Molecular Diagnostic Testing for Reproductive Health

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Medical Coverage Policy

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Code Compendium (Laboratory)

Description

Vaginitis is a general term for disorders of the vagina (and vulva) caused by infection, inflammation or changes in the normal vaginal flora (eg, *Lactobacillus* species). Symptoms may include vaginal or urethral discharge, discomfort, itching and/or odor. The infections responsible for these symptoms include one or more of the following:

- Bacterial vaginosis is an abnormal, noninflammatory condition of the vagina caused by an overgrowth or imbalance of anaerobic bacteria (eg, *Gardnerella vaginalis*, *Atopobium vaginae*, Megasphaera type 1, Bacterial Vaginosis Associated Bacteria-2 [BVAB-2], *Prevotella* species and/or *Mobiluncus* species) that is generally characterized by a white (or gray), malodorous discharge

- Candidiasis is a fungal infection of the vagina and vulva caused by a species of yeast (eg, C. albicans, C. glabrata, C. parapsilosis, C. kefyr, C. kruseii, C tropicalis, C. dubliniensis, C. lusitaniae, C. auris)

- Trichomoniasis or trichomonas is a common sexually transmitted disease caused by a protozoan parasite called *Trichomonas vaginalis*

Men may also experience symptoms associated with an overgrowth of anaerobic bacteria, candidiasis or trichomoniasis including, but may not be limited to, balanitis (inflammation of the glans penis), penile discharge, rash or urinary burning.

Vaginitis and balanitis are diagnosed with a series of standardized clinical tests, such as bacterial culture, physical examination, microscopy and/or vaginal pH. Molecular diagnostic testing for vaginitis may also be used and includes:

- Direct deoxynucleic acid (DNA) probe assays (nucleic acid hybridization) (eg, Affirm VP III) – A test that uses a DNA probe to detect the DNA of candida species, *Gardnerella vaginalis* and *Trichomonas vaginalis* in vaginal fluid specimens

- Nucleic acid amplification testing (NAAT) – A technique used to detect a particular virus or bacteria in blood, tissue or body fluid by locating and amplifying (making extra copies of the nucleic acids) the ribonucleic acid (RNA) or DNA of the pathogen using polymerase chain reaction (PCR), transcription-mediated amplification (TMA) or strand displacement amplification (SDA). Examples include, but may not be limited to **(Refer to Coverage Limitations section)**:

    - Aptima BV & CV/TV molecular assays
    - BD MAX Vaginal Panel (PCR)
    - MYCODART Dual Amplification Real Time PCR Panel
    - NuSwab VG (PCR)
    - SureSwab Bacterial Vaginosis/Vaginitis Panels (PCR and TMA)
    - Xpert Xpress MVP

Sexually transmitted infections (STIs), also known as sexually transmitted diseases (STDs), are typically acquired through sexual contact and affect both females and males. Symptoms may include cervicitis, genital pain or ulceration(s), penile or vaginal discharge, urethritis or vaginitis. In many situations, the health complications caused by the STI can be more serious for women. If a pregnant woman has an STI, it can cause health problems for the fetus. Examples of STIs include, but are not limited to:

- Chlamydia (*Chlamydia trachomatis*)
- Gonorrhea (*Neisseria gonorrhoeae*)
- Herpes simplex virus (HSV) type 1 (HSV-1) and type 2 (HSV-2)
- Human Papillomavirus (HPV)
- *Mycoplasma (Mycoplasma genitalium and Mycoplasma hominis)*
- Trichomoniasis (*Trichomonas vaginalis*)

Many STIs are diagnosed with the same methods as vaginitis, including molecular diagnostic techniques such as direct DNA probe assays and NAAT. Examples include, but may not be limited to:

- Alinity m STI assay (PCR) (urine or vaginal/endocervical swab)

- Aptima mycoplasma genitalium assay
- Aptima trichomonas vaginalis assay (TMA) (vaginal/endocervical swab)
- BD CTGCTV2 assay
- Binx Health CT/NG assay (PCR) (urine or vaginal/endocervical swab)
- Cobas 4800/6800/8800 CT/NG and TV/MG tests (PCR) (urine or vaginal/endocervical swab)
- GenPap – Cervicitis Profile, High Risk STI Profile, STI Lesion Profile (PCR) (vaginal/endocervical swab)
- NuSwab STD (PCR) (vaginal [preferred] or unisex swab)
- STI TriPlex Assay (PCR) (male urine)
- SureSwab CT/NG, *T. vaginalis* Panel (TMA) (vaginal [preferred] or unisex swab)
- Xpert CT/NG

Some labs offer expanded panel testing in which vaginitis and STIs are incorporated. Examples include, but may not be limited to **(Refer to Coverage Limitations section)**:

- GenPap – PID/Infertility/Pregnancy Loss Profile (PCR)
- NuSwab – Select, VG, VG+ (PCR)
- OneSwab (PCR)
- SureSwab Vaginosis/Vaginitis Plus (PCR)

HPV is the most common sexually transmitted infection in the United States. Approximately 100 types of HPV have been identified, at least 40 of which can infect the genital area. Oncogenic, high-risk HPV (types 16 and 18) causes most anal, cervical, oropharyngeal, penile, vaginal, vulvar cancers and precancers. Nononcogenic, low-risk HPV (types 6 and 11) cause genital warts.

