Coding Implications
Revision Log

CONCERT 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

Criteria Sections	Example Tests (Labs)	Ref
Vaginitis and Vaginosis Pathogen Tests		
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
	Vaginal Infection Testing (NxGen MDx, LLC)	
Urinary Tract and Kidney Infections		
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)	
	Urinary Tract Infection Testing (NxGen MDx, 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:

VAGINITIS AND VAGINOSIS PATHOGEN TESTS

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 six targets or fewer, with or without chlamydia and/or gonorrhea is 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. 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 six targets or fewer, with or without chlamydia and/or gonorrhea is considered **investigational** for all other indications, including:

   A. Asymptomatic pregnant members/enrollees (regardless of preterm labor risk).

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Expanded Multiplex Vaginitis/Vaginosis Pathogen Panels

I. Expanded multiplex vaginitis/vaginosis pathogen panels with more than six targets are considered **investigational**.

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URINARY TRACT AND KIDNEY INFECTIONS

Urine Culture for Asymptomatic Bacteriuria

I. Urine culture for asymptomatic bacteriuria is 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. Urine culture for asymptomatic bacteriuria is considered **investigational** for all other indications.

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Molecular/Multiplex UTI Panels

I. Molecular/multiplex UTI Panels are **investigational** for all indications.

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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.

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BACKGROUND AND RATIONALE

VAGINITIS AND VAGINOSIS PATHOGEN TESTS

Targeted Vaginitis/Vaginosis Pathogen Testing

UpToDate

"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"

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.

URINARY TRACT AND KIDNEY INFECTIONS

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
- Healthy 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 May 2024: Infectious Disease Society of America, American College of Obstetricians and Gynecologists.

Coding Implications

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CPT® Codes	Description
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
0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab
0371U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogen, semiquantitative identification, DNA from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qPCR), urine
0372U	Infectious disease (genitourinary pathogens), antibiotic-resistance gene detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score
0374U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 21 bacterial and fungal organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, urine
0504U	Infectious disease (urinary tract infection), identification of 17 pathologic organisms, urine, real-time PCR, reported as positive or negative for each organism

CPT® Codes	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
81515	Infectious disease, bacterial vaginosis and vaginitis, real-time PCR amplification of DNA markers for Atopobium vaginae, Atopobium species, Megasphaera 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 Trichomonas vaginalis and Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, when reported
87086	Culture, bacterial; quantitative colony count, urine
87088	Culture, bacterial; with isolation and presumptive identification of each isolate, urine
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
87490	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, amplified probe technique
87491	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, amplified probe technique
87492	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, quantification
87498	Infectious agent detection by nucleic acid (DNA or RNA); enterovirus, amplified probe technique, includes reverse transcription when performed
87500	Infectious agent detection by nucleic acid (DNA or RNA); vancomycin resistance (eg, enterococcus species van A, van B), amplified probe technique
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

CPT® Codes	Description
87528	Infectious agent detection by nucleic acid (DNA or RNA); Herpes simplex virus, direct probe technique
87529	Infectious agent detection by nucleic acid (DNA or RNA); Herpes simplex virus, amplified probe technique
87530	Infectious agent detection by nucleic acid (DNA or RNA); Herpes simplex virus, quantification
87531	Infectious agent detection by nucleic acid (DNA or RNA); Herpes virus-6, direct probe technique
87532	Infectious agent detection by nucleic acid (DNA or RNA); Herpes virus-6, amplified probe technique
87533	Infectious agent detection by nucleic acid (DNA or RNA); Herpes virus-6, quantification
87534	Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, direct probe technique
87535	Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, amplified probe technique, includes reverse transcription when performed
87536	Infectious agent detection by nucleic acid (DNA or RNA); HIV-1, quantification, includes reverse transcription when performed
87537	Infectious agent detection by nucleic acid (DNA or RNA); HIV-2, direct probe technique
87538	Infectious agent detection by nucleic acid (DNA or RNA); HIV-2, amplified probe technique, includes reverse transcription when performed
87539	Infectious agent detection by nucleic acid (DNA or RNA); HIV-2, quantification, includes reverse transcription when performed
87551	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria species, amplified probe technique
87556	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria tuberculosis, amplified probe technique
87561	Infectious agent detection by nucleic acid (DNA or RNA); Mycobacteria avium-intracellulare, amplified probe technique
87563	Infectious agent detection by nucleic acid (DNA or RNA); Mycoplasma genitalium, amplified probe technique
87590	Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, direct probe technique
87591	Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, amplified probe technique
87592	Infectious agent detection by nucleic acid (DNA or RNA); Neisseria gonorrhoeae, quantification
87640	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, amplified probe technique

CPT® Codes	Description
87641	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, methicillin resistant, amplified probe technique
87650	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, direct probe technique
87651	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, amplified probe technique
87652	Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group A, quantification
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
87797	Infectious agent detection by nucleic acid (DNA or RNA); not otherwise specified; direct probe technique, each organism
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism
87799	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; quantification, each organism
87800	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; direct probe(s) technique
87801	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique
87808	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Trichomonas vaginalis
87810	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Chlamydia trachomatis
87850	Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; Neisseria gonorrhoeae
87901	Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions
87903	Infectious agent phenotype analysis by nucleic acid (DNA or RNA) with drug resistance tissue culture analysis, HIV 1; first through 10 drugs tested
87904	Infectious agent phenotype analysis by nucleic acid (DNA or RNA) with drug resistance tissue culture analysis, HIV 1; each additional drug tested (List separately in addition to code for primary procedure)

CPT® Codes	Description
87906	Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, other region (eg, integrase, fusion)

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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	
Corrected CPT descriptions and removed 87510, 87480, 87660, 0371U, 0372U, 0374U, 0416U.	03/24	
Annual review. Added policy number to header. Minor rewording without clinical significance. For Urine Culture for Asymptomatic Bacteriuria: Addition of Urinary Tract Infection Testing (NxGen MDx, LLC) to Policy Reference Table. Changed policy statements for the following criteria sections from "may be considered medically necessary" to "are considered medically necessary": Targeted Vaginitis/Vaginosis Pathogen Testing, For Expanded Multiplex Vaginitis/Vaginosis Pathogen Panels: Addition of Vaginal Infection Testing (NxGen MDx, LLC) to Policy Reference Table. Additional codes added to coding table: 87510, 87660, 87808, 87810, 87850, 0371U, 0372U, 0374U, 0504U, 81515, 87528, 87529, 87530, 87531, 87532, 87533, 87534, 87535, 87536, 87537, 87538, 87539, 87901, 87903, 87904, 87906. Removed deleted code 0352U. Background and references updated.	11/24	02/25

REFERENCES

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3. Vaginitis in Nonpregnant Patients: ACOG Practice Bulletin, Number 215. Obstet Gynecol. 2020 Jan;135(1):e1-e17. doi: 10.1097/AOG.0000000000003604. PMID: 31856123.
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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):e83-e110.
6. Urinary tract infections in pregnant individuals. Obstet Gynecol. 2023;142(2):435-445.

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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.

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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.