Urogenital/Anogenital (UG/AG) Panels

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➲ Instructions for Use

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Coverage Rationale

Overview

Molecular Panel tests for infectious diseases have changed the landscape of clinical microbiology. They play an important role in diagnostic testing, as they simultaneously detect several different pathogens associated with similar and overlapping clinical symptomatology. For this reason, they are also known as “Syndromic Panel” tests. These Panels belong to a category of testing known as culture-independent diagnostic tests (CIDTs), which are tests that detect pathogens without the need to grow and isolate them in culture. These tests have shorter turnaround times, often have good test performance characteristics, and require limited technical expertise, making them appealing for use by clinicians as well as clinical laboratories.

CMS National Coverage Determinations (NCDs)

Medicare does not have an NCD for urogenital/anogenital (UG/AG) Panels.

CMS Local Coverage Determinations (LCDs) and Articles

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing.

For coverage guidelines for states/territories with no LCDs/LCAs, or when the LCDs/LCAs are silent on coverage criteria, refer to the coverage rationale below:

- For the UG/AG Panels, epidemiologic indication or potential exposure to sexually transmitted pathogens (i.e., in the case of clinical concern for multiple sexually transmitted infections (STIs) due to a high-risk experience) is considered reasonable and necessary even in the absence of clinical symptoms. The high-risk reason for Panel testing must clearly be documented.
- In the absence of a high-risk experience, if the primary clinical concern is for a few specific pathogens due to specific signs and symptoms [i.e., lesions suggestive of herpes simplex virus (HSV)], then it is expected that only a small, targeted Panel (i.e., including HSV-1 and HSV-2) will be performed. In such cases, expanded Panels are **not** considered reasonable and necessary and will **not** be covered.
- For the diagnosis of infectious vaginosis/vaginitis, it is reasonable and necessary to perform a (targeted or expanded) Panel that includes a combination of at least 2 of the following: Gardnerella vaginalis, other bacterial vaginosis (BV)-

associated bacteria (BVAB) (such as Atopobium vaginae and/or Megasphaera types), Trichomonas vaginalis, and Candida species.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is 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 health service; however, language may be included in the listing below to indicate if a code is non-covered. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0352U	Infectious disease (bacterial vaginosis and vaginitis), multiplex amplified probe technique, for detection of bacterial vaginosis-associated bacteria (BVAB-2, Atopobium vaginae, and Megasphera 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 (Deleted 12/31/2024 - see CPT code 81515)
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 reported as positive or negative for high likelihood of bacterial vaginosis, includes separate detection of Trichomonas vaginalis and Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, when reported (Effective 01/01/2025)

Diagnosis Code	Description
A51.0	Primary genital syphilis
A51.1	Primary anal syphilis
A51.31	Condyloma latum
A52.76	Other genitourinary symptomatic late syphilis
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
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
A54.22	Gonococcal prostatitis
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

Diagnosis Code	Description
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
A59.00	Urogenital trichomoniasis, unspecified
A59.01	Trichomonal vulvovaginitis
A59.02	Trichomonal prostatitis
A59.03	Trichomonal cystitis and urethritis
A59.09	Other urogenital trichomoniasis
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
A63.0	Anogenital (venereal) warts
B20	Human immunodeficiency virus [HIV] disease
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
B37.89	Other sites of candidiasis
B97.35	Human immunodeficiency virus, type 2 [HIV 2] as the cause of diseases classified elsewhere
D26.0	Other benign neoplasm of cervix uteri
L29.2	Pruritus vulvae
L29.3	Anogenital pruritus, unspecified
N34.1	Nonspecific urethritis
N34.2	Other urethritis
N41.0	Acute prostatitis
N41.3	Prostatocystitis
N48.5	Ulcer of penis
N76.0	Acute vaginitis
N76.1	Subacute and chronic vaginitis
N76.2	Acute vulvitis
N76.3	Subacute and chronic vulvitis
N76.5	Ulceration of vagina
N76.6	Ulceration of vulva
N76.82	Fournier disease of vagina and vulva

