Test Specific Guidelines

Genitourinary Conditions Molecular Testing

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Introduction

Molecular testing for genitourinary conditions is addressed by this guideline.

Procedures Addressed

The inclusion of any procedure code in this table is provided for informational purposes and is not a guarantee of coverage nor an indication that prior authorization is required.

Procedures addressed by this guideline	Procedure codes
Aptima BV Assay	81513
BD MAX Vaginal Panel	81514
Candida species	87480 87481 87482
Candida species panel (C. albicans, C. glabrata, C. parapsilosis, C. kruseii, C. tropicalis, and C. auris), amplified probe technique with qualitative report of the presence or absence of each species	0068U
Chlamydia trachomatis	87490 87491 87492
Gardnerella	87510 87511 87512
Herpes simplex virus	87528 87529 87530

Procedures addressed by this guideline	Procedure codes
Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; direct probe technique, each organism	87797
Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism	87798
Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; quantification, each organism	87799
Mycoplasma genitalium, amplified probe technique	87563
Neisseria gonorrhoeae	87590 87591 87592
Trichomonas vaginalis	87660 87661
Xpert CT/NG	0353U
Xpert Xpress MVP	0352U

Test Information

Introduction

Molecular testing for genitourinary conditions may include nucleic acid testing, flow cytometry, immunohistochemistry, or other specialized molecular studies.

Guidelines and Evidence

Introduction

This section includes relevant guidelines and evidence pertaining to molecular testing for genitourinary conditions.

Bacterial Vaginosis

American College of Obstetricians and Gynecologists

The American College of Obstetricians and Gynecologists (ACOG, 2020) Practice Bulletin Vaginitis in Nonpregnant Patients[1] stated that "[b]ecause the normal vaginal flora is heterogeneous, routine bacterial culture of the vagina is not specific for bacterial vaginosis. For this reason, bacterial culture is not recommended for the diagnosis."

ACOG further stated that a clinical diagnosis for bacterial vaginosis is based on the Amsel criteria and requires the presence of three out of four clinical criteria (abnormal discharge, pH >4.5, positive KOH whiff test result, and presence of more than 20% clue cells on microscopy). Gram stain with Nugent scoring is considered the reference standard for a bacterial vaginosis diagnosis, however, it is generally limited to research settings.

Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC, 2021) Sexually Transmitted Infections Treatment Guidelines stated that:[2]

"BV can be diagnosed by using clinical criteria (i.e., Amsel's diagnostic criteria or by determining the Nugent score from a vaginal Gram stain. Vaginal Gram stain, considered the reference standard laboratory method for diagnosing BV, is used to determine the relative concentration of lactobacilli (i.e., long gram-positive rods), small gram-negative and gram-variable rods (i.e., G. vaginalis or Bacterioides), and curved gram-negative rods (i.e., Mobiluncus) characteristic of BV."

"Multiple BV NAATs are available for BV diagnosis among symptomatic women. These tests are based on detection of specific bacterial nucleic acids and have high sensitivity and specificity for BV (i.e., G. vaginalis, A. vaginae, BVAB2, or Megasphaera type 1) and certain lactobacilli (i.e., Lactobacillus crispatus, Lactobacillus jensenii, and Lactobacillus gasseri)."

"BV NAATs should be used among symptomatic women only (e.g., women with vaginal discharge, odor, or itch) because their accuracy is not well defined for asymptomatic women. Despite the availability of BV NAATs, traditional methods of BV diagnosis, including the Amsel criteria, Nugent score, and the Affirm VP III assay, remain useful for diagnosing symptomatic BV because of their lower cost and ability to provide a rapid diagnosis."

Society of Obstetricians and Gynecologists of Canada

The Society of Obstetricians and Gynecologists of Canada (SOGC) has published guidelines for the screening and management of bacterial vaginosis (2015)[3] and additional guidelines for screening and management during pregnancy (2017) that state the following:[4]

"Bacterial vaginosis should be diagnosed using either clinical (Amsel's) or laboratory (Gram stain with objective scoring system) criteria. (II-2A)"

Candida Species

Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC, 2021) Sexually Transmitted Infections Treatment Guidelines recommended the following in regard to candida species testing:[2]

"Examination of a wet mount with KOH preparation should be performed for all women with symptoms or signs of VVC, and women with a positive result should be treated. For those with negative wet mounts but existing signs or symptoms, vaginal cultures for Candida should be considered. If Candida cultures cannot be performed for these women, empiric treatment can be considered. Identifying Candida by culture in the absence of symptoms or signs is not an indication for treatment because approximately 10%–20% of women harbor Candida species and other yeasts in the vagina. The majority of PCR tests for yeast are not FDA cleared, and providers who use these tests should be familiar with the performance characteristics of the specific test used. Yeast culture, which can identify a broad group of pathogenic yeasts, remains the reference standard for diagnosis."

Chlamydia Trachomatis

Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC, 2021) Sexually Transmitted Infections Treatment Guidelines recommended the following in regard to chlamydia trachomatis testing:[2]

“Annual screening of all sexually active women aged <25 years is recommended, as is screening of older women at increased risk for infection (e.g., women aged ≥25 who have a new sex partner, more than one sex partner, a sex partner with concurrent partners, or a sex partner who has an STI... Although chlamydia incidence might be higher in some women aged ≥25 years in certain communities, overall, the largest proportion of infection is among women aged <25 years.”

