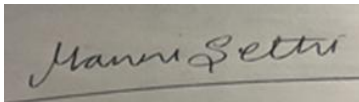


Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: AmeriHealth Caritas Pennsylvania Community HealthChoices & Keystone First Community HealthChoices		Submission Date: 4/1/2026
Policy Number: CCP.1325		Effective Date: 9/1/2017 Revision Date: 3/1/2026
Policy Name: Vaginitis Diagnostic Testing		
Type of Submission:		Type of Policy:
☐ New Policy	☒ Prior Authorization Policy	
☒ Revised Policy*	☐ Base Policy	
☐ Annual Review- no revisions	☐ Experimental/Investigational Policy	
	☐ Statewide PDL	
	☐ Other:	
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:		
Name of Authorized Individual (Please type or print):		Signature of Authorized Individual:
Manni Sethi, MD, MBA, CHCQM		

Vaginitis Diagnostic Testing

Clinical Policy ID: CCP.1325

Recent review date: 3/2026

Next review date: 7/2027

Policy contains: Bacterial vaginosis; vaginitis; vulvovaginal candidiasis; trichomoniasis.

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First Community HealthChoices, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

The following diagnostic tests for vaginitis, when provided in accordance with guideline-directed care, are clinically proven and, therefore, may be medically necessary for members who present with symptoms of vaginitis based on clinical examination and history (American College of Obstetricians and Gynecologists, 2020; Workowski, 2021):

- Point-of-care testing (i.e., pH testing, potassium hydroxide "whiff test," or saline microscopy) or Gram stain with Nugent scoring for bacterial vaginosis.
- Microscopy and, if necessary, vaginal yeast culture or nucleic acid amplification testing for *Candida* species (Workowski, 2021).
- Nucleic acid amplification testing as the first-line diagnostic method for *Trichomonas vaginalis* (American College of Obstetricians and Gynecologists, 2020; Workowski, 2021).
- U.S. Food and Drug Administration-cleared nucleic acid-based microbial testing for bacterial vaginosis, Trichomoniasis, and *Candida* species when any of the above tests are unavailable or inconclusive and the test results will impact care management (Workowski, 2021).

Repeat testing for *Trichomonas vaginalis* may be medically necessary within three months after treatment because of the high rates of infection recurrence (American College of Obstetricians and Gynecologists, 2020).

Limitations

The following tests are investigational/not clinically proven and, therefore, not medically necessary for diagnosis of vaginitis (American College of Obstetricians and Gynecologists, 2020; Workowski, 2021):

- Papanicolaou testing. However, for incidental findings of vulvovaginal candidiasis, bacterial vaginosis, or trichomoniasis on a Papanicolaou test, diagnostic confirmation may be medically necessary.

- Diagnostic testing that employs microarray or sequencing methods.
- Polymerase chain reaction testing for *Candida* species or bacterial vaginosis.

Routine screening for bacterial vaginosis in asymptomatic pregnant women for prevention of preterm delivery is investigational/not clinically proven and, therefore, not medically necessary (Owens, 2020).

Alternative covered services

In-network healthcare provider services for diagnosis and management of genital disorders.

Background

The most common causes of vaginitis include vulvovaginal candidiasis, bacterial vaginosis, and trichomoniasis. Less common etiologies include vulvar skin diseases, desquamative inflammatory vaginitis, and genitourinary syndrome of menopause. Bacterial vaginosis is associated with a high economic burden and marked racial disparities in prevalence (Peebles, 2019).

Vaginitis may have significant repercussions in terms of mental distress and physical discomfort, episodes of school or work absence, and sexual dysfunction (American College of Obstetricians and Gynecologists, 2020). Vaginitis is frequently seen in concert with sexually transmitted diseases, including human immunodeficiency virus. Distinguishing vaginal from vulvar symptoms is important to guide evaluation and treatment. Atrophic vaginitis is common with aging and the decreased ovarian production of estrogen. An accurate diagnosis of atrophic vaginitis among postmenopausal women is vitally important to choosing the appropriate treatment.

Diagnosis of vaginitis includes a clinical examination and history of perineal and vaginal discomfort, itching, or discharge, along with a choice of point-of-care testing, laboratory testing, and molecular (bacterial nucleic acid) diagnostic assays. Point-of-care testing includes pH testing, a potassium hydroxide “whiff test” (amine odor test), and saline microscopy. The standard of care for determining the initial diagnosis relies on applying three of the four results from point-of-care testing to Amsel clinical criteria (Coleman, 2018):

- Homogeneous, thin, white discharge that smoothly coats the vaginal walls.
- Clue cells (e.g., vaginal epithelial cells studded with adherent coccobacilli) on microscopic examination.
- pH of vaginal fluid > 4.5.
- A fishy odor of vaginal discharge before or after addition of 10% potassium hydroxide.

