



## Vaginitis Testing

LOB(s): <input checked="" type="checkbox"/> Commercial  <input checked="" type="checkbox"/> Medicare  <input checked="" type="checkbox"/> Medicaid	State(s): <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other:  <input checked="" type="checkbox"/> Oregon <input type="checkbox"/> Washington
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### Enterprise Policy

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans PacificSource Community Health Plans, and PacificSource Community Solutions, in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

### Background

Vaginitis is a general term for disorders of the vagina (and vulva) caused by infection, inflammation, or changes in the normal vaginal flora (e.g., Lactobacillus species). Bacterial vaginosis is the most common cause of abnormal vaginal discharge in reproductive-age females. Treatment is aimed at relieving symptoms, although many individuals are asymptomatic. Bacterial vaginosis can contribute to obstetrical complications, preterm delivery, pelvic inflammatory disease, increased risk of sexually transmitted infections and urogenital infections.

Testing methods for the diagnosis of Bacterial Vaginosis include bacterial culture and microscope examination, molecular testing-direct DNA probe assay (direct deoxynucleic acid/ nucleic acid hybridization, amplification- NAAT -nucleic acid amplification of RNA or DNA using polymerase chain reaction (PCR), transcription mediated amplification (TMA) or strand displacement amplification (SDA).

### Criteria

#### I. Vaginitis Testing

PacificSource covers the following diagnostic studies for Vaginitis:

- A. Single organism tests
- B. Tests approved by PacificSource New Technologies and Operational Criteria (NTOC) for multitarget coverage (additional coding information below):
  1. 0352U and 0353U (e.g., Xpert)

2. 81513 and 81514 (e.g., SureSwab, BD MAX Vaginal Panel, INFINITI Bacterial Vaginosis Quad Assay, INFINITI Candida, Vaginosis Quad Assay, OneSwab)

## Medicaid

PacificSource Community Solutions follows the diagnostic and general coverage requirements, limitations, and exclusions outlined in OARs 410-120-1200, 410-141-3820, and 410-141-3825 in conjunction with utilizing the OHP's Diagnostic Procedure Code Group 1119 for coverage for bacterial vaginosis testing.

PacificSource Community Solutions (PCS) follows the EPSDT coverage requirements in OAR 410-151-0002 and 410-151-0004 for members under the age of 21. A case-by-case review for EPSDT Medical Necessity and EPSDT Medical Appropriateness defined in OAR 410-151-0001 is required prior to a determination of non-coverage.

## Medicare

PacificSource Medicare follows Local Coverage Determination L39003 for Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing

## Coding Information

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The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

- 0352U Infectious disease (bacterial vaginosis and vaginitis), multiplex amplified probe technique, for detection of bacterial vaginosis-associated bacteria (BVAB-2, *Atopobium vaginae*, and *Megasphaera* 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 –
- 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
- 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
- 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
- 87482 Infectious agent detection by nucleic acid (DNA or RNA); *Candida* species, 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
- 87640 Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, amplified probe technique
- 87653 Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group B, amplified probe technique
- 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
- 87808 Infectious agent antigen detection by immunoassay with direct optical observation; Trichomonas vaginalis

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HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

## Related Policies

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New and Emerging Technologies – Coverage Status

## References

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Catlin B. W. (1992). Gardnerella vaginalis: characteristics, clinical considerations, and controversies. *Clinical microbiology reviews*, 5(3), 213–237. <https://doi.org/10.1128/CMR.5.3.213>

Kenyon, C. R., & Osbak, K. (2014). Recent progress in understanding the epidemiology of bacterial vaginosis. *Current opinion in obstetrics & gynecology*, 26(6), 448–454. <https://doi.org/10.1097/GCO.000000000000112>

Paladine, H. L., & Desai, U. A. (2018). Vaginitis: Diagnosis and Treatment. *American family physician*, 97(5), 321–329.

Vaginitis. ACOG. (2023). <https://www.acog.org/womens-health/faqs/vaginitis>

OHP's Diagnostic Procedure Codes Group 1119.

[https://data.oregon.gov/Health-Human-Services/Diagnostic-Procedure-Codes-Group-1119-/gmb4-77ea/about\\_data](https://data.oregon.gov/Health-Human-Services/Diagnostic-Procedure-Codes-Group-1119-/gmb4-77ea/about_data)

## Appendix

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Policy Number:

Effective: 10/1/2023

Next review: 10/1/2025

**Policy type:** Enterprise

**Author(s):**

**Depts.:** Health Services

**Applicable regulation(s):** OAR 410-141-3820, 410-141-3825, 410-151-0001, 410-151-0002, 410-151-0004

**Commercial Ops:** 8/2024

**Government Ops:** 8/2024