“Although evidence is insufficient to recommend routine screening for C. trachomatis among sexually active young men because of certain factors (i.e., feasibility, efficacy, and cost-effectiveness), screening of sexually active young men should be considered in clinical settings with a high prevalence of chlamydia (e.g., adolescent clinics, correctional facilities, or STD specialty clinics) or for populations with a high burden of infection (e.g., MSM).”

"NAATs are . . . the recommended test for detecting C. trachomatis infection."

"Among symptomatic patients, POC tests for C. trachomatis can optimize treatment by limiting unnecessary presumptive treatment at the time of clinical decision-making and improve antimicrobial stewardship. Thus, using a POC test will likely be a cost-effective diagnostic strategy for C. trachomatis infection. Newer NAAT-based POC tests have promising performance and are becoming commercially available."

The Centers for Disease Control and Prevention (CDC, 2017) Preexposure Prophylaxis for the Prevention of HIV Infection in the United States Clinical Practice Guideline recommended the following:[5]

"Tests to screen for chlamydia are recommended for all sexually active MSM prescribed PrEP, both at screening prior to initiation and at semi-annual visits."

"Because chlamydia is very common, especially in young women and does not strongly correlate with risk of HIV acquisition, regular screening for chlamydia is not recommended for all sexually active women as a component of PrEP care. However, clinicians should refer to the 2015 STD guidelines for recommendations about chlamydia testing frequency for women regardless of PrEP use."

U.S. Preventive Services Task Force

The U.S. Preventive Services Task Force (USPSTF, 2021) further recommended:[6]

"The USPSTF recommends screening for chlamydia in sexually active females aged 24 years or younger and in older women who are at increased risk for infection. (B recommendation)"

"The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for chlamydia and gonorrhea in men. (I statement)"

Gardnerella Vaginalis

Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC, 2021) Sexually Transmitted Diseases Treatment Guidelines stated the following in regard to gardnerella vaginalis testing:[2]

"BV can be diagnosed by using clinical criteria (i.e., Amsel's diagnostic criteria) or by determining the Nugent score from a vaginal Gram stain. Vaginal Gram stain, considered the reference standard laboratory method for diagnosing BV, is used to determine the relative concentration of lactobacilli (i.e., long gram-positive rods), small gram-negative and gram-variable rods (i.e., G. vaginalis or Bacteroides), and curved gram-negative rods (i.e., Mobiluncus) characteristic of BV. A Nugent score of 0–3 is consistent with a Lactobacillus-predominant vaginal microbiota, 4–6 with intermediate microbiota (emergence of G. vaginalis), and 7–10 with BV."

"In addition to the Amsel criteria, multiple POC tests are available for BV diagnosis. The Osom BV Blue test (Sekisui Diagnostics) detects vaginal sialidase activity. The Affirm VP III (Becton Dickinson) is an oligonucleotide probe test that detects high concentrations of G. vaginalis nucleic acids (>5 x 105 CFU of G. vaginalis/mL of vaginal fluid) for diagnosing BV, Candida species, and T. vaginalis. This test has been reported to be most useful for symptomatic women in conjunction with vaginal pH measurement and presence of amine odor (sensitivity of 97%); specificity is 81% compared with Nugent."

"Despite the availability of BV NAATs, traditional methods of BV diagnosis, including the Amsel criteria, Nugent score, and the Affirm VP III assay, remain useful for diagnosing symptomatic BV because of their lower cost and ability to provide a rapid diagnosis. Culture of G. vaginalis is not recommended as a diagnostic tool because it is not specific."

Herpes Simplex Virus

Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC, 2021) Sexually Transmitted Infections Treatment Guidelines recommended the following in regard to herpes simplex virus testing:[2]

"[A]ll persons who have genital, anal, or perianal ulcers should be evaluated. Specific evaluation of genital, anal, or perianal ulcers includes syphilis serology tests and darkfield examination from lesion exudate or tissue, or NAAT if available; NAAT or culture for genital herpes type 1 or 2; and serologic testing for type-specific HSV antibody."

"HSV PCR of the blood should not be performed to diagnose genital herpes infection, except in cases in which concern exists for disseminated infection (e.g., hepatitis)."

Mycoplasma Genitalium

Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC, 2021) Sexually Transmitted Infections Treatment Guidelines stated that the main use of testing for M. genitalium is in patients with persistent or recurrent urethritis, cervicitis or pelvic inflammatory disease (PID).[2] The CDC noted that the main method for testing is NAAT.[2] The guideline stated:

"M. genitalium is an extremely slow-growing organism. Culture can take up to 6 months, and technical laboratory capacity is limited to research settings. NAAT for M. genitalium is FDA cleared for use with urine and urethral, penile meatal, endocervical, and vaginal swab samples."

"M. genitalium should be suspected in cases of persistent or recurrent urethritis and or cervicitis and considered for PID."