Diagnosis Code	Description
N76.89	Other specified inflammation of vagina and vulva
N77.1	Vaginitis, vulvitis and vulvovaginitis in diseases classified elsewhere
N89.8	Other specified noninflammatory disorders of vagina
N90.89	Other specified noninflammatory disorders of vulva and perineum
N93.0	Postcoital and contact bleeding
N93.8	Other specified abnormal uterine and vaginal bleeding
O09.90	Supervision of high risk pregnancy, unspecified, unspecified trimester (Effective 09/02/2025)
O09.91	Supervision of high risk pregnancy, unspecified, first trimester (Effective 09/02/2025)
O09.92	Supervision of high risk pregnancy, unspecified, second trimester (Effective 09/02/2025)
O09.93	Supervision of high risk pregnancy, unspecified, third trimester (Effective 09/02/2025)
O98.711	Human immunodeficiency virus [HIV] disease complicating pregnancy, first trimester
O98.712	Human immunodeficiency virus [HIV] disease complicating pregnancy, second trimester
O98.713	Human immunodeficiency virus [HIV] disease complicating pregnancy, third trimester
R10.2	Pelvic and perineal pain (Deleted 09/30/2025)
R10.20	Pelvic and perineal pain unspecified side (Effective 10/01/2025)
R10.21	Pelvic and perineal pain right side (Effective 10/01/2025)
R10.22	Pelvic and perineal pain left side (Effective 10/01/2025)
R10.23	Pelvic and perineal pain bilateral (Effective 10/01/2025)
R10.24	Suprapubic pain (Effective 10/01/2025)
R10.8A3	Suprapubic tenderness (Effective 10/01/2025)
R30.0	Dysuria
T74.21XA	Adult sexual abuse, confirmed, initial encounter
T74.21XD	Adult sexual abuse, confirmed, subsequent encounter
T74.21XS	Adult sexual abuse, confirmed, sequela
T74.51XA	Adult forced sexual exploitation, confirmed, initial encounter
T74.51XD	Adult forced sexual exploitation, confirmed, subsequent encounter
T74.51XS	Adult forced sexual exploitation, confirmed, sequela
T76.21XA	Adult sexual abuse, suspected, initial encounter
T76.21XD	Adult sexual abuse, suspected, subsequent encounter
T76.21XS	Adult sexual abuse, suspected, sequela
T76.51XA	Adult forced sexual exploitation, suspected, initial encounter
T76.51XD	Adult forced sexual exploitation, suspected, subsequent encounter
T76.51XS	Adult forced sexual exploitation, suspected, sequela
Z04.41	Encounter for examination and observation following alleged adult rape
Z04.71	Encounter for examination and observation following alleged adult physical abuse
Z04.81	Encounter for examination and observation of victim following forced sexual exploitation
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
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
Z33.1	Pregnant state, incidental
Z33.3	Pregnant state, gestational carrier
Z34.00	Encounter for supervision of normal first pregnancy, unspecified trimester (Effective 09/02/2025)
Z34.01	Encounter for supervision of normal first pregnancy, first trimester (Effective 09/02/2025)
Z34.02	Encounter for supervision of normal first pregnancy, second trimester (Effective 09/02/2025)

Diagnosis Code	Description
Z34.03	Encounter for supervision of normal first pregnancy, third trimester (Effective 09/02/2025)
Z34.80	Encounter for supervision of other normal pregnancy, unspecified trimester (Effective 09/02/2025)
Z34.81	Encounter for supervision of other normal pregnancy, first trimester (Effective 09/02/2025)
Z34.82	Encounter for supervision of other normal pregnancy, second trimester (Effective 09/02/2025)
Z34.83	Encounter for supervision of other normal pregnancy, third trimester (Effective 09/02/2025)
Z34.90	Encounter for supervision of normal pregnancy, unspecified, unspecified trimester (Effective 09/02/2025)
Z34.91	Encounter for supervision of normal pregnancy, unspecified, first trimester (Effective 09/02/2025)
Z34.92	Encounter for supervision of normal pregnancy, unspecified, second trimester (Effective 09/02/2025)
Z34.93	Encounter for supervision of normal pregnancy, unspecified, third trimester (Effective 09/02/2025)
Z72.51	High risk heterosexual behavior
Z72.52	High risk homosexual behavior
Z72.53	High risk bisexual behavior
Z72.89	Other problems related to lifestyle

Definitions

Analytical Validity (AV): A process intended to determine if a test, tool, or instrument has acceptable technical performance (sensitivity, specificity, accuracy, precision, etc.). Analytical validation is an assessment of the test's technical performance (the test measures what it was designed to measure), not its usefulness or clinical significance. Analytical Validity includes the ability of the test to accurately and reliably detect the mutation and/or variant.

