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# PA.258.MPC Genitourinary Pathogen Nucleic Acid Amplification (NAAT) Panel Testing

Appropriate use of nucleic acid infectious pathogen testing for sexually transmitted infections is determined by statements from Infectious Disease Society of America, Centers for Disease Control, US Preventative Task Force, Centers for Medicare & Medicaid, and professional society recommendations such as American College of Obstetrics & Gynecology.

Maryland Physicians Care **considers Genitourinary Pathogen Nucleic Acid Amplification (NAAT) Panel Testing** medically necessary for Bacterial Vaginosis when:

1. A patient is presenting with symptoms for the first time
2. Has no complicating health factors such as:
    a. Sexual assault;
    b. Pregnancy;
    c. Menopause;
    d. Immunodeficiency
3. A patient has a clear clinical presentation
4. Microscopic analysis is indeterminate, or self-treatment with a microbicide has already occurred

*NOTE: Studies have shown that syndromic diagnosis alone has low to moderate specificity and is insufficient to determine the etiology of vaginitis.*

**Prior Authorization**

***Up to two (2) DNA Amplification Code units are covered without prior authorization. Any additional units beyond the initial two will require prior authorization.***

**Limitations and Exclusions**

Due to insufficient evidence of efficacy, the following are unproven and not medically necessary:

- Amplified DNA probe testing for vulvovaginitis due to Candida
- Multiplex polymerase chain reaction (PCR) panel testing of genitourinary pathogens, including but not limited to pathogens commonly associated with Vaginitis
- Screening of asymptomatic individuals for Vaginitis (Routine screening for Candida and Gardnerella in asymptomatic women).

- Pap smear for the diagnosis of Candida vulvo-vaginitis.

**All other ICD-10-CM Codes not covered include:**

| ICD-10 Code | Description |
|---|---|
| Z01.419 | Encounter for gynecological examination (general) (routine) without abnormal findings |

**The screening of asymptomatic pregnant women for bacterial vaginosis to reduce the likelihood of pre-term birth is considered experimental and investigational and is not covered.**

**Background**

Bacterial Vaginosis (BV), Vaginal Candidiasis, and Trichomonas Vaginosis are the most common causes of Vaginitis. Vaginitis is defined as inflammation or infection of the vagina. Vaginosis is caused by the overgrowth of a number of organisms that are normally found in the vagina. Table 1 describes the main features of these three causes.

**Table 1. Features of Vaginitis/Vaginosis**

| Infection | Discharge | Whiff Test | pH | Microscopy |
|---|---|---|---|---|
| Candida species | Thick, curdy, usually white | Negative | Normal (<4.5) | Yeasts, hyphae |
| Bacterial Vaginosis | Thin, greyish,copious, fishy smell, homogeneous | Positive | Increased (>4.5) | Clue cells, decreased Lactobacilli |
| Trichomonas vaginalis | Frothy, yellow green | Positive | Increased (>4.5) | Protozoa |

The diagnosis of Bacterial Vaginosis (BV) using clinical criteria is performed by assessing a patient swab via wet prep microscopy for at least three out of four of Amsel's Criteria:

1. Abnormal gray discharge
2. Vaginal pH greater than 4.5
3. A positive amine test, and

4. 20% of the epithelial cells being clue cells

These criteria are indicative of the change in flora which allow overgrowth of species such as Gardnerella vaginalis.

**Beginning with microscopy is appropriate and cost effective:**

- If microscopic analysis is indeterminate and/or the clinical picture is complicated by self-treatment, the additional cost of sending a swab for NAAT for the specific organisms suspected may be worth the diagnostic clarity.
- Direct and amplified DNA probe testing for bacterial Vaginosis (i.e., Gardnerella vaginalis) provided microscopy has been completed and still diagnosis is undetermined, or microscopy is not available

BV NAATs should be used among symptomatic women only (e.g., women with vaginal discharge, odor, or itch) because their accuracy is not well defined for asymptomatic women.

The gold standard for diagnosing Bacterial Vaginosis remains Gram staining to evaluate the quantity of normal flora vs BV flora with a Nugent score greater or equal to 7 or meeting Amsel's criteria, which has a sensitivity of 92% and specificity of 75%. This method also confers the advantage of in-office diagnosis and immediate treatment upon presentation.

