

INFECTIOUS DISEASE: GENITOURINARY TESTING

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

OVERVIEW

Genitourinary diseases are common ailments that affect all age ranges. Urinary tract infections are caused by microorganisms that enter the urethra from the surrounding skin which can be contaminated by vaginal pathogens, fecal remnants, or mechanically introduced (e.g., during urinary catheter insertion or sexual intercourse, or less commonly, arrive to the kidney via its blood flow from infection at a different site). Pathogens can infect the lower urinary tract, causing inflammation and painful urination, or the upper urinary tract, leading to complications such as kidney infection.

Vaginitis is inflammation specifically affecting the vagina. Bacterial vaginosis (BV) is a major cause of vaginitis along with yeast infections and infection with the protozoa *Trichomonas vaginalis*. Vaginitis, particularly when observed with cervicitis, can indicate chlamydia or gonorrhea infection. The cause of vaginitis cannot be determined based on symptoms alone. Additionally, coinfection with more than one organism is not uncommon. Untreated or improperly treated infectious vaginitis can lead to poor health outcomes and increased need for follow-up visits.

Testing urine and genital secretions may enable providers to choose precise therapy and afford the patient a better outcome. Cultures, microscopic examination and molecular identification are all common testing methods for evaluating the infectious causes of various genitourinary conditions.

This policy is intended for use in the outpatient setting.

POLICY REFERENCE TABLE

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2022, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are

included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| Criteria Sections | Example Tests (Labs) | Common CPT Codes | Common ICD Codes | Ref |
|--|---|-----------------------------------|---|------------|
| Targeted Vaginitis/Vaginosis Pathogen Testing | SureSwab Advanced Bacterial Vaginosis (BV), TMA (Kit by Hologic, Inc.; billing lab varies) | 81513 | L29.2, L29.3, N76.0, N76.1, | 1, 2, 3, 4 |
| | Vaginosis/Vaginitis (BV, Candida, Trich) by PCR (Kit by Becton Dickinson and Company; billing lab varies) | 81514 | N76.2, N76.3, N76.8, N76.89, N93.0, | |
| | Bacterial Vaginosis/Vaginitis Panel (Quest Diagnostic Laboratory) | 87480, 87510, 87660 | N94.1, R30.0, N89.8, Z34 | |
| | Vaginitis (VG), NuSwab (Mayo Clinic Laboratories) | 87801, 87798, 87661 | | |
| | Vaginitis Plus (VG+) With Candida (Six Species), NuSwab (LabCorp) | 87491, 87591, 87661, 87798, 87801 | | |
| | SureSwab Advanced Vaginitis Plus, TMA (Quest) | 81513, 87481, 87661, 87491, 87591 | | |
| | Xpert® Xpress MVP (Cepheid) | 0352U | | |
| Expanded Multiplex Vaginitis/Vaginosis Pathogen Panels | Bridge Women’s Health Infectious Disease Detection Test (Bridge Diagnostics) | 0330U | | 1, 2, 3, 4 |
| Urine Culture for Asymptomatic Bacteriuria | Urine Culture, Routine (LabCorp) | 87086, 87088 | Z33-Z33.3, Z34, Z3A.0-Z3A.49, Z36-Z36.9, Z01.81, Z01.818, | 5 |

| | | | | |
|--|--|-------|--|------|
| | | | Z01.82, Z01.89, 52601, 52648, 52356, 52353, 50080, 50081, 52214, 52601, 52647, 52649, 53850, 53852, 53854, 55705, 55706 | |
| <u>Molecular/Multiple x UTI Panels</u> | Bridge Urinary Tract Infection Detection and Resistance Test (Bridge Diagnostics) | 0321U | | 5, 6 |
| | Qlear UTI (Lifescan Labs of Illinois, Thermo Fisher Scientific) | 0371U | | |
| | Qlear UTI – Reflex ABR (Lifescan Labs of Illinois, Thermo Fisher Scientific) | 0372U | | |
| | Urogenital Pathogen with Rx Panel (UPX) (Lab Genomics LLC, Thermo Fisher Scientific) | 0374U | | |
| | GENETWORx UTI with ABR (RCA Laboratory Services LLC) | 0416U | | |