Clinical Utility (CU): The ability of a test to provide information related to the patient's care and management, and thus, its ability to inform treatment decisions. Centers for Medicare and Medicaid Services (CMS) is most focused on assessing Clinical Utility in the context of whether or not a test is used to guide patient management and whether or not use of the test results leads to treatment that improves health outcomes.

Clinical Validity (CV): The ability of a test to classify a patient's specific circumstance into a diagnostic, prognostic, or predictive functional category. It should be noted that Clinical Validity is not a fixed value. Clinical Validity includes the ability of the test to accurately and reliably detect the disease of interest in the defined population.

Panel: A test that detects > 1 pathogen.

Syndromic Panel: A test that simultaneously detects multiple different pathogens associated with similar and overlapping clinical symptomatology.

Centers for Medicare and Medicaid Services (CMS) Related Documents

After checking the table below and searching the Medicare Coverage Database, if no NCD, LCD, or LCA is found, refer to the criteria as noted in the Coverage Rationale section above.

NCD	LCD	LCA	Contractor Type	Contractor Name
Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing				
N/A	L39038 MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	A58747 Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	Part A and B MAC	CGS

NCD	LCD	LCA	Contractor Type	Contractor Name
Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing				
N/A	L39001 MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	A58720 Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	Part A and B MAC	Noridian
N/A	L39003 MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	A58726 Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	Part A and B MAC	Noridian
N/A	L38988 MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	A58710 Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	Part A and B MAC	Palmetto**
N/A	L39044 MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	A58761 Billing and Coding: MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	Part A and B MAC	WPS*

Medicare Administrative Contractor (MAC) With Corresponding States/Territories	
MAC Name (Abbreviation)	**States/Territories**
CGS Administrators, LLC (CGS)	KY, OH
First Coast Service Options, Inc. (First Coast)	FL, PR, VI
National Government Services, Inc. (NGS)	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
Noridian Healthcare Solutions, LLC (Noridian)	AS, AK, AZ, CA, GU, HI, ID, MT, NV, ND, Northern Mariana Islands, OR, SD, UT, WA, WY
Novitas Solutions, Inc. (Novitas)	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX, VA**
Palmetto GBA (Palmetto)	AL, GA, NC, SC, TN, VA**, WV
Wisconsin Physicians Service Insurance Corporation (WPS)*	IA, IN, KS, MI, MO, NE
Notes	
*Wisconsin Physicians Service Insurance Corporation: Contract Number 05901 applies only to WPS Legacy Mutual of Omaha MAC A Providers. **For the state of Virginia: Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction.	

CMS Benefit Policy Manual

Chapter 15; § 80.1-80.1.3 Clinical Laboratory Services

CMS Claims Processing Manual

Chapter 12; § 60 Payment for Pathology Services
Chapter 16; § 10.2 General Explanation of Payment; § 20 Calculation of Payment Rates-Clinical Laboratory Test Fee Schedules; § 40 Billing for Clinical Laboratory Tests

Others

CMS Lab NCDs - ICD-10; CMS.gov

Palmetto GBA MolDx Website
Palmetto GBA MolDx Manual, Palmetto GBA MolDx Website
L36021 Molecular Diagnostic Tests (MDT)
A56973 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)
L35160 MolDX: Molecular Diagnostic Tests (MDT)
A57526 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)
L36256 MolDX: Molecular Diagnostic Tests (MDT)
A57527 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)
L35025 MolDX: Molecular Diagnostic Tests (MDT)
A56853 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)
L36807 MolDX: Molecular Diagnostic Tests (MDT)
A57772 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)
L34519 Molecular Pathology Procedures
A58918 Billing and Coding: Molecular Pathology and Genetic Testing
L35062 Biomarkers Overview
A58917 Billing and Coding: Molecular Pathology and Genetic Testing
L39365 Genetic Testing in Oncology: Specific Tests

Clinical Evidence

Test Performance

In recent years, molecular syndromic panels have become routinely used for a number of infection types, including respiratory, gastrointestinal, central nervous system, bloodstream, and urogenital/anogenital. These panels provide rapid turnaround times for results and are often more sensitive than traditional testing for the various organisms included (Dien Bard et al., 2020; Ramanan et al., 2017). However, test performance characteristics do vary depending on the specific panels and pathogens.