HPV tests are available to detect oncogenic types of HPV infection and are used in cervical cancer screening and management or follow-up of abnormal cervical cytology or histology. These tests should not be used for male partners of women with HPV.[11] HPV infection can also contribute to the pathogenesis of squamous cell carcinomas of the head and neck. Although oropharyngeal swab testing has been proposed for this indication, there are currently no US Food & Drug Administration (FDA) approved tests. Biopsy and in situ hybridization or PCR testing to detect HPV DNA are considered the gold standard for appropriate staging and treatment.

Cervical cancer screening utilizes combinations of cervical cytology with Papanicolaou (Pap) testing and testing for HPV strains that are high risk for causing cervical cancer. Current US FDA approved methods for detecting cervical HPV infection are HPV DNA or HPV ribonucleic acid (RNA) testing which may be used in conjunction with Pap testing or alone for primary screening. These tests are also proposed as an alternative

approach to repeat cytology for women with borderline or low-grade cytologic abnormalities. Examples of HPV DNA and HPV RNA tests include:

- APTIMA HPV 16 18/45 Genotype assay
- APTIMA HPV assay
- BD Onclarity HPV assay
- Cervista HPV HR test
- Cobas HPV test
- Hybrid Capture 2 High-Risk HPV test

Coverage Determination

Vaginitis
Humana members may be eligible under the Plan for **molecular diagnostic testing with direct DNA probe assay (87480, 87510, 87660) (eg, Affirm VP III [indicated for vaginal specimens]) for vaginitis (BV, trichomoniasis, vaginal candidiasis)** for the diagnosis of symptomatic women (eg, vaginal discharge).

Sexually Transmitted Infections
Humana members may be eligible under the Plan for **molecular diagnostic testing for chlamydia and/or gonorrhea with multitarget testing (eg, Alinity [0402U]), direct DNA probe assay or NAAT (87490, 87491, 87492, 87590, 87591, 87592, 0353U)** for the following indications:

- Diagnosis for symptomatic men (eg, urethral discharge) or women (eg, vaginal discharge); **OR**
- Screening***** for asymptomatic men or women (including pregnancy) when the following criteria are met:
    - Individuals at high risk for infection (eg, history of STIs, new or multiple sexual partners or sexual contact with an individual with active chlamydia or gonorrhea infection); **OR**
    - Individuals infected with HIV; **OR**
    - Individuals that are sexually active and age 24 years or younger; **OR**
    - Men who engage in sexual activity with men

Humana members may be eligible under the Plan for **molecular diagnostic testing for genital or oral HSV with PCR assay (87528, 87529)** when active lesions are present.

Humana members may be eligible under the Plan for **molecular diagnostic testing for m*ycoplasma* (eg, *genitalium, hominis)* with multitarget testing (eg, Alinity [0402U]) or NAAT (87563)** to diagnose symptomatic men (eg, urethritis) or women (eg, cervicitis or pelvic inflammatory disease).

Humana members may be eligible under the Plan for **molecular diagnostic testing for trichomoniasis with multitarget testing (eg, Alinity [0402U]), direct DNA probe assay or NAAT (87660, 87661)** when the following criteria are met:

- Diagnosis for symptomatic men (eg, urethral discharge) or women (eg, vaginal discharge); **OR**
- Screening* of asymptomatic women who are at high risk for infection (eg, women who have a history of STIs or multiple sexual partners)

*Refers to annual screening unless otherwise indicated such as part of routine screening during pregnancy.

Humana members may be eligible under the Plan for **molecular diagnostic testing for HPV (FDA-approved HPV DNA and HPV RNA tests) (G0476, 87624, 87625)** when the following criteria are met:

- Assessment or follow-up of women with atypical glandular cells not otherwise specified (AGC NOS); **OR**
- Assessment of women with atypical squamous cells of undetermined significance (ASCUS); **OR**
- Stand-alone testing (primary screening) every 5 years in women 30 to 65 years of age **OR** in combination with Pap testing (co-testing) every 5 years for women 30 to 65 years of age

Note: The criteria for **molecular diagnostic testing for vaginitis and sexually transmitted infections** are not consistent with the Medicare National Coverage Policy and therefore may not be applicable to Medicare members. Refer to the CMS website for additional information.

