mitchell, C. (2023, 09/09/2022). *Trichomoniasis*. Retrieved 09/09/2022 from <https://www.uptodate.com/contents/trichomoniasis>

Sobel, J. D., Subramanian, C., Foxman, B., Fairfax, M., & Gygax, S. E. (2013). Mixed vaginitis-more than coinfection and with therapeutic implications. *Curr Infect Dis Rep*, 15(2), 104-108. <https://doi.org/10.1007/s11908-013-0325-5>

Spiegel, C. A. (1991). Bacterial vaginosis. *Clin Microbiol Rev*, 4(4), 485-502. <http://dx.doi.org/>

Tabrizi, S. N., Pirotta, M. V., Rudland, E., & Garland, S. M. (2006). Detection of Candida species by PCR in self-collected vaginal swabs of women after taking antibiotics. In *Mycoses* (Vol. 49, pp. 523-524). <https://doi.org/10.1111/j.1439-0507.2006.01312.x>

USPSTF. (2008). Screening for bacterial vaginosis in pregnancy to prevent preterm delivery: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*, 148(3), 214-219. <http://dx.doi.org/>

van Schalkwyk, J., & Yudin, M. H. (2015). Vulvovaginitis: screening for and management of trichomoniasis, vulvovaginal candidiasis, and bacterial vaginosis. *J Obstet Gynaecol Can*, 37(3), 266-274. [https://doi.org/10.1016/s1701-2163\(15\)30316-9](https://doi.org/10.1016/s1701-2163(15)30316-9)

Weissenbacher, T., Witkin, S. S., Ledger, W. J., Tolbert, V., Ginkelmaier, A., Scholz, C., Weissenbacher, E. R., Friese, K., & Mylonas, I. (2009). Relationship between clinical diagnosis of recurrent vulvovaginal candidiasis and detection of *Candida* species by culture and polymerase chain reaction. *Arch Gynecol Obstet*, 279(2), 125-129. <https://doi.org/10.1007/s00404-008-0681-9>

Workowski, K. A., & Bolan, G. A. (2015). Sexually transmitted diseases treatment guidelines, 2015. *MMWR Recomm Rep*, 64(Rr-03), 1-137. <http://dx.doi.org/>

Yudin, M. H., & Money, D. M. (2017). No. 211-Screening and Management of Bacterial Vaginosis in Pregnancy. *J Obstet Gynaecol Can*, 39(8), e184-e191. <https://doi.org/10.1016/j.jogc.2017.04.018>

Policy Update History:

7/17/2023	Document updated with literature review. Reimbursement information revised for clarity. Added specific NAAT testing language to #8 and #9. References revised; some added, others removed.
11/1/2022	New policy