Molecular panel tests are also increasingly being used for the detection of urogenital and anogenital infections. The BD MAX™ vaginal panel has reported sensitivities and specificities of 89.8%/96.5%, 97.4%/96.8%, and 100%/100% for bacterial vaginosis (BV), vulvovaginal candidiasis (VVC), and trichomoniasis (TV), respectively (Aguirre-Quiñonero et al., 2019). In another study, the BD Affirm™ VPIII Microbial Identification Test showed a lower specificity of 81.6% for BV and lower sensitivity of 69.4% for VVC, while it performed equally well as the BD MAX™ for TV (Thompson et al., 2020). These panels, however, have been shown to perform better than clinician assessment of vaginitis, for which many diagnoses remain empirical and for which guideline non-adherence is broad (Schwebke et al., 2018; Nyirjesy et al., 2020; Schwebke et al., 2020). Further, high rates of coinfection with sexually transmitted infections (STIs) (24.4%-25.7%) have been observed (Van Der Pol et al., 2019; Van Der Pol et al., 2017; Ginocchio et al., 2012). Panels detecting sexually transmitted pathogens have also become routine in clinical laboratories, as they provide a rapid result for organisms like Chlamydia species, that can be difficult to culture. Moreover, it is well-established that N. gonorrhoeae and C. trachomatis not only cause similar clinical syndromes but also coexist in a significant proportion of patients, highlighting the need for panel testing (Kreisel et al., 2018).

The Xpert Xpress MVP test (MVP) test is a qualitative *in vitro* polymerase chain reaction (PCR) test designed to detect DNA targets from anaerobic bacteria associated with bacterial vaginosis (BV), trichomoniasis (TV), and *Candida* species associated with vulvovaginal candidiasis (VVC) through an automated system which allows an untrained operator to run a test sample with results available in less than an hour. In a prospective, multicenter, cross-sectional, method comparison clinical study, Lillis et al. (2023) assessed MVP using clinician collected vaginal swabs (CVS) and self-collected vaginal swabs (SVS). Both sample types were collected in a clinical setting. The study took place at 12 facilities (including point-of-care settings) in geographically diverse locations in the United States and included individuals 14 years of age or older who exhibited signs/symptoms of vaginitis or vaginosis. A total of 1,478 individuals were eligible to be evaluated for at least one of the four MVP reportable results. Results of testing with MVP for BV were compared to the BD Max Vaginal Panel (BDVP), while results for *Candida* group and *Candida glabrata* and *Candida krusei* targets (species not differentiated) were compared to yeast culture followed by mass spectrometry for identification of species. A composite method including results from BDVP and InPouch TV culture were the comparison method used to assess MVP TV results. These comparisons yielded high positive percent agreement which ranged from 93.6 to 99% as well as negative percent agreement ranging from 92.1% to 99.8% for both CVS and SVS samples. The authors concluded that based on this evaluation, MVP may be a helpful tool for diagnosis and subsequent treatment of vaginitis/vaginosis in laboratory and point-of-care settings. This study was sponsored by the test manufacturer; the sponsor (Cepheid) was involved in the study design and conduction as well as the collection of data and interpretation of the data, creating potential for bias.

Additional large, high-quality studies demonstrating clinical utility are needed to support the use of the MVP in clinical settings.