Coverage Limitations:

Humana members may **NOT** be eligible under the Plan for **molecular diagnostic testing for vaginitis and sexually transmitted infections** for any indications other than those listed above including, but may not be limited to:

- Biomarker-based HPV testing (eg, CINtec *PLUS* Cytology)
- HSV quantification PCR testing (87530)
- HSV serology testing (86694, 86695 and 86696)
- mRNA HPV oncogene expression testing (eg, HPV E6/E7 QuantaSURE, PreTect HPV-Proofer'7 [0354U])
- MYCODART Dual Amplification Real Time PCR Panel (0068U)
- NAAT (87481, 87511) or subsequent quantification testing for BV (eg, *Gardnerella vaginalis*) or vaginal candidiasis (87482 and 87512)
- Oropharyngeal swab testing for HPV (0429U)
- Screening for low-risk (nononcogenic) HPV types (87623)

- Self-collected or self-sampling HPV tests for screening of cervical cancer (0500T)

- Testing for HPV, high risk types (16, 18 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68, via male urine [0096U])

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **molecular diagnostic testing for vaginitis and sexually transmitted infections for general population screening.** This is considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **multipathogen panels** unless ALL pathogens being tested in the panel meet the criteria above.** Examples of multipathogen tests include but may not be limited to, the following:

- BD MAX Vaginal Panel (81514)
- Bridge Women's Health Infectious Disease Detection Test (0330U)
- GenPap – PID/Infertility/Pregnancy Loss Profile (PCR)
- INFINITI Bacterial Vaginosis Quad Assay (PCR)
- INFINITI Candida Vaginosis Quad Assay (PCR)
- NuSwab
- OneSwab
- Simple Swab
- SureSwab (81513)
- Xpert Xpress MVP (0352U)

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

******Individual pathogen targets (eg, chlamydia, gonorrhea, m*ycoplasma, trichomoniasis)* within a multipathogen panel (eg, GenPap, BD MAX Vaginal Panel, NuSwab, OneSwab, SureSwab) may be medically necessary if criteria in the Coverage Determination are met

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments

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	**Not Covered**
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	**Not Covered**
86694	Antibody; herpes simplex, non-specific type test	**Not Covered**
86695	Antibody; herpes simplex, type 1	**Not Covered**
86696	Antibody; herpes simplex, type 2	**Not Covered**
87480	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, direct probe technique	
87481	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique	**Not Covered**
87482	Infectious agent detection by nucleic acid (DNA or RNA); Candida species, quantification	**Not Covered**
87490	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia trachomatis, direct 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	
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	**Not Covered**
87512	Infectious agent detection by nucleic acid (DNA or RNA); Gardnerella vaginalis, quantification	**Not Covered**
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	**Not Covered**

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	
87623	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), low-risk types (eg, 6, 11, 42, 43, 44)	**Not Covered**
87624	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)	
87625	Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), types 16 and 18 only, includes type 45, if performed	**Not Covered if used to report any test outlined in Coverage Limitations section**
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	**Not Covered if used to report any test outlined in Coverage Limitations section**
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism	**Not Covered if used to report any test outlined in Coverage Limitations section**
87799	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; quantification, each organism	**Not Covered if used to report any test outlined in Coverage Limitations section**
88199	Unlisted cytopathology procedure	**Not Covered if used to report any test outlined in Coverage Limitations section**
0068U	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	**Not Covered**

0096U	Human papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68), male urine	**Not Covered**
0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab	**Not Covered**
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	**Not Covered**
0353U	Infectious agent detection by nucleic acid (DNA), Chlamydia trachomatis and Neisseria gonorrhoeae, multiplex amplified probe technique, urine, vaginal, pharyngeal, or rectal, each pathogen reported as detected or not detected	
0354U	Human papilloma virus (HPV), high-risk types (ie, 16, 18, 31, 33, 45, 52 and 58) qualitative mRNA expression of E6/E7 by quantitative polymerase chain reaction (qPCR)	**Not Covered**
0402U	Infectious agent (sexually transmitted infection), Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium, multiplex amplified probe technique, vaginal, endocervical, or male urine, each pathogen reported as detected or not detected	**New Code Effective 10/01/2023**
0429U	Human papillomavirus (HPV), oropharyngeal swab, 14 high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68)	**Not Covered** **New Code Effective 01/01/2024**
CPT® Category III Code(s)	**Description**	**Comments**
0500T	Infectious agent detection by nucleic acid (DNA or RNA), human papillomavirus (HPV) for five or more separately reported high-risk HPV types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) (ie, genotyping)	**Not Covered**
HCPCS Code(s)	**Description**	**Comments**
G0476	Infectious agent detection by nucleic acid (DNA or RNA); human papillomavirus HPV), high-risk types (e.g., 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) for cervical cancer screening, must be performed in addition to pap test	

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Change Summary

- 03/28/2024 Annual Review, No Coverage Change.