**Nucleic Acid Amplification Tests (NAT or NAAT)**
In contrast, testing with nucleic acid amplification tests (also known as NAT or NAAT) confers higher sensitivity and specificity than microscopic diagnosis, but is much more costly and can delay diagnosis and treatment. Molecular testing for diagnosis of vaginal infections is based on the detection of one or more specific nucleic acid sequences.

Multiple BV NAATs are available for BV diagnosis among symptomatic patients. These tests are based on detection of specific bacterial nucleic acids and have high sensitivity and specificity for BV.

- Two of these assays are FDA cleared (BD Max Vaginal Panel and Aptima BV), and the other three are laboratory-developed tests (NuSwab VG (LabCorp), OneSwab BV Panel PCR with Lactobacillus Profiling by qPCR (Medical Diagnostic Laboratories), and SureSwab BV (Quest Diagnostics)).

- The three laboratory-developed tests (NuSwab VG, OneSwab BV Panel PCR with Lactobacillus Profiling by qPCR, and SureSwab BV) must be internally validated before use for patient care yet have good sensitivity and specificity, similar to FDA-cleared assays.

BV is primarily based on clinical examination and findings.

**Review Documentation**
The following documentation should be considered when making a review determination:

1. Patient's medical history and reason for the test;
2. Ordering healthcare provider's information;
3. Specimen collection date and time;
4. Specimen type and source;
5. Amplification technique used;
6. Nucleic acid probe information, including the label used;
7. Test results and interpretation; and
8. Any additional relevant clinical information

**CPT/HCPCS/ICD-10 Codes**

***Applicable CPT and HCPCS Codes provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered service.***

***Note: Modifier 59 may be present to indicate that multiple tests were performed.***

**Applicable CPT and corresponding ICD-10-CM Codes**

| Symptomatic Individuals | Test CPT Code | ICD-10-CM Code | Description |
|---|---|---|---|
| Trichomoniasis (Trichomonas vaginalis) | 81514<br>81515<br>87660 | A59.00 | Urogenital trichomoniasis, unspecified |
| | | A59.01 | Trichomonal vulvovaginitis |
| | | A59.03 | Trichomonal cystitis and urethritis |

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|---|---|---|---|
| | 87661 | A59.09 | Other urogenital trichomoniasis |
| | | A59.8 | Trichomoniasis of other sites |
| | | A59.9 | Trichomoniasis, unspecified |
| | | Z11.3 | Encounter for screening for infections with a predominantly sexual mode of transmission |
| | | Z11.6 | Encounter for screening for other protozoal diseases and helminthiases |
| | | Z11.8 | Encounter for screening for other infectious and parasitic diseases |
| Candida | 81514<br>81515<br>87480<br>87481<br>87482 | B37.31 | Acute candidiasis of vulva and vagina |
| | | B37.32 | Chronic candidiasis of vulva and vagina |
| | | B37.41 | Candidal cystitis and urethritis |
| | | B37.42 | Candidal balanitis |
| | | B37.49 | Other urogenital candidiasis |
| | | B37.9 | Candidiasis, unspecified |
| | | Z11.8 | Encounter for screening for other infectious and parasitic diseases |
| Gardnerella Vaginalis | 81513<br>81514<br>87510<br>87511<br>87512 | B96.89 | Other specified bacterial agents as the cause of diseases classified elsewhere |
| | | N76.0 | Acute vaginitis |
| | | N76.1 | Subacute and chronic vaginitis |
| | | N76.2 | Acute vulvitis |
| | | N76.3 | Subacute and chronic vulvitis |
| | | Z11.2 | Encounter for screening for other bacterial diseases |
| Chlamydia (Chlamydia trachomatis) | 87490<br>87491<br>87492 | A55 | Chlamydial lymphogranuloma (venereum) |
| | | A56.00 | Chlamydial infection of lower genitourinary tract, unspecified |
| | | A56.01 | Chlamydial cystitis and urethritis |
| | | A56.02 | Chlamydial vulvovaginitis |
| | | A56.09 | Other chlamydial infection of lower genitourinary tract |
| | | A56.11 | Chlamydial female pelvic inflammatory disease |
| | | A56.19 | Other chlamydial genitourinary infection |
| | | A56.2 | Chlamydial infection of genitourinary tract, unspecified |
| | | A56.3 | Chlamydial infection of anus and rectum |