Schwebke et al. (2020) performed a prospective, multicenter clinical study to validate the performance of an in vitro diagnostic transcription-mediated nucleic acid amplification tests (NAATs) for the diagnosis of bacterial vaginosis (BV), vulvovaginal candidiasis (VVC), and trichomonas vaginalis (TV). Clinician and patient obtained swab samples were collected from symptomatic women and were tested using the Aptima BV and Aptima Candida/Trichomonas vaginitis (CV/TV) assays. Results were compared to Nugent (plus Amsel for intermediate Nugent) scores for BV, Candida, and DNA sequencing for VVC, and a composite of NAAT and culture for TV. There were 1,519 subjects enrolled. Clinician collected samples for the investigational tests revealed a 95.0% sensitivity and 89.6% specificity for BV; a 91.7% sensitivity and 94.9% specificity for Candida; 84.7% sensitivity and 99.1 % specificity for C. glabrata; and a 96.5% sensitivity and 95.1% specificity for TV. Similar results were observed from the patient collected samples. Clinician diagnosis, in-clinic assessments and investigational assay results were compared with gold standard reference methods in a secondary assessment. This secondary assessment for BV resulted in a sensitivity of ≥ 96.2% and specificity of ≥ 92.4% for the investigational-assay samples compared to 83.4% and 85.5% for clinicians' diagnoses, 75.9% and 94.4% for original Amsel criteria, 81.1% and 90.1% for modified Amsel criteria, and ≤ 82.8% and ≤ 91.1% for any of the individual Amsel criterion components (vaginal pH, clue cells, and whiff test). For VVC due to the Candida species group or C. glabrata, sensitivity and specificity were ≥ 91.2% and ≥ 98.9%, respectively for the investigational-assay samples compared to ≤ 27.9% and ≤ 56.4% for potassium hydroxide testing and ≤ 54.9% and ≤ 85.5% for clinicians' diagnoses. For trichomoniasis, sensitivity was ≥ 96.4% for the investigational-assay samples compared to 78.8% for culture and 38.1% for clinicians' diagnoses; specificity estimates were greater than 95% for all trichomoniasis detection methods. The authors reported that overall, the investigational tests revealed a higher sensitivity and specificity for detecting and diagnosing the causes of vaginitis compared to traditional methodologies for diagnosis. Study limitations included lack of diversity with regard to ethnic groups and high specificity of molecular testing, impacting sensitivity to disease attributable to minor species (e.g., Prevotella, Candida krusei), which were not included in assay design.

Thompson et al. (2020) conducted a comparative study to examine the performance of the BD Max Vaginal Panel (MAX VP) compared to BD Affirm VPIII (Affirm), noting Affirm to be the "standard of care". Four vaginal swabs were collected from each of 200 symptomatic participants. Candida culture, Gram stain and Nugent scoring and the Hologic Aptima Trichomonas vaginalis assay were used as part of the analysis. When at least two tests were positive for any vaginitis target, the results were considered true positive. Sensitivity and specificity of MAX VP for bacterial vaginosis (BV) was 96.2% and 96.1%, respectively. For Affirm, sensitivity and specificity for BV were 96.2% and 81.6%, respectively. The sensitivity of MAX VP for Candida spp. was 98.4% and specificity was 95.4% whereas sensitivity for Affirm was 69.4% and specificity was 100%. Lastly, MAX VP and Affirm were 100% concordant in the detection of trichomonas vaginalis (TV). The authors concluded that MAX VP showed better accuracy when compared to Affirm for detection of Candida spp. and BV, and the two tests were equally accurate for detection of TV. The study was limited by its small sample size.

Aguirre-Quiñonero et al. (2019) conducted a single-center test validation study to evaluate the BD MAX™ vaginal panel for the diagnosis of bacterial vaginosis (BV), vulvovaginal candidiasis (VVC) and trichomoniasis and compared the test to conventional diagnostic methods. The study included 1,000 vaginal samples of women ≥ 14 years of age (median age 39 years) with 5% of the samples belonging to pregnant women. The authors reported that 19.3% of the samples were classified as BV while 33.6% were classified as VVC and 2.1% of the samples resulted in a diagnosis of T. vaginalis. The authors also reported that 43 of the 1000 (4.3%) samples analyzed were initially invalidated; however, after they were re-analyzed, 30.2% (13/43) remained invalidated whereas 69.8% (30/43) provided a valid result. There were three limitations of the study including the fact that vaginitis, especially VVC is often clinical diagnosed without laboratory confirmation, as such, microbiological analysis is only obtained when the patient does not recover following initial treatment. This may have resulted in the measurement of the burden of VVC being overestimated. Another limitation noted by the authors was the lack of information regarding prior treatment the participants may have received, and the third limitation was that the clinical outcomes for patients with discordant results were not evaluated. The authors concluded that the BD MAX vaginal panel was highly sensitive and specific and that it simplified the identification of infectious vaginitis.