Laboratory examination (e.g., Gram stain) might include a microscopic examination of the discharge or vaginal vault with culture for bacterial, fungal, and parasitic etiologies. Direct deoxyribonucleic acid probe and nucleic acid amplification assays are the primary commercial molecular assays available in the United States for diagnosing bacterial vaginosis. Microarray and sequencing technologies are emerging methods that are currently available for research purposes. The U.S. Food and Drug Administration provides an online source for commercially available nucleic acid-based tests approved for diagnosing an infection with pathogens causing bacterial vaginosis (U.S. Food and Drug Administration, 2025).

Findings

Guidelines

There is uniform consensus among guidelines for testing recommendations in patients presenting with symptomatic vaginitis. There is less consensus for testing asymptomatic populations, regardless of risk status.

The Centers for Disease Control and Prevention does not recommend routine screening for bacterial vaginosis among asymptomatic pregnant women at high risk for preterm delivery, but symptomatic women should be evaluated and treated. Routine screening of adolescents and young adults who are asymptomatic for certain sexually transmitted diseases such as bacterial vaginosis is not typically recommended. In addition to clinical criteria, bacterial vaginosis can be diagnosed with the following tests (Workowski, 2021):

- Vaginal Gram stain (Nugent score of 7 to 10 indicating bacterial vaginosis).
- Point-of-care tests (e.g., Affirm VP III, Becton, Dickinson and Company, New Jersey).
- Nucleic acid amplification tests for symptomatic women only, because their accuracy is not well defined for asymptomatic women.
- U.S. Food and Drug Administration-cleared quantitative multiplex polymerase chain reaction assays. Laboratory-developed tests appear to have good sensitivity and specificity but have not been internally validated for use in patient care.

However, for diagnosing bacterial vaginosis, culture of *Gardnerella vaginalis* is not recommended, because it is not specific, and cervical Papanicolaou tests have no clinical utility because of their low sensitivity and specificity (Workowski, 2021).

Evidence-based guidance from the American College of Obstetricians and Gynecologists (2020) are as follows:

- For the initial evaluation of patients with vaginitis symptoms, a complete medical history, physical examination of the vulva and vagina, and point-of-care testing of vaginal discharge (i.e., pH testing, a potassium hydroxide whiff test, and microscopy) are recommended (Level C = recommendation based primarily on consensus and expert opinion).
- For the diagnosis of bacterial vaginosis, Amsel criteria based on clinical testing or Gram stain with Nugent scoring is recommended (Level A = recommendations based on good and consistent scientific evidence).
- For the diagnosis of trichomoniasis, nucleic acid amplification testing is recommended (Level A).
- Patients should be retested within three months after treatment for *Trichomonas vaginalis* because of the high rates of infection recurrence (Level B = recommendations based on limited or inconsistent scientific evidence).
- For diagnosis of vulvovaginal candidiasis, one of the following two findings is required:
 - Visualization of spores, pseudohyphae, or hyphae on wet-mount microscopy.
 - Vaginal fungal culture or commercial diagnostic test results positive for *Candida* species.
- Papanicolaou tests are not reliable for the diagnosis of vaginitis (Level B).
- Diagnostic confirmation is recommended for incidental findings of vulvovaginal candidiasis, bacterial vaginosis, or trichomoniasis on a Papanicolaou test (Level B).

The U.S. Preventive Services Task Force (Owens, 2020) provides screening recommendations for bacterial vaginosis informed by findings from a systematic review and meta-analysis (Kahwati, 2020). In pregnant persons who are not at increased risk for preterm delivery, the Task Force recommends against screening for bacterial vaginosis (Grade D). In pregnant persons who are at increased risk for preterm delivery, the evidence is insufficient to assess the balance of benefits and harms of screening for bacterial vaginosis (Grade I).

To prevent infection after abortion, the Society for Family Planning recommends testing patients empirically for gonorrhea and chlamydia at the time of the procedure if there is high clinical suspicion, and recommends against

screening for bacterial vaginosis before abortion. Both recommendations were GRADE 1C, indicating a strong recommendation based on low quality evidence, clinical experience, or expert consensus (Cheng, 2025).