CRITERIA

It is the policy of health plans affiliated with Centene Corporation® that the specific tests noted below are medically necessary when meeting the related criteria:

Targeted Vaginitis/Vaginosis Pathogen Testing

- I. Targeted vaginitis/vaginosis pathogen testing via direct probe for *Gardnerella vaginalis*, *Candida albicans*, and/or *Trichomonas vaginalis*, OR nucleic acid/PCR tests for bacterial vaginosis, candidiasis, and/or trichomoniasis, OR multipathogen panel of 6 targets or fewer, with or without chlamydia and/or gonorrhea, may be considered **medically necessary** when:
 - A. The member has at least one of the following:
 1. Abnormal vaginal discharge, **OR**
 2. Vulvovaginal itching, irritation, or redness (e.g., pruritus, erythema, edema), **OR**
 3. Painful sexual intercourse (dyspareunia), **OR**
 4. Painful urination (dysuria), **OR**
 5. Postcoital or contact bleeding.
 - II. Current evidence does not support the use of targeted vaginitis/vaginosis pathogen testing via direct probe for *Gardnerella vaginalis*, *Candida albicans*, and/or *Trichomonas vaginalis*, OR nucleic acid/PCR tests for bacterial vaginosis, candidiasis, and/or trichomoniasis, OR multipathogen panel of 6 targets or fewer, with or without chlamydia and/or gonorrhea for all other indications, including:
 - A. Asymptomatic pregnant members (regardless of preterm labor risk).

Expanded Multiplex Vaginitis/Vaginosis Pathogen Panels

- I. Current evidence does not support the use of expanded multiplex vaginitis/vaginosis pathogen panels with more than 6 targets.

Urinary Tract and Kidney Infections

Urine Culture for Asymptomatic Bacteriuria

- I. Urine culture for asymptomatic bacteriuria may be considered **medically necessary** when:
 - A. The member is pregnant, **OR**
 - B. The member will undergo an [endoscopic urologic procedure with mucosal trauma](#).

- II. Current evidence does not support the use of urine culture for asymptomatic bacteriuria for all other indications.

Molecular/Multiplex UTI Panels

- I. Current evidence does not support the use of molecular/multiplex UTI Panels.

NOTES AND DEFINITIONS

1. **Endoscopic urologic procedure with mucosal trauma:** examples of such procedures include, but are not limited to: transurethral surgery of the prostate or bladder, ureteroscopy including lithotripsy, and percutaneous stone surgery.

BACKGROUND AND RATIONALE

Targeted Vaginitis/Vaginosis Pathogen Testing

Up To Date

“Ideally, the abnormal vaginal discharge is tested for evidence of BV, Candida species, and trichomonas when the patient is symptomatic... The traditional gold standard tests have been culture (for candida species and trichomoniasis) and microscopy with Nugent score, followed by Amsel criteria for indeterminate tests, for BV. However, NAATs have become an established alternative to both as NAATs have similar or better test sensitivity and specificity... NAATs can be used as the initial diagnostic tool or as a follow-up to negative microscopy in patients with high clinical suspicion” (see algorithm 1 for additional details).

American College of Obstetricians and Gynecologists (ACOG)

In ACOG Practice Bulletin #215 which discusses vaginitis in nonpregnant patients, Table 1 delineates the symptoms and clinical findings associated with the various causes of vaginitis: abnormal textured/colored/malodorous vaginal discharge; pruritus, irritation, dysuria, burning, dyspareunia; vaginal or cervical-vaginal erythema with petechiae; edema, excoriations, and fissures. (p. e4) The guidelines also state that “...symptomatic patients with trichomoniasis may report...postcoital bleeding.” (p. e2)

“Nucleic acid amplification testing is recommended for the diagnosis of trichomoniasis.” (p. e11)

Kong et al.