Van Der Pol et al. (2019) conducted a non-matched, retrospective, multi-center study using de-identified residual specimens from the BD MAX Vaginal Panel (MVP) clinical study to evaluate the likelihood of STIs (sexually transmitted infections) in women using a molecular diagnostic assay. The study included specimens from 581 adult women (median age 28.2 years, 23.9% white, 58% black) who previously provided specimens for the MVP study. Positivity rates were calculated for Chlamydia trachomatis (CT), Neisseria gonorrhoeae (GC), and Trichomonas vaginalis (TV) DNA, detected using the BD MAX CT/GC/TV (MCGT) assay. Trichomonas vaginalis results were consistent between the BD MAX CT/GC/TV assay and the BD MAX Vaginal Panel (MVP) assay in 559 of 560 samples. Concordance between the BD MAX CT/GC/TV assay and the BD MAX Vaginal Panel for detection of T. vaginalis was determined. Women with bacterial vaginosis alone or with concurrent Candida spp infections had high rates of coinfection with STIs (24.4%–25.7%);

samples from women who were negative for vaginitis had substantially lower positivity rates (7.9%; p < .001). Trichomonas vaginalis results were consistent between the BD MAX CT/GC/TV assay and the BD MAX Vaginal Panel in 559 out of 560 samples. The authors concluded that the data suggested, as have other studies, that women with symptoms of vaginitis may be at risk for an STI. Regardless of the type of clinic in which patients are treated, molecular testing may provide broad diagnostic coverage for symptomatic women and improve the management of a patient's care. This study had 3 limitations. First, since the MCGT assay was performed on frozen remaining specimens, the specimens were tested beyond the stability period. Second, the samples were chosen to include all available TV-positive specimens, resulting in the distribution of TV in the study population was not completely representative of that previously published. Third, the statistical power for comparison of STI rates in vaginitis positive and negative groups for this pathogen was limited by the low numbers of GC-positive samples.

Schwebke et al. (2018) analyzed the BD MAX vaginal panel compared to reference for detection of bacterial vaginosis (BV), Candida spp., and trichomonas vaginalis (TV). Specimens from 1,740 women were analyzed using the BD MAX panel. Clinician diagnosis (Amsel's test, KOH preparation, and wet mount) were also performed. All testing methods were compared to the respective reference methods. The BD MAX panel resulted in significantly higher sensitivity and negative predictive value than clinician diagnosis. In addition, this test showed a statistically higher overall percent agreement with each of the three reference methods than did clinician diagnosis. The authors concluded that findings from the current study supported the potential utility of the BD MAX vaginal panel in the differential diagnosis of vaginitis. The authors indicated that future studies are required to establish the benefits regarding the application of this investigational test in a practical setting. Study limitations included observations for each type of infection that were excluded because of the inability to report or noncompliance and results may have led to overdiagnosis of vaginitis as the assay could not distinguish pathogenic growth from nonpathogenic colonization.

Van Der Pol et al. (2017) conducted a comparative study with 2,114 women and 840 men to assess the performance of the BD Max CT/GC/TV Assay for combined chlamydia (CT), gonorrhea (GC), and trichomonas (TV) testing. Samples included endocervical swabs, vaginal swabs, and urine specimens. Testing for CT, GC, and TV included 1,143 women with an additional 847 tested for CT and GC only, for a total of 1,990 women. Positivity rates for CT, GC, and TV were 7.1%, 2.3% and 13.5%, respectively. For men, only urine specimens were used and TV performance was not evaluated. For the male specimens, 181/830 (21.8%) and 108/840 (12.9%) chlamydia and gonorrhea infections, respectively, were noted. Comparator assays included BD ProbeTec Chlamydia trachomatis Qx (CTQ)/Neisseria gonorrhoeae Qx (GCQ), Hologic Aptima Combo 2 (AC2) and Aptima TV (ATV), trichomonas microscopy, and culture. MAX CT sensitivity was 99.3%, 95.7%, 91.5%, and 96.1% for vaginal swabs, endocervical swabs, female urine samples, and male urine samples, respectively. MAX GC sensitivity was 95.5%, 95.5%, 95.7%, and 99.1% in the same order. MAX TV sensitivity was 96.1% for vaginal swabs, 93.4% for endocervical swabs, and 92.9% for female urine samples. Across all sample types, specificity for all organisms was ≥ 98.6%. Performance estimates for the BD MAX assays were concordant with estimates calculated for the comparator assays. The authors concluded that the availability of CT/GC/TV multiplexed assay on a benchtop instrument with a broad menu has the potential to aid in local sexually transmitted infection (STI) testing at smaller laboratories and has the potential to encourage expanded screening for these widespread infections. This study was limited by the fact that males were not tested for TV, and that some of the sample collections were done by the participants which may lead to variability in sample collection.