Other Guidelines

The British Association for Sexual Health and HIV (2018) published a national guideline for the management of infection with M. genitalium.[7] The guideline does not recommend screening asymptomatic individuals, but it does recommend testing for sexual partners of infected individuals. It stated:[7]

"The evidence suggests that the majority of people infected with M. genitalium in the genital tract do not develop disease….Current treatments are imperfect and associated with development of antimicrobial resistance… There is no evidence that screening asymptomatic individuals will be of benefit, and indeed is likely to do harm at a population level."

"We recommend testing current sexual partners of persons infected with *M. genitalium*."

Neisseria Gonorrhoeae

Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC, 2021) Sexually Transmitted Infections Treatment Guidelines recommended the following in regard to neisseria gonorrhoeae testing:[2]

"Annual screening for N. gonorrhoeae infection is recommended for all sexually active women aged <25 years and for older women at increased risk for infection (e.g., those aged ≥25 years who have a new sex partner, more than one sex partner, a sex partner with concurrent partners, or a sex partner who has an STI)."

The Centers for Disease Control and Prevention (CDC, 2017) Preexposure Prophylaxis for the Prevention of HIV Infection in the United States Clinical Practice Guideline recommended the following:[5]

"Tests to screen for gonorrhea are recommended for all sexually active adults prescribed PrEP, both at screening and at semi-annual visits."

U.S. Preventive Services Task Force

The U.S. Preventive Services Task Force (USPSTF, 2021) further recommended:[6]

"The USPSTF recommends screening for gonorrhea in all sexually active women 24 years or younger and in women 25 years or older who are at increased risk for infection. (B recommendation)"

"The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for chlamydia and gonorrhea in men. (I statement)"

Trichomonas Vaginalis

Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC, 2021) Sexually Transmitted Infections Treatment Guidelines recommended the following in regard to trichomonas vaginalis testing:[2]

“Symptomatic pregnant women, regardless of pregnancy stage, should be tested and treated. . . . The benefit of routine screening for T. vaginalis in asymptomatic pregnant women has not been established.”

"Because of the high prevalence of T. vaginalis among women with HIV and the potential for adverse reproductive health, poor birth outcomes, and possibly amplified HIV transmission, routine screening and prompt treatment are recommended for all women with HIV infection; screening should occur at entry to care and then at least annually thereafter."

Criteria

Introduction

Requests for molecular testing for genitourinary conditions are reviewed using these criteria.

Bacterial Vaginosis

Test name	Procedure Code	Reimbursement
Aptima Bacterial Vaginosis Assay	81513	Procedure code is not eligible for reimbursement under any circumstances
BD MAX Vaginal Panel	81514	Procedure code is not eligible for reimbursement under any circumstances
Miscellaneous Infectious Agent Detection, Direct Molecular Method	87797	Procedure code is not eligible for reimbursement for indications addressed by this guideline
Miscellaneous Infectious Agent Detection, Amplified Molecular Method	87798	Procedure code is not eligible for reimbursement for indications addressed by this guideline
Miscellaneous Infectious Agent Detection, Quantitative Molecular Method	87799	Procedure code is not eligible for reimbursement for indications addressed by this guideline
Xpert Xpress MVP	0352U	Procedure code is not eligible for reimbursement for indications addressed by this guideline

Bacterial Vaginosis

Medical necessity requirements:

Medical necessity of testing for bacterial vaginosis using any marker organisms or technologies not already addressed in this guideline has not been demonstrated, and is therefore determined to be investigational and experimental. These procedure codes are not eligible for reimbursement for any clinical indications. This includes but is not limited to, the procedure codes in the table above, as well as other BV panels, such as:

NuSwab®, Vaginitis Plus (VG+) (A vaginae, BVAB-2, Megasphaera Type 1)[8]

OneSwab® (A vaginae, Megasphaera Type 1 and 2, BVAB-2)[2]

SureSwab® Vaginosis, Vaginitis Plus (G vaginalis, A vaginae, Megasphaera species)[9]

Billing and reimbursement:

Testing for bacterial vaginosis is not considered medically necessary and therefore, neither organism-specific procedure codes, nor agent not otherwise specified (NOS) procedure codes, will be reimbursed for this indication.

The following criteria are used to determine if testing for infectious agents NOS is being performed in the setting of genitourinary condition detection or management, including bacterial vaginosis:

When billed with any ICD code included in Table: ICD Codes Indicating NOS Testing Billed for Genitourinary Conditions

When billed on the same date of services with any other organism-specific CPT code referenced in this guideline.

Candida Species

Test name	Procedure code	Reimbursement
Candida Detection, Direct Method	87480	Procedure code is eligible for reimbursement when criteria are met.
Candida Detection, Amplified Method	87481	Procedure code is eligible for reimbursement when criteria are met.
Candida Detection, Quantification Method	87482	Procedure code is not eligible for reimbursement under any circumstances.
Candida Species Panel, Amplified Method	0068U	Procedure code is not eligible for reimbursement under any circumstances.

Direct or amplified Candida detection

Medical necessity requirements:

Nucleic acid amplification testing (NAAT) for Candida albicans through either direct (CPT 87480) or amplified (CPT 87481) probe studies is considered medically necessary for individuals with clinical indications as outlined here.

