Coding Implications
Revision log

INFECTIOUS DISEASE: GENITOURINARY LAB 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

Criteria Sections	Example Tests (Labs)	References

Targeted Vaginitis/Vaginosis Pathogen Testing	SureSwab Advanced Bacterial Vaginosis (BV), TMA (Kit by Hologic, Inc.; billing lab varies)	1, 2, 3, 4
	Vaginosis/Vaginitis (BV, Candida, Trich) by PCR (Kit by Becton Dickinson and Company; billing lab varies)	
	Bacterial Vaginosis/Vaginitis Panel (Quest Diagnostic Laboratory)	
	Vaginitis (VG), NuSwab (Mayo Clinic Laboratories)	
	Vaginitis Plus (VG+) With Candida (Six Species), NuSwab (LabCorp)	
	SureSwab Advanced Vaginitis Plus, TMA (Quest)	
	Xpert® Xpress MVP (Cepheid)	
Expanded Multiplex Vaginitis/Vaginosis Pathogen Panels	Bridge Women's Health Infectious Disease Detection Test (Bridge Diagnostics)	1, 2, 3, 4
Urine Culture for Asymptomatic Bacteriuria	Urine Culture, Routine (LabCorp)	5
Molecular/Multiplex UTI Panels	Bridge Urinary Tract Infection Detection and Resistance Test (Bridge Diagnostics)	5, 6
	Qlear UTI (Lifescan Labs of Illinois, Thermo Fisher Scientific)	
	Qlear UTI – Reflex ABR (Lifescan Labs of Illinois, Thermo Fisher Scientific)	
	Urogenital Pathogen with Rx Panel (UPX) (Lab Genomics LLC, Thermo Fisher Scientific)	
	GENETWORx UTI with ABR (RCA Laboratory Services LLC)	

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/enrollee 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/enrollees (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/enrollee is pregnant, **OR**

   B. The member/enrollee 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.

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 2023, 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.

CPT® Codes	Description
81513	Acute hepatitis panel This panel must include the following: Hepatitis A antibody (HAAb), IgM antibody (86709) Hepatitis B core antibody (HBcAb), IgM antibody (86705) Hepatitis B surface antigen (HBsAg) (87340) Hepatitis C antibody (86803)
81514	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
87086	Culture, presumptive, pathogenic organisms, screening only; with colony estimation from density chart
87088	Culture, bacterial; with isolation and presumptive identification of each isolate, urine
87481	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique
87482	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique
87490	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia pneumoniae, quantification
87491	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, direct probe technique
87492	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, amplified probe technique

CPT® Codes	Description
87498	Infectious agent detection by nucleic acid (DNA or RNA); cytomegalovirus, quantification
87500	Infectious agent detection by nucleic acid (DNA or RNA); enterovirus, amplified probe technique, includes reverse transcription when performed
87511	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, direct probe technique
87512	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, amplified probe technique
87551	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria species, direct probe technique
87556	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria tuberculosis, direct probe technique
87561	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria avium-intracellulare, direct probe technique
87563	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria avium-intracellulare, quantification
87590	Infectious agent detection by nucleic acid (DNA or RNA); Mycoplasma pneumoniae, quantification
87591	Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, direct probe technique
87592	Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, amplified probe technique
87640	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique
87641	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, amplified probe technique
87650	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, methicillin resistant, amplified probe technique
87651	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, direct probe technique
87652	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, amplified probe technique
87653	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, quantification
87661	Infectious agent detection by nucleic acid (DNA or RNA); Trichomonas vaginalis, direct probe technique
87797	Infectious agent detection by nucleic acid (DNA or RNA); Zika virus, amplified probe technique
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; direct probe technique, each organism
87799	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism
87800	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; quantification, each organism
87801	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; direct probe(s) technique
0321U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms and identification of 16 associated antibiotic-resistance genes, multiplex amplified probe technique

CPT® Codes	Description
0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab
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
87510	Infectious agent detection by nucleic acid (DNA or RNA), gardnerella vaginal direct probe
87480	Infectious agent detection by nucleic acid (DNA or RNA); Borrelia miyamotoi, amplified probe technique
87660	Infectious agent detection by nucleic acid (DNA or RNA) trichomonas vaginal
0371U	Infectious agent detection by nucleic acid gu pthgn semiq dna16&1
0372U	Infectious agent detection by nucleic acid nfct ds gu pathogen erg detection
0374U	Urogenital Pathogen with Rx Panel
0416U	Infectious agent detection by nucleic acid (DNA or RNA); GU pathogen 20BCT and fungal organism ID 20 ARG urine

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Reviewed by external specialist.	11/23	02/24
Added “lab” to policy title. Removed CPT and ICD-10 codes from policy reference table. Added CPT code table and moved the “coding implications” section.	02/24	

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

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.