Evidence review

Bacterial vaginosis during pregnancy

Bacterial vaginosis during pregnancy is associated with obstetric complications such as spontaneous abortions, premature rupture of membranes, preterm labor and delivery, chorioamnionitis, and post-cesarean endometritis. Evidence of the benefits of screening in asymptomatic pregnant women at low or high risk in reducing the rate of preterm deliveries is not established.

A systematic review and meta-analysis of seven randomized controlled trials (n = 738) examined whether screening and treatment for bacterial vaginosis effectively reduced the rate of preterm deliveries in high-risk populations. The risk factor for preterm delivery was a previous preterm delivery in six studies and a positive fetal fibronectin test in one study. Testing methods were point-of-care testing (i.e., pH testing, potassium hydroxide “whiff test,” or saline microscopy) or Gram stain with Nugent scoring. Treatment for bacterial vaginosis in high-risk women reduced the rate of preterm deliveries (pooled relative risk = 0.65, 95% confidence interval 0.44 to 0.98). Authors observed a statistically significant protective effect in women treated with clindamycin and when treatment was started after 20 gestational weeks. Additional randomized clinical trials are needed to confirm these findings (Yefet, 2025).

A systematic review and meta-analysis of 13 trials (143,534 samples) compared screening with Gram stain, pH screening, pH self-screening, or pH screening plus Gram stain to no screening in asymptomatic pregnant women. Regular screening of vaginal flora compared to no screening significantly reduced the odds of preterm birth before 37 weeks, extreme preterm birth before 32 weeks, low birthweight under 2500 grams, and very low birthweight under 1000 grams. However, the quality of evidence was considered very low for most results, the overall risk of bias was concerning, and testing and treatment protocols were highly variable (Hoffmann, 2023).

Trichomonas vaginalis detection

For detecting *Trichomonas vaginalis*, culture and direct microscopic examination are commonly used, and nucleic acid amplification tests offer improved sensitivity and specificity. Simple, rapid diagnostic tests with acceptable sensitivity and specificity have been proposed to improve diagnosis at the point of care. Real-time polymerase chain reaction assay offers another testing option with improved diagnostic performance and rapid testing.

In a meta-analysis of 11 studies with 5,884 samples, rapid antigen tests yielded a pooled sensitivity of 87.0% and a pooled specificity of 98.3%. Antigen tests demonstrated greater sensitivity in diagnosing symptomatic patients compared to asymptomatic individuals. The sensitivity of antigen testing was 58.5% compared to polymerase chain reaction and 95.9% compared to culture. Diagnostic performance depended on the reference standard and presence of symptoms (Hsiao, 2025).

Babafemi (2025) assessed the diagnostic accuracy of real-time polymerase chain reaction assay in clinical vaginal samples from symptomatic and asymptomatic women compared to Trichomonads culture as the reference standard. A meta-analysis of 27 eligible studies found high pooled sensitivity (99%) and pooled specificity (100%). A subgroup meta-analysis of 13 studies (10,796 total specimens) conducted in the United States produced similar results; in addition, the area under the receiver operating characteristic curve was 0.99. There was significant heterogeneity across studies, which authors attributed to variation in assays and testing protocols.

In 2020, we included updated guidance from the Centers for Disease Control and Prevention, the American College of Obstetricians and Gynecologists, and the U.S. Preventive Services Task Force, along with a

systematic review and meta-analysis (Kahwati, 2020) that informed the Task Force recommendations. We modified coverage criteria to align with these recommendations.

In 2022, we updated the references and made no policy changes.

In 2024, we added results of a systematic review (Hoffmann, 2023) to the policy that provided conflicting results regarding the clinical value of routinely screening for bacterial vaginosis in low-risk pregnant women. No policy changes are warranted.

In 2025, we updated policy criteria to align with revised guidance from the Centers for Disease Control and Prevention (Workowski, 2021).

In 2026, we updated the references and reorganized the findings section with no policy changes warranted.

References

On January 15, 2026, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “vaginitis/diagnosis” (MeSH), “vaginosis, bacterial/diagnosis” (MeSH), “vaginitis,” “vaginal discharge” and “vaginal infection.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Yefet E, Mirin D, Massalha M, Alter A, Nachum Z. Screening for and treatment of bacterial vaginosis reduced preterm delivery in high-risk pregnant women: A systematic review and meta-analysis. *Gynecol Obstet Invest*. 2025;90(4):353-362. Doi: 10.1159/000543502.

