MASSACHUSETTS

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Medical Policy

Multitarget Polymerase Chain Reaction Testing for Diagnosis of Bacterial Vaginosis

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Policy Number: 711

BCBSA Reference Number: 2.04.127 (For Plan internal use only)
NCD/LCD: N/A

Related Policies

Identification of Microorganisms Using Nucleic Acid Probe, #555

Policy[1]

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Multitarget polymerase chain reaction (PCR) testing for the diagnosis of bacterial vaginosis may be considered **MEDICALLY NECESSARY** when the following criteria are met:

- For symptomatic individuals,
- When used as an alternative to Amsel clinical criteria or gram stain with Nugent scoring, **AND**
- When using FDA approved assays, **AND**
- For specimens collected by prescribing provider.

Multitarget polymerase chain reaction (PCR) testing for diagnosis of bacterial vaginosis is considered **INVESTIGATIONAL** in all other scenarios.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required.
Commercial PPO and Indemnity	Prior authorization is not required.

Medicare HMO Blue℠	Prior authorization is not required.
Medicare PPO Blue℠	Prior authorization is not required.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.
Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
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
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
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 ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
B37.31	Acute candidiasis of vulva and vagina
B37.32	Chronic candidiasis of vulva and vagina
B37.9	Candidiasis, unspecified
L29.2	Pruritus vulvae
L29.3	Anogenital pruritus, unspecified
L29.9	Pruritus, unspecified
N76.0	Acute vaginitis

N76.1	Subacute and chronic vaginitis
N76.2	Acute vulvitis
N76.3	Subacute and chronic vulvitis
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
N89.9	Noninflammatory disorder of vagina, unspecified
N93.0	Postcoital and contact bleeding
N95.2	Postmenopausal atrophic vaginitis
O86.13	Vaginitis following delivery
R30.0	Dysuria
R30.9	Painful micturition, unspecified

The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

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

Description

Bacterial Vaginosis

BV is a condition caused by an imbalance in the normal bacteria vaginal flora. It is common, especially in women 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.

(Policy # 555 addresses the use of direct or amplified nucleic acid probes with or without quantification to detect microorganisms of clinical significance, including single microorganisms associated with BV.

Proposed Multitarget PCR Tests

The SureSwab Total (Quest Diagnostics) test involves obtaining vaginal swab specimens, extracting total DNA, and quantitating the 4 types of bacteria using PCR. Results are reported as log cells per milliliter for each organism and concentrations of all *Lactobacilli* species are reported together then classified into 1 of the following 3 categories: not supportive, equivocal, and supportive.

A classification of *not supportive* of BV diagnosis is based on:

- The presence of *Lactobacillus* species, *G. vaginalis* levels <6.0 log cells/mL, and absence of *Atopobium vaginae* and *Megasphaera* species; or
- The absence of *Lactobacillus* species, *G. vaginalis* levels <6.0 log cells/mL, and absence of *A. vaginae* and *Megasphaera* species; or
- The absence of all targeted organisms.

A classification of equivocal is based on:
- The presence of *Lactobacillus* species, plus *G. vaginalis* at least 6.0 log cells/mL, and/or presence of *A. vaginae* and/or *Megasphaera* species.

A classification of supportive of BV diagnosis is based on the absence of *Lactobacillus* species, and presence of *G. vaginalis* levels of at least 6.0 log cells/mL, and presence of *A. vaginae and*/or *Megasphaera* species.

Another product, the BD Max (Becton, Dickinson), tests for markers of BV and vaginitis and was approved by the FDA in 2016. The test uses a similar process to that described for SureSwab. Vaginal swab specimens are collected, DNA is extracted, and real-time PCR is used to quantitate targeted organisms. Results of BV marker tests are not reported for individual organisms. Instead, qualitative BV results are reported as positive or negative for BV based on the relative quantity of the various organisms. The Aptima BV Assay was approved by the U.S. Food and Drug Administration in 2019 with the BD Max as the predicate device. The Aptima assay is a nucleic acid amplification test (NAAT) for detection and quantitation of ribosomal RNA.

Medical Diagnostics Laboratory offers a Bacterial Vaginosis Panel. Markers are assessed using real-time PCR and *Lactobacillus* is profiled using quantitative PCR. GenPath Diagnostics also offers a bacterial vaginosis test.

The NuSwab® Select BV test (Laboratory Corporation of America) uses semiquantitative PCR analysis of 3 predictive marker organisms of vaginal dysbiosis to generate a total score that is associated with the presence or absence of BV. In this test system, samples with a total score of 0 to 1 are considered negative for BV, samples with a score of 3 to 6 are positive for BV, and samples with a score of 2 are indeterminate for BV.

Several of the manufacturers of the BV tests also have extensions that include other causes of vaginitis such as *Trichomonas vaginalis* and *Candidiasis* species.

Summary

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.

Summary of Evidence

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.

PCR testing allows for screening of multiple bacteria at one time and is associated with improved turnaround times for patients resulting in quicker treatment. Symptomatic individuals have a high rate of

co-infection which is not often addressed by standard diagnostic workups. The American College of Obstetricians Gynecologists have recommended the use of PCR based testing for bacteria vaginitis in symptomatic individuals and as an alternative to traditional methods of screening. The evidence is sufficient to determine that the technology results in an improvement in net health outcome.

Policy History

Date	Action
5/2024	Clarified coding information. 5/1/2024.
4/2024	Policy revised to include coverage for 0352U and 0353U when policy criteria are met. Effective 4/1/2024.
10/2023	Clarified coding information.
3/2023	New medically necessary indications for polymerase chain reaction testing for bacterial vaginosis. Effective 3/1/2023. Clarified coding information.
10/2022	Clarified coding information.
7/2022	Clarified coding information.
2/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
2/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Clarified coding information.
1/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
2/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
8/2017	Annual policy review. New references added.
1/2016	Annual policy review. New references added.
3/2015	New medical policy describing investigational indications. Effective 3/1/2015.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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Endnotes

[1] Based on expert opinion