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Area	Medical Policy
Lines Of Business	All Lines of Business

## Vaginitis Diagnostic Testing

### PURPOSE:

This policy is designed to discuss the medical necessity criteria related to the diagnosis of vaginitis, both bacterial and fungal.

### DEFINITIONS:

Vaginitis: A general term for disorders of the vagina caused by infection, inflammation, or changes in the normal vaginal flora. Symptoms include vaginal discharge, odor, pruritus, and/or discomfort. The initial evaluation typically consists of a history, physical examination, microscopy, and tests for sexually transmitted infections (STIs).

Vulvovaginal candidiasis: One of the most common causes of vulvovaginal itching and discharge. The disorder is characterized by inflammation in the setting of *Candida* species and results in the common vaginitis symptoms of itching and erythema.

Trichomoniasis: A genitourinary infection with the protozoan *Trichomonas vaginalis*. It is the most common non-viral sexually transmitted infection (STI) worldwide. Females are affected more often than males.

Bacterial vaginosis (BV): A clinical condition characterized by a shift in vaginal microbiota away from *Lactobacillus* species toward more diverse bacterial species, including facultative anaerobes. The altered microbiome causes a rise in vaginal pH and symptoms that range from none to very bothersome. Future health implications of BV include, but are not limited to, increased susceptibility to other sexually transmitted infections (STIs), including HIV, and preterm birth.

### PROCEDURE:

Testing for vaginitis may be considered medically necessary for individuals in either of the following clinical settings:

- Symptomatic individuals; OR
- Pregnant individuals that are asymptomatic and have a history of preterm birth.

When the above criteria are met the following types of tests may be medically necessary to aid in the diagnosis of vaginitis:

- Direct or amplified DNA probe testing for *Trichomonas vaginalis*, *Chlamydia trachomatis*, *Gardnerella vaginalis*, *Neisseria gonorrhoeae*
- Direct probe testing for candida species,
- Measurement of vaginal sialidase activity (e.g., Osom BV Blue tets).

All other tests and indications are considered not medically necessary including, but not limited to, the following:

- Screening of asymptomatic individuals,
- Multiplex polymerase chain reaction (PCR) panel testing of genitourinary pathogens, including but not limited to pathogens commonly associated with vaginitis,
- Amplified DNA probe testing for candida species,
- Vaginal pathogen panels,
- Testing the level of vaginal pH, combined with the presence trimethylamine and proline aminopeptidase (e.g., FemExam Test).

**Note:** The Health Plan complies with all Medicare National Coverage Determinations (NCDs) and applicable Local Coverage Determinations (LCDs) for all therapies, items, services, and/or procedures that are covered benefits under Medicare. If the coverage criteria in this policy conflicts with any NCDs or relevant LCD, the relevant document controls the application of services regardless of the version of the NCD or LCD listed in the reference section.

## CODING:

Covered CPT Codes:

CPT Code	Description
87480	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique
87491	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, amplified probe technique
87510	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, direct probe technique
87591	Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, amplified probe technique
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
87905	Infectious agent enzymatic activity other than virus (e.g., sialidase activity in vaginal fluid) [BVBlue test]

Non-covered Codes (This may not be an all-inclusive list):

<b>CPT/HCPCS Code</b>	<b>Description</b>
0068U	Candida species panel (C. albicans, C. glabrata, C. parapsilosis, C. kruseii, C. tropicalis, and C. auris), amplified probe technique with qualitative report of the presence or absence of each species
0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab
0352U	Infectious disease (bacterial vaginosis and vaginitis), multiplex amplified probe technique, for detection of bacterial vaginosis-associated bacteria (BVAB-2, Atopobium vaginae, and Megasphaera type 1), algorithm reported as detected or not detected and separate detection of Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, and trichomonas vaginalis, vaginal-fluid specimen, each result reported as detected or not detected
81513	Infectious disease, bacterial vaginosis, quantitative real-time amplification of RNA markers for Atopobium vaginae, Gardnerella vaginalis, and Lactobacillus 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 Gardnerella vaginalis, Atopobium vaginae, Megasphaera type 1, Bacterial Vaginosis Associated Bacteria-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
82120	Amines, vaginal fluid, qualitative
83986	pH, body fluid, except blood