Clinical Utility: Impact on Patient Management and Interpretation of Results

Molecular panel tests can detect additional pathogens that were not detected in the past with conventional methods of testing. Positive results may not indicate current active infection, therefore, it is important to determine whether the detected organisms represent pathogens or colonizers that could not be detected before.

Prevalence

Van Der Pol et al. (2025) evaluated the BD MAX Vaginal Panel in identifying vaginal co-infections. Using remanent vaginal specimens from symptomatic patients who were previously tested for sexually transmitted infections (STIs), including neisseria gonorrhoeae (GC), chlamydia trachomatis (CT), and trichomonas vaginalis (TV) with the Becton Dickinson (BD) CTGCTV2 assay for BD MAX System, positivity for Candida spp (associated with vulvovaginal andidiasis (VVC)) and bacterial vaginosis (BV) were evaluated using the molecular-based BD MAX Vaginal Panel. The rate of sexually transmitted infection (STI)/BV co-infection was 79.4% (227/286) and the rate of STI/VVC co-infection was 27.0% (77/285). Women who were diagnosed with any 1 of the 3 STIs tested had an OR 2.86 (95% CI, 1.99, 4.11; p < 0.0001) for a concurrent BV infection and OR 0.96 (95% CI, 0.67, 1.37; p = 0.8085) for infection with Candida species. The authors concluded that their findings suggest that women being tested for STI have a high prevalence of co-infection with BV. They have a lower, although appreciable, prevalence of co-infection with VVC. The identification of co-occurring vaginal infections can be facilitated by molecular testing using a single sample. Study limitations included its limited capability to precisely predict the impact of STI and vaginitis causes on one another due to only a subset of the population

from the parent study was tested. Also, BV and VCC estimates were likely conservative since testing was done on stored, residual specimens.

Hernández-Rosas et al. (2023) performed a prospective cross-sectional study to describe the prevalence of sexually transmitted infections (STIs) and vaginosis in urogenital samples from patients who had been tested exclusively for human papillomavirus (HPV) genotyping. The study included 408 females and males ages 20-80. Eligible participants had negative and positive HPV genotyping test results and agreed to early detection or had HPV antecedents. They provided the same urogenital samples used for HPV detection and, through their multiplex in-house PCR assay, they screened for Chlamydia trachomatis, Candida spp., Ureaplasma spp., Neisseria gonorrhoeae, Mycoplasma spp., molluscum contagiosum virus (MCV), Trichomonas vaginalis, herpes simplex virus 1 and 2 (HSV), Treponema pallidum, Staphylococcus aureus, Haemophilus spp., and Klebsiella spp. The subsequent statistical analysis aimed to show correlations between HPV genotypes and the identified pathogens. Out of the participants, 72.1% (n = 294) tested positive for HPV genotypes. HR-HPV (high-risk HPV) genotypes comprised 51 (8.1%), 66 (7.1%), and 58 (6.1%). Haemophilus spp., Ureaplasma spp., Candida spp., Staphylococcus aureus, and Mycoplasma spp. often co-occurred with HPV infection. Gender-based variations were notorious for Mycoplasma spp., Ureaplasma spp., and MCV. Coinfections were prevalent (43.9%), with a positive HPV result elevating the risk for Trichomonas vaginalis, Mycoplasma spp., Staphylococcus aureus, HSV, and MCV. HPV 16 correlated with Ureaplasma spp. and HSV, while HPV 6 was linked with MCV and HSV. Coinfections with HPV positive test for Trichomonas vaginalis was 0.2% (n = 1), Neisseria gonorrhoeae 0.7% (n = 3), Chlamydia trachomatis 2.7% (n = 11) and HSV 1/2 1.0% (n = 4). The authors concluded there are significant coinfections, mainly Haemophilus spp 32.4% (n = 132) and Ureaplasma spp. 24.8% (n = 101), and associations between HPV genotypes and pathogens, emphasizing the importance of routine screening to explore clinical implications in urogenital health. This study was conducted in Mexico which may represent a geographical limitation.