Indications for asymptomatic individuals:

Evidence does not support routine screening for Candida species in asymptomatic pregnant women, non-pregnant women, or men unless HIV status is positive.

Indications for symptomatic individuals:

Candida testing is generally diagnosed by non-molecular methods (clinical criteria, microscopy, culture, etc.). Molecular testing for Candida should rarely be necessary.

However, guidelines do support molecular testing for Candida in symptomatic females when microscopy and culture are not available or unable to provide a diagnosis.

Post-service medical necessity review may be employed to ensure appropriate non-molecular methods have been utilized or were unavailable.

Billing and reimbursement:

The medical necessity of testing will be determined based on the following claims data:

When testing asymptomatic males or females, an ICD code that supports positive HIV status must be submitted on the claim (see Table:ICD Codes Indicating HIV Positive Status). Note that testing for males is only indicated when HIV positive (i.e., no symptomatic or other testing indications).

When testing symptomatic females, an ICD code that describes the common symptoms must be submitted on the claim (see Table:ICD Codes Indicating Symptoms of Genitourinary Conditions).

When testing is medically necessary, the following limitations apply:

It should only be necessary to test one site. Therefore, only one unit per date of service is reimbursable.

Subtyping for Candida glabrata and other non-albicans Candida species is not routinely medically necessary, so only one unit will be routinely reimbursed. Exceptions may be considered if complicated vulvovaginal candidiasis (VVC) is diagnosed. Complicated VVC may include:

Recurrent VVC (defined as 3 or more episodes of symptomatic VVC within 1 year), or

Severe VVC (i.e. extensive vulvar erythema, edema, excoriation, and fissure formation)

VVC in patients with immunosuppression or diabetes mellitus

More than one type of molecular test for the same organism will not be reimbursed for the same date of service (e.g., 87480 and 87481 may not be billed together).

Quantitative Candida testing

Medical necessity requirements:

Medical necessity of quantitative testing for Candida albicans (CPT 87482) has not been demonstrated, and is therefore determined to be investigational and experimental. This procedure code is not eligible for reimbursement for any clinical indications.

Billing and reimbursement:

If the laboratory's testing platform consists of direct or amplified and quantitative testing methodologies, yet only direct or amplified testing is considered medically necessary based on these criteria, the lab may request reimbursement for only the medically necessary components of the test by using a procedure code that does not represent all testing methodologies performed.

Chlamydia Trachomatis

Test name	Procedure code	Reimbursement
Chlamydia Trachomatis Detection, Direct Method	87490	Procedure code is eligible for reimbursement when criteria are met
Chlamydia Trachomatis Detection, Amplified Method	87491	Procedure code is eligible for reimbursement when criteria are met
Chlamydia Trachomatis Detection, Quantification Method	87492	Procedure code is not eligible for reimbursement under any circumstances

Direct or amplified Chlamydia trachomatis detection

Medical necessity requirements:

Nucleic acid amplification testing (NAAT) for Chlamydia trachomatis through either direct (CPT 87490) or amplified (CPT 87491) probe studies is considered medically necessary for individuals with clinical indications as outlined here.

Indications for testing in asymptomatic individuals:

Routine annual screening of all sexually active women aged less than or equal to 25 years

Screening of sexually active women greater than 25 years of age with risk factors (e.g., those who have a new sex partner or multiple sex partners)

Routine screening for all pregnant women during one of the first prenatal visits

Retesting of all pregnant women aged less than or equal to 25 years performed during the third trimester

Retesting of all pregnant women over age 25 during the third trimester when at increased risk for Chlamydia (e.g., women who have a new or multiple sex partners, women with a history of a previous STI, high risk behavior such as inconsistent condom use, sex work)

Screening of sexually active men with risk factors (e.g., men in correctional facilities, presenting to STI or adolescent clinics, or who have infected partner)

Screening of all sexually active men who have sex with men (MSM), including those prescribed preexposure prophylaxis (PrEP) for prevention of HIV infection

Indications for testing in symptomatic individuals:

Cervicitis

Urethritis

Test frequency:

Repeat testing to document eradication of infection after completing an appropriate treatment regimen is recommended only in the following settings: patient is pregnant, symptoms persist, re-infection is suspected, or compliance with therapy is in question. Routine test of cure is not recommended.

Non-pregnant recently infected women should be retested 3 to 12 months after treatment.

Based on guidelines for initial and repeat testing, no more than five screenings in a year should be necessary regardless of pregnancy or other risk factors.

Billing and reimbursement:

When testing is medically necessary, the following limitations apply:

NAAT may be performed on urine, rectal, vaginal, or cervical samples. It is usually sufficient to test one site. When necessary to test more than one site, no more than 3 units of 87490 or 87491 for chlamydia trachomatis molecular testing may be billed for the same date of service.

More than one type of molecular test for the same organism will not be reimbursed for the same date of service (e.g., 87490 and 87491 may not be billed together).

Quantitative Chlamydia trachomatis testing

Medical necessity requirements:

Medical necessity of quantitative testing for chlamydia trachomatis (CPT 87492) has not been demonstrated, and is therefore determined to be investigational and experimental. This procedure code is not eligible for reimbursement for any clinical indications.