Covered Diagnosis Codes (This may not be an all-inclusive list):

<b>ICD-10 Code</b>	<b>Description</b>
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A59.01	Trichomonal vulvovaginitis
B96.89	Other specified bacterial agents as the cause of diseases classified elsewhere [Gardnerella vaginitis]
B37.31	Acute candidiasis of vulva and vagina
B37.32	Chronic candidiasis of vulva and vagina
L29.2	Pruritus vulvae
L29.3	Anogenital pruritus, unspecified
N76.0	Acute vaginitis
N76.1	Subacute and chronic vaginitis
N76.2	Acute vulvitis
N76.3	Subacute and chronic vulvitis
N77.1	Vaginitis, vulvitis and vulvovaginitis in diseases classified elsewhere
N89.8	Other specified noninflammatory disorders of vaginitis
Z72.51	High risk heterosexual behavior
Z72.52	High risk homosexual behavior
Z72.53	High risk bisexual behavior

## REFERENCES:

Centers for Disease Control and Prevention (CDC). Morbidity and Mortality Weekly Report. Sexually Transmitted Infections Treatment Guidelines, 2021. Recommendations and Reports / Vol. 70 / No. 4. July 23, 2023. Accessed July 17, 2023.

American College of Obstetrics and Gynecology (ACOG). Practice Bulletin: Vaginitis in Non-pregnant Patients - Number 215. January 2020. Accessed July 17, 2023.

Centers for Disease Control and Prevention (CDC). Sexually Transmitted Infections Treatment Guidelines, 2021: Bacterial Vaginosis. Last reviewed July 22, 2021. Accessed July 18, 2023.

Yudin MH, Money DM. No. 211-Screening and Management of Bacterial Vaginosis in Pregnancy. *J Obstet Gynaecol Can.* 2017;39(8):e184-e191. doi:10.1016/j.jogc.2017.04.018. Accessed July 18, 2023.

van Schalkwyk J, Yudin MH; INFECTIOUS DISEASE COMMITTEE. Vulvovaginitis: screening for and management of trichomoniasis, vulvovaginal candidiasis, and bacterial vaginosis. *J Obstet Gynaecol Can.* 2015;37(3):266-274. doi:10.1016/S1701-2163(15)30316-9. Accessed July 18, 2023.

Sobel JD. Vaginal discharge (vaginitis): Initial evaluation. UpToDate. Last updated October 14, 2022. Accessed July 18, 2023.

Sobel JD, Mitchell C. Candida vulvovaginitis: Clinical manifestations and diagnosis. UpToDate. Last updated May 25, 2023. Accessed July 18, 2023.

Sobel JD, Mitchell C. Trichomoniasis: Clinical manifestations and diagnosis. UpToDate. Last updated July 17, 2023. Accessed July 18, 2023.

Sobel JD, Mitchell C. Bacterial vaginosis: Clinical manifestations and diagnosis. UpToDate. Last Updated Jun 16, 2023. Accessed July 18, 2023.

## **POST-PAYMENT AUDIT STATEMENT:**

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by THP at any time pursuant to the terms of your provider agreement.

## **DISCLAIMER:**

This policy is intended to serve as a guideline only and does not constitute medical advice, any guarantee of payment, plan pre-authorization, an explanation of benefits, or a contract. This policy is intended to address medical necessity guidelines that are suitable for most individuals. Each individual's unique clinical situation may warrant individual consideration based on medical records. Individual claims may be affected by other factors, including but not necessarily limited to state and federal laws and regulations, legislative mandates, provider contract terms, and THP's professional judgment. Reimbursement for any services shall be subject to member benefits and eligibility on the date of service, medical necessity, adherence to plan policies and procedures, claims editing logic, provider contractual agreement, and applicable referral, authorization, notification, and utilization management guidelines. Unless otherwise noted within the policy, THP's policies apply to both participating and non-participating providers and facilities. THP reserves the right to review and revise these policies periodically as it deems necessary in its discretion, and it is subject to change or termination at any time by THP. THP has full and final discretionary authority for its interpretation and application. Accordingly, THP may use reasonable discretion in interpreting and applying this policy to health care services provided in any particular case.

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### **All Revision Dates**

8/11/2023