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|---|---|---|---|
| | | A56.8 | Sexually transmitted chlamydial infection of other sites |
| | | A63.8 | Other specified predominantly sexually transmitted diseases |
| | | A64 | Unspecified sexually transmitted disease |
| | | A74.81 | Chlamydial peritonitis |
| | | A74.89 | Other chlamydial diseases |
| | | A74.9 | Chlamydial infection, unspecified |
| | | N34.1 | Nonspecific urethritis |
| | | Z11.3 | Encounter for screening for infections with a predominantly sexual mode of transmission |
| | | Z11.8 | Encounter for screening for other infectious and parasitic diseases |
| Herpes Simplex Virus (HSV) Types 1 and 2 | 87528<br>87529<br>87530 | A60.00 | Herpesviral infection of urogenital system, unspecified |
| | | A60.01 | Herpesviral infection of penis |
| | | A60.02 | Herpesviral infection of other male genital organs |
| | | A60.03 | Herpesviral cervicitis |
| | | A60.04 | Herpesviral vulvovaginitis |
| | | A60.09 | Herpesviral infection of other urogenital tract |
| | | A60.1 | Herpesviral infection of perianal skin and rectum |
| | | A60.9 | Anogenital herpesviral infection, unspecified |
| | | B00.9 | Herpesviral infection, unspecified |
| | | Z11.3 | Encounter for screening for infections with a predominantly sexual mode of transmission |
| | | Z11.59 | Encounter for screening for other viral diseases |
| Gonorrhea (Neisseria gonorrhea) | 87590<br>87591<br>87592<br>0483U | A54.00 | Gonococcal infection of lower genitourinary tract, unspecified |
| | | A54.01 | Gonococcal cystitis and urethritis, unspecified |
| | | A54.02 | Gonococcal vulvovaginitis, unspecified |
| | | A54.03 | Gonococcal cervicitis, unspecified |

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|---|---|---|---|
| | | A54.09 | Other gonococcal infection of lower genitourinary tract |
| | | A54.1 | Gonococcal infection of lower genitourinary tract with periurethral and accessory gland abscess |
| | | A54.21 | Gonococcal infection of kidney and ureter |
| | | A54.23 | Gonococcal infection of other male genital organs |
| | | A54.24 | Gonococcal female pelvic inflammatory disease |
| | | A54.29 | Other gonococcal genitourinary infections |
| | | A54.6 | Gonococcal infection of anus and rectum |
| | | A54.89 | Other gonococcal infections |
| | | Z11.2 | Encounter for screening for other bacterial diseases |
| | | Z11.3 | Encounter for screening for infections with a predominantly sexual mode of transmission |
| Human Papillomavirus (HPV), high-risk types (e.g., types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) | 87624<br>87625<br>87626 | A63.0 | Anogenital (venereal) warts |
| | | B97.7 | Papillomavirus as the cause of diseases classified elsewhere |
| | | C53.0 | Malignant neoplasm of endocervix |
| | | C53.1 | Malignant neoplasm of exocervix |
| | | C53.8 | Malignant neoplasm of overlapping sites of cervix uteri |
| | | C53.9 | Malignant neoplasm of cervix uteri, unspecified |
| | | D06.0 | Carcinoma in situ of endocervix |
| | | D06.1 | Carcinoma in situ of exocervix |
| | | D06.7 | Carcinoma in situ of other parts of cervix |
| | | D06.9 | Carcinoma in situ of cervix, unspecified |
| | | D26.0 | Other benign neoplasm of cervix uteri |
| | | R85.81 | Anal high risk human papillomavirus (HPV) DNA test positive |
| | | R87.810 | Cervical high risk human papillomavirus (HPV) DNA test positive |
| | | R87.811 | Vaginal high risk human papillomavirus (HPV) DNA test positive |