Billing and reimbursement:

If the laboratory's testing platform consists of direct or amplified and quantitative testing methodologies, yet only direct or amplified testing is considered medically necessary based on these criteria, the lab may request reimbursement for only the medically necessary components of the test by using a procedure code that does not represent all testing methodologies performed.

Gardnerella Vaginalis

Test name	Procedure code	Reimbursement
Gardnerella Vaginalis Detection, Direct Method	87510	Procedure code is eligible for reimbursement when criteria are met.
Gardnerella Vaginalis Detection, Amplified Method	87511	Procedure code is eligible for reimbursement when criteria are met.
Gardnerella Vaginalis Detection, Quantification	87512	Procedure code is not eligible for reimbursement under any circumstances

Direct or amplified Gardnerella vaginalis detection

Medical necessity requirements:

Nucleic acid amplification testing (NAAT) for Gardnerella vaginalis through either direct (CPT 87510) or amplified (CPT 87511) probe studies is considered medically necessary for individuals with clinical indications as outlined here.

Indications for asymptomatic individuals:

Evidence does not support routine screening for Gardnerella vaginalis in asymptomatic pregnant women, non-pregnant women, or men for any indications.

Indications for symptomatic individuals:

Gardnerella vaginalis testing is generally diagnosed by non-molecular methods (clinical criteria and microscopy.). Molecular testing for Gardnerella vaginalis should rarely be necessary.

However, guidelines do support molecular testing for Gardnerella vaginalis in symptomatic females.

Billing and reimbursement:

The medical necessity of testing will be determined based on the following claims data:

When testing symptomatic females, an ICD code that describes the common symptoms must be submitted on the claim (see Table: ICD Codes Indicating Symptoms of Genitourinary Conditions

Note that there are no medically necessary indications for testing in males

When testing is medically necessary, the following limitations apply:

Medical necessity of quantitative testing for Gardnerella vaginalis (CPT 87512) has not been demonstrated for any indication, and is therefore determined to be investigational and experimental.

It should only be necessary to test one site. Therefore, only one unit per date of service is reimbursable.

More than one type of molecular test for the same organism will not be reimbursed for the same date of service (e.g., 87510 and 87511 may not be billed together).

Quantitative Gardnerella vaginalis testing

Medical necessity requirements:

Medical necessity of quantitative testing for Gardnerella vaginalis (CPT 87512) has not been demonstrated, and is therefore determined to be investigational and experimental. This procedure code is not eligible for reimbursement for any clinical indications.

Billing and reimbursement:

If the laboratory's testing platform consists of direct or amplified and quantitative testing methodologies, yet only direct or amplified testing is considered medically necessary based on these criteria, the lab may request reimbursement for only the medically necessary components of the test by using a procedure code that does not represent all testing methodologies performed.

Herpes Simplex Virus (HSV)

Test name	Procedure code	Reimbursement
Herpes Simplex Virus Detection, Direct Method	87528	Procedure code is eligible for reimbursement when criteria are met.

Test name	Procedure code	Reimbursement
Herpes Simplex Virus Detection, Amplified Method	87529	Procedure code is eligible for reimbursement when criteria are met.
Herpes Simplex Virus Detection, Quantification Method	87530	Procedure code is eligible for reimbursement when criteria are met.

Direct or amplified Herpes simplex virus (HSV) detection

Medical necessity requirements:

Nucleic acid amplification testing (NAAT) for Herpes simplex virus (HSV) through either direct (CPT 87528) or amplified (CPT 87529) probe studies is considered medically necessary for individuals with clinical indications as outlined here.

Indications for testing in asymptomatic Individuals:

Current guidelines explicitly recommend against testing asymptomatic adults for HSV.

Indications for testing in symptomatic Individuals:

New or recurrent vesicular and/or ulcerative lesions, vesicles or ulcers on or around the genitals, rectum, buttocks, thighs, back

Recurrent genital symptoms or atypical symptoms and negative HSV cultures

Billing and reimbursement:

When testing is medically necessary, the following limitations apply:

It should only be necessary to test one site. Therefore, only one unit per date of service is reimbursable.

More than one type of molecular test for the same organism will not be reimbursed for the same date of service (e.g., 87528 and 87529 may not be billed together).

Quantitative Herpes simplex virus testing

Medical necessity requirements:

Quantitative testing for Herpes simplex virus (HSV) (CPT 87530) may be reasonable for monitoring disease in some circumstances.

Therefore, quantitative HSV testing will be reimbursable when a diagnosis has been established and the need for monitoring is documented in the medical record. Quantitative HSV testing should not be used for the primary diagnosis of HSV.

Billing and reimbursement:

If the laboratory's testing platform consists of direct or amplified and quantitative testing methodologies, yet only direct or amplified testing is considered medically necessary based on these criteria, the lab may request reimbursement for only the medically necessary components of the test by using a procedure code that does not represent all testing methodologies performed.

Human Papillomavirus (HPV)

Please refer to the guideline *Human Papillomavirus (HPV) Molecular Testing*, as this testing is not addressed here.