“This study tracks health care spending among women diagnosed with vaginitis and finds that nucleic acid amplification tests (NAATs) are cost-effective for the diagnosis of vaginal symptoms. Women who receive a NAAT on the day of their diagnosis have significantly lower

12-month follow-up costs compared to women who receive a direct probe test or those women who are clinically evaluated without the use of a molecular test.” (p. 515)

United States Preventive Services Task Force

The USPSTF published guidelines in 2020 discussing bacterial vaginosis (BV) screening in pregnant individuals. The guidelines recommend against screening for BV in pregnant patients who are not at increased risk for preterm labor. These guidelines also state that there is insufficient evidence to conclusively determine if BV screening for pregnant patients at increased risk for preterm labor is beneficial.

Expanded Multiplex Vaginitis/Vaginosis Pathogen Panels

There are no professional guidelines or recommendations we identified to support the use of these tests. The following guidelines and publications were reviewed in-depth in September 2023: United States Preventive Services Task Force, UpToDate, American College of Obstetricians and Gynecologists, Kong et al.

Urine Culture for Asymptomatic Bacteriuria

Infectious Diseases Society of America

The IDSA published an updated guideline in 2019 with clinical practice recommendations for the management of asymptomatic bacteriuria (ASB). The guidelines recommend screening for ASB in pregnant individuals (p. e85), and in individuals who are undergoing endoscopic urologic procedures associated with mucosal trauma (p. e86).

The guidelines recommend against screening for ASB, or make no recommendations for or against screening for ASB, in most other individuals, including:

- Infants and children
- Health nonpregnant people
- Functionally impaired older adults
- Older residents of long-term care facilities
- Recipients of a solid organ transplant (including kidney)
- Individuals with neutropenia
- Individuals with impaired voiding following a spinal cord injury
- Individuals with an indwelling urethral catheter
- Individuals undergoing elective nonurologic surgery
- Individuals with a urologic implant, or who are undergoing surgical implantation of a urologic device (p. e85 and e86)

Molecular/Multiplex UTI Panels

There are no professional guidelines or recommendations we identified to support the use of these tests. The following guidelines and publications were reviewed in-depth in September 2023: Infectious Disease Society of America, ACOG.

| Reviews, Revisions, and Approvals | Revision Date | Approval Date |
|--|---------------|---------------|
| Policy developed. Reviewed by external specialist. | 11/23 | |

REFERENCES

1. Bacterial Vaginosis in Pregnant Persons to Prevent Preterm Delivery: Screening. United States Preventive Services Task Force. Updated April 7, 2020. Accessed January 3, 2024. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/bacterial-vaginosis-in-pregnancy-to-prevent-preterm-delivery-screening>
2. Sobel JD. Vaginitis in adults: Initial evaluation. UpToDate. www.uptodate.com. Updated November 6, 2023. Accessed January 3, 2024.
3. Vaginitis in Nonpregnant Patients: ACOG Practice Bulletin, Number 215. *Obstet Gynecol.* 2020;135(1):e1-e17. doi:10.1097/AOG.0000000000003604
4. Kong AM, Jenkins D, Troeger KA, Kim G, London RS. Diagnostic Testing of Vaginitis: Improving the Value of Care. *Popul Health Manag.* 2021;24(4):515-524. doi:10.1089/pop.2021.0143
5. Nicolle LE, Gupta K, Bradley SF, et al. Clinical Practice Guideline for the Management of Asymptomatic Bacteriuria: 2019 Update by the Infectious Diseases Society of America. *Clin Infect Dis.* 2019;68(10):1611-1615. doi:10.1093/cid/ciz021
6. Urinary Tract Infections in Pregnant Individuals. *Obstet Gynecol.* 2023;142(2):435-445. doi:10.1097/AOG.0000000000005269

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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