Medical Coverage Policy | Multitarget Polymerase Chain Reaction Testing for Diagnosis of Bacterial Vaginosis

EFFECTIVE DATE: 01|01|2024
POLICY LAST REVIEWED: 01|17|2024

OVERVIEW

Bacterial vaginosis (BV) is a common medical condition resulting from an imbalance in the normal vaginal flora. Although the identification of Gardnerella vaginalis has traditionally been associated with BV, there is no single etiologic agent. Most cases are asymptomatic, and most symptomatic cases can be diagnosed using clinical and microscopic evaluation. Multitarget polymerase chain reaction (PCR) testing is proposed as an alternative to currently available laboratory tests to diagnose BV. This test may improve outcomes if it is a more accurate and reliable method to diagnose BV.

The following tests are addressed in this policy:

- Aptima® BV Assay (Hologic, Inc.) CPT code 81513
- BD MAX™ Vaginal Panel (Becton Dickson and Company) CPT code 81514
- Bridge Women's Health Infectious Disease Detection Test (Bridge Diagnostics) CPT code 0330U
- Xpert® Xpress MVP (Cepheid) CPT code 81515 (New Code Effective 1/1/2025; Prior to Dates of Service 1/1/2025, CPT code 0352U should be filed)
- Xpert® CT/NG (Cepheid) CPT code 0353U

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

The following test(s) are covered without an authorization requirement:

- Xpert® CT/NG (CPT code 0353U)

Commercial Products

The following multitarget PCR test(s) for the diagnosis of bacterial vaginosis is not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

- Xpert® CT/NG (CPT code 0353U)

Medicare Advantage Plans and Commercial Products

The following multitarget polymerase chain reaction (PCR) tests for the diagnosis of bacterial vaginosis may be considered medically necessary:

- Aptima® BV Assay (Hologic, Inc.) CPT code 81513
- BD MAX™ Vaginal Panel (Becton Dickson and Company) CPT code 81514
- Xpert® Xpress MVP (Cepheid) CPT code 81515 (New Code Effective 1/1/2025; Prior to Dates of Service 1/1/2025, CPT code 0352U should be filed)

The following multitarget PCR test(s) for the diagnosis of bacterial vaginosis is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products, as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

- Bridge Women's Health Infectious Disease Detection Test (Bridge Diagnostics) CPT code 0330U

Note: Laboratories are not allowed to obtain clinical authorization or participate in the authorization process on behalf of the ordering physician. Only the ordering physician shall be involved in the authorization, appeal or other administrative processes related to prior authorization/medical necessity.

In no circumstance shall a laboratory or a physician/provider use a representative of a laboratory or anyone with a relationship to a laboratory and/or a third party to obtain authorization on behalf of the ordering physician, to facilitate any portion of the authorization process or any subsequent appeal of a claim where the authorization process was not followed and/or a denial for clinical appropriateness was issued, including any element of the preparation of necessary documentation of clinical appropriateness. If a laboratory or a third party is found to be supporting any portion of the authorization process, BCBSRI will deem the action a violation of this policy and severe action will be taken up to and including termination from the BCBSRI provider network. If a laboratory provides a laboratory service that has not been authorized, the service will be denied as the financial liability of the participating laboratory and may not be billed to the member.

Commercial Products
Some genetic testing services are not covered and a contract exclusion for any self-funded group that has excluded the expanded coverage of biomarker testing related to the state mandate, R.I.G.L**. §27-19-81** described in the Biomarker Testing Mandate policy. For these groups, a list of which genetic testing services are covered with prior authorization, are not medically necessary or are not covered because they are a contract exclusion can be found in the Coding section of the Genetic Testing Services or Proprietary Laboratory Analyses policies. Please refer to the appropriate Benefit Booklet to determine whether the member's plan has customized benefit coverage. Please refer to the list of Related Policies for more information.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable laboratory benefits/coverage.

BACKGROUND

Bacterial Vaginosis (BV)
BV is a condition caused by an imbalance in the normal bacteria vaginal flora. It is common, especially in individuals of reproductive age. While there is no single known etiologic agent, there is a shift in vaginal flora that involves depletion of hydrogen peroxide-producing Lactobacillus species with a rise in vaginal pH and overgrowth of other bacteria, including Gardnerella vaginalis, Mycoplasma hominis, Peptostreptococcus, Mobiluncus species, and other anaerobic gram-negative rods.

Vaginal culture is not an appropriate diagnostic method to identify BV because BV is not caused by the presence of a particular bacterial species.

Various commercial tests provide rapid and accurate pH evaluation and amine detection. For example, automated devices that measure the volatile gases produced from vaginal samples and a colorimetric pH test are commercially available.

Nucleic acid probes of DNA fragments are available to detect and quantify specific bacteria in vaginal fluid samples. Polymerase chain reaction (PCR) methods extract and amplify the DNA fragments using either universal or specific primers. The result can be qualitative (to assess whether a specific microorganism is present) or quantitative (to assess how many microorganisms are present). The technology can be used to measure multiple organisms (eg, those known to be associated with BV) at the same time and is commercially available as multitarget PCR testing.

In individuals who have signs or symptoms of BV who receive multitarget PCR testing, the evidence includes several prospective studies on technical performance and diagnostic accuracy. The relevant outcomes are test validity, symptoms, and change in disease status. Several studies have evaluated the diagnostic accuracy of

multitarget PCR tests for BV, including 5 studies evaluating commercially available tests. The studies found sensitivities between 84% and 95% and specificities between 85% and 97%compared with standard methods of diagnosis. Most studies used a combination of the Amsel criteria and Nugent scoring as the reference standard. There is a lack of direct evidence on the clinical utility of PCR testing for BV (ie, studies showing that testing leads to better patient management decisions and/or better health outcomes than current approaches). Moreover, a chain of evidence does not currently support multitarget testing because most symptomatic individuals can be diagnosed with a standard workup. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

The following code(s) is covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

This code can be used for Xpert® CT/NG:

0353U Infectious agent detection by nucleic acid (DNA), Chlamydia trachomatis and Neisseria gonorrhoeae, multiplex amplified probe technique, urine, vaginal, pharyngeal, or rectal, each pathogen reported as detected or not detected

The following CPT code(s) are covered when filed with an ICD-10 diagnosis code(s)* listed below:

This code can be used for the Aptima® BV Assay:

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

This code can be used for the BD MAX™ Vaginal Panel:

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

ICD-10 diagnosis code(s) list for CPT codes 81513 and 81514*

B37.31-B37.32
L29.2-L29.3
L29.9
N76.0-N76.3
N76.89
N77.1
N89.8-N89.9
N93.0
N95.2
O86.13
R30.0
R30.9

The following CPT code(s) are covered when filed with an ICD-10 diagnosis code(s)* listed below:

This code(s) can be used for Xpert® Xpress MVP:

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 (New Code Effective 1/1/2025)

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 (Code deleted 12/31/2024)

ICD-10 Diagnosis Code List for 81515 (0352U)

The following CPT code(s) is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

This code can be used for Bridge Women's Health Infectious Disease Detection Test:

0330U Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab

RELATED POLICIES

Biomarker Testing Mandate
Genetic Testing Services
Preventive Services for Medicare Advantage Plans
Proprietary Laboratory Analyses (PLA)

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