Infectious Agent, Not Otherwise Specified

Test name	Procedure code	Reimbursement
Miscellaneous Infectious Agent Detection, Direct Molecular Method	87797	Procedure code is not eligible for reimbursement for indications addressed by this guideline
Miscellaneous Infectious Agent Detection, Amplified Molecular Method	87798	Procedure code is not eligible for reimbursement for indications addressed by this guideline
Miscellaneous Infectious Agent Detection, Quantitative Molecular Method	87799	Procedure code is not eligible for reimbursement for indications addressed by this guideline

Miscellaneous infectious agent detection

Medical necessity requirements:

Molecular testing to detect a variety of organisms that do not have organism-specific procedure codes may be billed under the infectious agents not otherwise specified (NOS) codes (CPT 87797, 87798, 87799). This guideline only addresses some organisms and clinical settings. It does not apply to all testing performed under these codes.

The genitourinary organisms for which molecular testing is supported by guidelines are represented by organism-specific CPT codes. There are no clinical indications for any infectious agents billed under not otherwise (NOS) specified procedure codes that are supported by current evidence for the evaluation or management of genitourinary conditions, including bacterial vaginosis

(addressed elsewhere in this guideline).Therefore, testing for organisms NOS is considered investigational and experimental in the setting of screening for genitourinary conditions.

Billing and reimbursement:

The following criteria are used to determine if testing for infectious agents NOS is being performed in the setting of genitourinary condition detection or management, including bacterial vaginosis:

When billed with any ICD code included in Table: *ICD Codes Indicating NOS Testing Billed for Genitourinary Conditions*.

When billed on the same date of service with any other organism-specific CPT code referenced in this guideline.

Mycoplasma Genitalium

Test name	Procedure code	Reimbursement
Mycoplasma genitalium, Direct Method	87563	Procedure code is eligible for reimbursement when criteria are met

Direct Mycoplasma genitalium detection

Medical necessity requirements:

Nucleic acid amplification testing (NAAT) for Mycoplasma genitalium is considered medically necessary for individuals with clinical indications as outlined here.

Indications for testing in asymptomatic individuals:

Screening for M. genitalium in sexual partners of people who are infected with M. genitalium is considered medically necessary.

Routine screening for M. genitalium in asymptomatic individuals is otherwise not considered medically necessary, as the main benefit of testing is to determine appropriate course of treatment.

Indications for testing in symptomatic individuals:

Cervicitis

Urethritis

Persistent PID when gonorrhea and chlamydia are negative

Test frequency:

Repeat testing to document eradication of infection no earlier than 3 weeks after completing an appropriate treatment regimen is recommended in the following settings:

symptoms persist

re-infection is suspected

compliance with therapy is in question

Routine test of cure in the absence of symptoms may be performed no earlier than 3 weeks after completing an appropriate treatment regimen.

Based on guidelines for initial and repeat testing, no more than five screenings in a year should be necessary regardless of risk factors.

Billing and reimbursement:

When testing is medically necessary, the following limitations apply:

NAAT for M. genitalium may be performed on urine, vaginal, cervical, male urethral, or penile meatal samples. It is usually sufficient to test one site.

No more than 3 units of 87563 for M. genitalium molecular testing may be billed for the same date of service.

Neisseria Gonorrhoeae

Test name	Procedure code	Reimbursement
Neisseria Gonorrhoeae, Direct Method	87590	Procedure code is eligible for reimbursement when criteria are met
Neisseria Gonorrhoeae, Amplified Method	87591	Procedure code is eligible for reimbursement when criteria are met
Neisseria Gonorrhoeae, Quantification Method	87592	Procedure code is not eligible for reimbursement under any circumstances

Direct or amplified Neisseria gonorrhoeae detection

Medical necessity requirements:

Nucleic acid amplification testing (NAAT) for Neisseria gonorrhoeae through either direct (CPT 87590) or amplified (CPT 87591) probe studies is considered medically necessary for individuals with clinical indications as outlined here.

Indications for testing in asymptomatic individuals:

Annual screening of all sexually active women aged less than or equal to 25 years.

Annual screening of women greater than 25 years who are at increased risk for infection (e.g., women with previous gonorrhea infection, other STIs, new or multiple sex partners, and inconsistent condom use, sex workers, or women living in communities with a high prevalence of disease).

All pregnant women at increased risk for gonorrhea (as defined in the above criteria) should be screened at the first prenatal visit for N. gonorrhoeae.

Uninfected pregnant women who remain at high risk for gonococcal infection also should be retested during the third trimester.

Screening of sexually active individuals who have an infected partner.

Screening of all sexually active adults prescribed preexposure prophylaxis (PrEP) for prevention of HIV infection.

Indications for testing in symptomatic individuals:

Cervicitis

Urethritis

Test frequency:

When indicated, repeat testing to document eradication should not be performed until 3-4 weeks after the positive result. Pregnant women diagnosed with gonococcal infection during the first trimester should be retested within approximately 3–6 months, preferably in the third trimester. Recently infected individuals should be retested 3 to 12 months after treatment. When repeat testing is indicated, the following limitations apply:

Repeat testing will not be reimbursed if performed within three weeks (less than 21 days) from a previous test.