Lee et al. (2022) performed a prevalence study to analyze coinfections with sexually transmitted pathogens according to age in the Republic of Korea from 2018-2020. 65,191 samples of urine, swab, and other types submitted for STI screening were obtained from U2Bio Co. Ltd. (Seoul, Republic of Korea). Multiplex polymerase chain reaction was performed, which is a sensitive and rapid method for simultaneous detection of STIs caused by multiple different pathogens. Patients were tested for coinfections with 12 sexually transmitted pathogens: Candida albicans, Trichomonas vaginalis, Chlamydia trachomatis, Herpes simplex virus type 1 (HSV1), Herpes simplex virus type 2 (HSV2), Mycoplasma genitalium, Mycoplasma hominis, Gardnerella vaginalis, Neisseria gonorrhoeae, Treponema pallidum, Ureaplasma parvum, and Ureaplasma urealyticum. Out of the 65,191 samples tested, 35,366 (54.3%) tested positive for one or more sexually transmitted pathogens. The prevalence of coinfections with two or more sexually transmitted pathogens was inversely proportional to age. The average age of patients coinfected with two types of pathogens was 36, and the age of the individual coinfected with nine types of pathogens was 19. The rates of coinfection with sexually transmitted pathogens and age distribution also differed according to sex and the sexually transmitted pathogen type. Coinfections in male patients were more frequent in the 30-39 year age group, whereas the age of female patients with coinfections varied from 19-40 years. Patients with N. gonorrhoeae and C. trachomatis infection had a low rate of coinfection, whereas those infected with M. hominis and T. vaginalis had a high rate of coinfection with other sexually transmitted pathogens. In a study conducted at an STI clinic in Birmingham, Alabama, USA, coinfection with M. genitalium in women with C. trachomatis was found to be uncommon. It was present in only 7.3% of the confection patients. A study of pregnant women who visited a hospital in Ghana revealed that Candida (53%) coinfection was common in women with T. vaginalis infection. In another study from Iran where coinfection with sexually transmitted pathogens was confirmed using mPCR, 10/300 patients (3.3%) tested had confirmed coinfections, including 3 cases of C. trachomatis/T. vaginalis, 2 cases of C. trachomatis/N. gonorrhoeae, and 5 cases of N. gonorrhoeae/T. vaginalis coinfections. In a study conducted in Beijing, China, among the patients with coinfections, 60.6% of men and 71.4% of women were coinfected with U. urealyticum and C. trachomatis. Limitations of the study included that it was not possible to determine the characteristics of sexual partners. Another limitation was that this was a retrospective study that used lab records and no data on clinical characteristics of the patients. The authors concluded that a substantial proportion of patients with STIs are coinfected with multiple pathogens.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

There are several commercial nucleic acid-based tests including Aptima® BV Assay, BD MAX™ Vaginal Panel, and Xpert® Xpress MVP for genitourinary pathogen detection that have been cleared through the FDA 510(k) clearance process. More information regarding specific tests and FDA approval status may be found on the FDA website at: https://www.fda.gov/medical-devices/vitro-diagnostics/nucleic-acid-based-tests. (Accessed June 11, 2025)

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Policy History/Revision Information

Date	Summary of Changes
11/01/2025	**Applicable Codes** • Added ICD-10 diagnosis codes O09.90, O09.91, O09.92, O09.93, R10.20, R10.21, R10.22, R10.23, R10.24, R10.8A3, Z34.00, Z34.01, Z34.02, Z34.03, Z34.80, Z34.81, Z34.82, Z34.83, Z34.90, Z34.91, Z34.92, and Z34.93 • Added notation to indicate ICD-10 diagnosis code R10.2 was “deleted Sep. 30, 2025” **Supporting Information** • Archived previous policy version MMP373.32

Instructions for Use

The Medicare Advantage Policy documents are generally used to support UnitedHealthcare coverage decisions. It is expected providers retain or have access to appropriate documentation when requested to support coverage. This document may be used as a guide to help determine applicable:

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- Medicare coding or billing requirements.

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Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes this policy. For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.

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UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing certain items or services referenced in this Medical Policy have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, in these circumstances, UnitedHealthcare applies internal coverage criteria as referenced in this Medical Policy. The internal coverage criteria in this Medical Policy was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Providers are responsible for submission of accurate claims. Medicare Advantage Policies are intended to ensure that coverage decisions are made accurately. UnitedHealthcare Medicare Advantage Policies use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate’s requirements need to be followed.