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| | | Z11.51 | Encounter for screening for human papillomavirus (HPV) |

| **Asymptomatic individual with any of the following:** | **ICD-10-CM Codes/Ranges:** | **Description** |
|---|---|---|
| •high-risk behavior (e.g., exposure to possible infected partner)<br><br>•high-risk condition (e.g., pregnancy, HIV infection)<br><br>•high-risk experience (e.g., assault)<br><br>•chlamydia and/or gonorrhea screening in sexually active individual<br><br>•human papillomavirus (HPV) cervical cancer screening | B20 | Human immunodeficiency virus [HIV] disease |
| | B97.35 | Human immunodeficiency virus, type 2 [HIV 2] as the cause of diseases classified elsewhere |
| | F11.20 – F11.229 | Opioid dependence |
| | F13.20 – F13.229 | Sedative, hypnotic, or anxiolytic-related dependence |
| | F14.20 – F14.29 | Cocaine dependence |
| | F15.20 – F15.29 | Other stimulant dependence |
| | F16.20 – F16.29 | Hallucinogen dependence |
| | F19.20 – F19.2 | Other psychoactive substance dependence |
| | O09 High Risk Pregnancy Range | Supervision of high-risk pregnancy |
| | O98 Maternal Infections and parasitic diseases range | Maternal infectious and parasitic diseases classifiable elsewhere but complicating pregnancy, childbirth, and the puerperium |
| | Z11.8 | Encounter for screening for other infectious and parasitic diseases |
| | Z20.2 | Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission |
| | Z20.6 | Contact with and (suspected) exposure to human immunodeficiency virus [HIV] |
| | Z21 | Asymptomatic human immunodeficiency virus [HIV] infection status |

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|---|---|---|
| | Z29.81 | Encounter for HIV pre-exposure prophylaxis |
| | Z72.89 | Other problems related to lifestyle |
| | Z72.51 | High risk heterosexual behavior |
| | Z72.52 | High risk homosexual behavior |
| | Z72.53 | High risk bisexual behavior |
| | Z77.9 | Other contact with and (suspected) exposures hazardous to health |

**CPT Code / HCPCS Code Descriptions**

| Code | Description |
|---|---|
| 0483U | Infectious disease (Neisseria gonorrhoeae), sensitivity, ciprofloxacin resistance (gyrA S91F point mutation), oral, rectal, or vaginal swab, algorithm reported as probability of fluoroquinolone resistance |
| 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 |
| 81515 | Infectious disease, bacterial vaginosis and vaginitis, real-time PCR amplification of DNA markers for Atopobium vaginae, Atopobium species, Megasphaera type 1, and Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), utilizing vaginal-fluid specimens, algorithm |
| 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 |

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| 87482 | Infectious agent detection by nucleic acid (DNA or RNA); Candida species, quantification |
| 87490 | Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, direct probe technique |
| 87491 | Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, amplified probe technique |
| 87492 | Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, 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 |
| 87528 | Infectious agent detection by nucleic acid (DNA or RNA); Herpes simplex virus, direct probe technique |
| 87529 | Infectious agent detection by nucleic acid (DNA or RNA); Herpes simplex virus, amplified probe technique |
| 87530 | Infectious agent detection by nucleic acid (DNA or RNA); Herpes simplex virus, quantification |
| 87590 | Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, direct probe technique |
| 87591 | Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, amplified probe technique |
| 87592 | Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, quantification |
| 87624 | Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) |
| 87625 | Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), types 16 and 18 only, includes type 45, if performed |

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|---|---|
| 87626 | Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), separately reported high-risk types (eg, 16, 18, 31, 45, 51, 52) and high-risk pooled result(s) |
| 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 |
| 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 |
| 87802 | Infectious agent antigen detection by immunoassay with direct optical (i.e., visual) observation; Streptococcus, group B |

Not Otherwise Specified (NOS) CPT Codes: 87797, 87798, 87799, for molecular microbe testing are **not reimbursable** when a more specific CPT/HCPCS code is available for use.

| Code | Description |
|---|---|
| 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 |

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