Based on guidelines for initial and repeat testing, no more than five screenings in a year should be necessary regardless of pregnancy or other risk factors.

Billing and reimbursement

When testing is medically necessary, the following limitations apply:

Nucleic acid amplification test (NAAT) may be performed on urine, vaginal, or cervical samples. It is usually sufficient to test one site. When necessary to test more than one site, no more than 3 units of 87590 or 87591 for Neisseria gonorrhoeae molecular testing may be billed for the same date of service.

More than one type of molecular test for the same organism will not be reimbursed for the same date of service (e.g., 87590 and 87591 may not be billed together).

Quantitative Neisseria gonorrhoeae testing

Medical necessity requirements:

Medical necessity of quantitative testing for Neisseria gonorrhoeae (CPT 87592) has not been demonstrated, and is therefore determined to be investigational and experimental. This procedure code is not eligible for reimbursement for any clinical indications.

Billing and reimbursement:

If the laboratory's testing platform consists of direct or amplified and quantitative testing methodologies, yet only direct or amplified testing is considered medically necessary based on these criteria, the lab may request reimbursement for only the medically necessary components of the test by using a procedure code that does not represent all testing methodologies performed.

Trichomonas Vaginalis

Test name	Procedure code	Reimbursement
Trichomonas Vaginalis Detection, Direct Method	87660	Procedure code is eligible for reimbursement when criteria are met
Trichomonas Vaginalis Detection, Amplified Method	87661	Procedure code is eligible for reimbursement when criteria are met

Direct or amplified Trichomonas vaginalis detection

Medical necessity requirements:

Nucleic acid amplification testing (NAAT) for Trichomonas vaginalis through either direct (CPT 87660) or amplified (CPT 87661) probe studies is considered medically necessary for individuals with clinical indications as outlined here.

Indications for testing in asymptomatic individuals:

Evidence does not support routine screening for Trichomonas vaginalis in asymptomatic women (pregnant or non-pregnant) or men who are not at high risk for infection.

Screening can be considered in those at increased risk for Trichomonas vaginalis infection for reasons such as new or multiple sex partners, history of STIs, sex work, or drug use.

Screening should also be performed in sexually active women who are HIV-positive at entry into care and then at least annually.

Indications for testing in symptomatic individuals:

Vaginitis, abnormal vaginal discharge, cervicitis, nongonococcal urethritis, vulvar pruritis, or pelvic inflammatory disease.

Sexually active women with trichomoniasis may be rescreened for Trichomonas vaginalis at 3 months following initial infection.

Screening of sexually active individuals who have an infected partner.

Test frequency:

Repeat testing should not be necessary more frequently than every three months.

Based on guidelines for initial and repeat testing, no more than five screenings in a year should be necessary regardless of pregnancy or other risk factors.

Billing and reimbursement:

The medical necessity of testing will be determined based on the following claims data:

When testing asymptomatic individuals, an ICD code that supports increased risk, infected partner, or positive HIV status must be submitted on the claim. For guidance, see Tables: ICD Codes Indicating High Risk Indications, ICD Codes Indicating Infected Partner, ICD Codes Indicating HIV Positive Status

When testing symptomatic individuals, an ICD code that describes the common symptoms, as defined in Table ICD Codes Indicating Symptoms of Genitourinary Conditions **must be submitted on the claim.**

When testing is medically necessary, the following limitations apply:

Nucleic acid amplification test (NAAT) may be performed on urine, vaginal, or cervical samples. It is usually sufficient to test one site. When necessary to test more than one site:

Additional units must be billed with modifier 59.

No more than 3 units of 87660 or 87661 for Trichomonas vaginalis molecular testing may be billed for the same date of service.

More than one type of molecular test for the same organism will not be reimbursed for the same date of service (e.g., 87660 and 87661 may not be billed together).

ICD Codes

ICD codes in this section may be used to support medical necessity as described in the above guidelines.

ICD Codes Indicating High Risk Indications

ICD Code or Range	Description
F10.X	Alcohol related disorders
F11.X	Opioid related disorders
F12.X	Cannabis related disorders
F13.X	Sedative, hypnotic, or anxiolytic related disorders
F14.X	Cocaine related disorders
F15.X	Other stimulant related disorders
F16.X	Hallucinogen related disorders
F18.X	Inhalant related disorders
F19.X	Other psychoactive substance related disorders
O99.32X	Drug use complicating pregnancy, childbirth, and the puerperium
Z72.5X	High risk sexual behavior
Z77.9	Other contact with and (suspected) exposures hazardous to health

ICD Codes Indicating Infected Partner

ICD Code or Range	Description
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus [HIV]
Z20.8X	Contact with and (suspected) exposure to other communicable diseases
Z20.9	Contact with and (suspected) exposure to unspecified communicable disease

ICD Codes Indicating HIV Positive Status

ICD Code or Range	Description
B20	Human immunodeficiency virus [HIV] disease
B97.35	Human immunodeficiency virus, type 2 [HIV-2]
O98.7X	Human immunodeficiency virus [HIV] disease complicating pregnancy, childbirth and the puerperium

ICD Code or Range	Description
R75	Inconclusive laboratory evidence of human immunodeficiency virus [HIV]
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status

The ICD codes in the following table suggest medical necessity for the procedure codes for trichmonas vaginalis (87661), candida (87480, 87481), and gardnerella vaginalis (87510, 87511).

ICD Codes Indicating Symptoms of Genitourinary Conditions

ICD Code or Range	Description
A56.X	Other sexually transmitted chlamydial diseases
A59.X	Urogenital trichomoniasis
B37.3	Candidiasis of vulva and vagina
B37.4X	Candidiasis of other urogenital sites
L29.X	Pruritus
N34.X	Urethritis and urethral syndrome
N35.1X	Postinfective urethral stricture, not elsewhere classified
N37	Urethral disorders in diseases classified elsewhere
N72	Inflammatory disease of cervix uteri
N73.X	Other female pelvic inflammatory diseases
N75.X	Diseases of Bartholin's gland
N76.X	Other inflammation of vagina and vulva
N77.X	Vulvovaginal ulceration and inflammation in diseases classified elsewhere
N89.8	Other specified noninflammatory disorders of vagina
N89.9	Noninflammatory disorder of vagina, unspecified
N94.1	Dyspareunia
N95.2	Postmenopausal atrophic vaginitis
O23.X	Infections of genitourinary tract in pregnancy
O86.X	Other puerperal infections
R10.2	Pelvic and perineal pain

The ICD codes in the following table indicate when procedure codes for infectious agent detection by nucleic acid not otherwise specified (NOS) (87787-87799) are billed for GU organisms.

ICD Codes Indicating NOS Testing Billed for Genitourinary Conditions

ICD Code or Range	Description
A50.X	Congenital syphilis
A51.X	Early syphilis
A52.X	Late syphilis
A53.X	Other and unspecified syphilis
A54.X	Gonococcal infection
A55	Chlamydial lymphogranuloma (venereum)
A56.X	Other sexually transmitted chlamydial diseases
A57	Chancroid
A58	Granuloma inguinale
A59.X	Trichomoniasis
A60.X	Anogenital herpesviral [herpes simplex] infections
A63.X	Other predominantly sexually transmitted diseases, not elsewhere classified
A64	Unspecified sexually transmitted disease
A74.89	Other chlamydial diseases
A74.9	Chlamydial infection, unspecified (includes childbirth and postpartum)
B37.3	Candidiasis of vulva and vagina
B37.4X	Candidiasis of other urogenital sites
B97.7	Papillomavirus as the cause of diseases classified elsewhere
L29.X	Pruritus
M02.30	Reiter's disease, unspecified site
N34.X	Urethritis and urethral syndrome
N35.X	Urethral stricture
N37	Urethral disorders in diseases classified elsewhere
N39.0	Urinary tract infection, site not specified
N39.9	Disorder of urinary system, unspecified

ICD Code or Range	Description
N70.X	Salpingitis and oophoritis
N71.X	Inflammatory disease of uterus, except cervix
N72	Inflammatory disease of cervix uteri
N73.X	Other female pelvic inflammatory diseases
N74	Female pelvic inflammatory disorders in diseases classified elsewhere
N75.X	Diseases of Bartholin's gland
N76.X	Other inflammation of vagina and vulva
N77.X	Vulvovaginal ulceration and inflammation in diseases classified elsewhere
N87.X	Dysplasia of cervix uteri
N94.1	Dyspareunia
O09.X	Supervision of high risk pregnancy
O23.X	Infections of genitourinary tract in pregnancy
O86.X	Other puerperal infections
R87.5	Abnormal microbiological findings in specimens from female genital organs
R87.6X	Abnormal cytological findings in specimens from female genital organs
R87.8X	Other abnormal findings in specimens from female genital organs
Z00.00	Encounter for general adult medical examination without abnormal findings
Z00.8	Encounter for other general examination
Z01.4X	Encounter for gynecological examination
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
Z11.51	Encounter for screening for human papillomavirus (HPV)
Z11.59	Encounter for screening for other viral diseases
Z11.8	Encounter for screening for other infectious and parasitic diseases
Z11.9	Encounter for screening for infectious and parasitic diseases, unspecified
Z12.4	Encounter for screening for malignant neoplasm of cervix

ICD Code or Range	Description
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
Z20.6	Contact with and (suspected) exposure to human immunodeficiency virus [HIV]
Z20.8X	Contact with and (suspected) exposure to communicable diseases
Z20.9	Contact with and (suspected) exposure to unspecified communicable disease
Z30.X	Encounter for contraceptive management
Z31.X	Encounter for procreative management
Z32.X	Encounter for pregnancy test and childbirth and childcare instruction
Z33.X	Pregnant state
Z34.X	Encounter for supervision of normal pregnancy
Z36	Encounter for antenatal screening of mother
Z39.X	Encounter for maternal postpartum care and examination
Z64.0	Problems related to unwanted pregnancy
Z64.1	Problems related to multiparity
Z71.7	Human immunodeficiency virus [HIV] counseling
Z72.5X	High risk sexual behavior
Z77.9	Other contact with and (suspected) exposures hazardous to health
Z97.5	Presence of (intrauterine) contraceptive device

References

Introduction

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