Policy updates

7/2017: initial review date and clinical policy effective date: 9/2017

7/2018: Policy references updated. Policy ID changed.

8/2019: Policy references updated.

10/2020: Policy references updated. Coverage modified.

10/2021: Policy references updated.

11/2022: Policy references updated.

3/2024: Policy references updated.

3/2025: Policy references updated.

3/2026: Policy references updated.

Related Codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1325. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code Description
0402U	Infectious agent (sexually transmitted infection), <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , <i>Trichomonas vaginalis</i> , <i>Mycoplasma genitalium</i> , multiplex amplified probe technique, vaginal, endocervical, or male urine, each pathogen reported as detected or
0455U	Infectious agents (sexually transmitted infection), <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , and <i>Trichomonas vaginalis</i> , multiplex amplified probe technique, vaginal, endocervical, gynecological specimens, oropharyngeal swabs, rectal swabs, female or male urine, each pathogen reported as detected or not detected
0557U	Infectious disease (bacterial vaginosis and vaginitis), real-time amplification of DNA markers for <i>Atopobium vaginae</i> , <i>Gardnerella vaginalis</i> , <i>Megasphaera</i> types 1 and 2, bacterial vaginosis associated bacteria-2 and -3 (BVAB-2, BVAB-3), <i>Mobiluncus</i> species, <i>Trichomonas vaginalis</i> , <i>Neisseria</i>

Code	Code Description
81513	gonorrhoeae, <i>Candida</i> species (<i>C. albicans</i> , <i>C. tropicalis</i> , <i>C. parapsilosis</i> , <i>C. glabrata</i> , <i>C. krusei</i>), Herpes simplex viruses 1 and 2, vaginal fluid, reported as detected or not detected for each organism
81514	Infectious disease, bacterial vaginosis, quantitative real-time amplification of RNA markers for <i>Atopobium vaginae</i> , <i>Gardnerella vaginalis</i> , and <i>Lactobacillus</i> species, utilizing vaginal-fluid specimens, algorithm reported as a positive or negative result for bacterial vaginosis
81515	Infectious disease, bacterial vaginosis and vaginitis, quantitative real-time amplification of DNA markers for <i>Gardnerella vaginalis</i> , <i>Atopobium vaginae</i> , <i>Megasphaera</i> type 1, Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), and <i>Lactobacillus</i> species (<i>L. crispatus</i> and <i>L. jensenii</i>), utilizing vaginal-fluid specimens, algorithm reported as a positive or negative for high likelihood of bacterial vaginosis, includes separate detection of <i>Trichomonas vaginalis</i> and/or <i>Candida</i> species (<i>C. albicans</i> , <i>C. tropicalis</i> , <i>C. parapsilosis</i> , <i>C. dubliniensis</i>), <i>Candida glabrata</i> , <i>Candida krusei</i> , when reported
87070	Infectious disease, bacterial vaginosis and vaginitis, real-time PCR amplification of DNA markers for <i>Atopobium vaginae</i> , <i>Atopobium species</i> , <i>Megasphaera</i> 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 <i>Trichomonas vaginalis</i> and <i>Candida</i> species (<i>C. albicans</i> , <i>C. tropicalis</i> , <i>C. parapsilosis</i> , <i>C. dubliniensis</i>), <i>Candida glabrata</i> / <i>Candida krusei</i> , when reported
87071	Culture, bacterial; any other source except urine, blood or stool, aerobic, with isolation and presumptive identification of isolates
87075	Culture, bacterial; quantitative, aerobic with isolation and presumptive identification of isolates, any source except urine, blood or stool
87480	Culture, bacterial; any source, except blood, anaerobic with isolation and presumptive identification of isolates
87481	Infectious agent detection by nucleic acid (DNA or RNA); <i>Candida</i> species, direct probe technique
87510	Infectious agent detection by nucleic acid (DNA or RNA); <i>Candida</i> species, amplified probe technique
87511	Infectious agent detection by nucleic acid (DNA or RNA); <i>Gardnerella vaginalis</i> , direct probe technique
87660	Infectious agent detection by nucleic acid (DNA or RNA); <i>Gardnerella vaginalis</i> , amplified probe technique
87661	Infectious agent detection by nucleic acid (DNA or RNA); <i>Trichomonas vaginalis</i> , direct probe technique
87798	Infectious agent detection by nucleic acid (DNA or RNA); <i>Trichomonas vaginalis</i> , amplified probe technique
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism