Multiplex Pathogen Identification Panels for Infectious Disease

Humana

Medicaid Medical Coverage Policy

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States: VA

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Description

Microbes (eg, bacteria, fungi, parasites, viruses) cause infections in humans. Testing methods for detecting microbes traditionally include detection by cultures or antibody testing. However, since microbes contain genetic material (DNA and RNA), genetic testing methods can be applied to detect pathogens. The genetic material in microbes differs from the genetic material in human cells. Samples used for genetic testing for infectious disease include, but may not be limited to, aspirated fluid around joints, blood, cerebrospinal fluid, sputum, stool and urine. Genetic testing can be used to diagnose infections, identify and type the microbes causing an infection as well as determine if a microbe will respond to a specific treatment.

Genetic testing for infectious disease differs from genetic tests for inherited conditions. Microbes associated with infectious disease contain genetic material, but the genetic material contained within microbes differs from genetic material within human cells. Genetic testing for inherited conditions, also known as germline mutation testing, analyzes an individual's DNA and can identify genetic mutations to determine inherited risk of disease. An individual's germline DNA is constant and identical in all body tissue types. The DNA and RNA of microbes are present only in the tissue sampled, are not representative of an individual's germline DNA and are not inheritable.

The scope of this policy pertains to the outpatient setting only.

Coverage Determination

Nucleic Acid Amplification Tests for Bacterial Vaginitis
Humana members may be eligible under the Plan for **nucleic acid amplification tests (NAATs) for diagnosis of bacterial vaginitis** (eg, BD MAX Vaginal Panel [81514], Aptima BV Assay [81513]) in women with symptoms of vaginitis (eg, abnormal discharge, burning, irritation).[29]

Respiratory Infection Multiplex Pathogen Identification Panel – Expanded (6 to or More Targets)
Humana members may be eligible under the Plan for **respiratory infection multiplex pathogen identification panel containing 6 or more pathogen targets** (87632, 87633) (eg, BioFire FilmArray Pneumonia (PN) Panel [0528U], BioFire Respiratory Panel 2.1 [0202U], ePlex Respiratory Pathogen (RP) Panel [0115U], ePlex Respiratory Pathogen Panel 2 [0225U], QIAstat-Dx Respiratory SARS-CoV-2 [0223U]) when the following criteria are met:

- Individual presents with signs and symptoms of respiratory infection (eg, cough, dyspnea [short of breath], fever, nasal congestion, runny nose, sore throat, tight chest, wheezing)[2,4,34]; **AND**
- Results of the test will determine therapeutic management (eg, antibiotic or antiviral treatment)[2]; **AND**
- Targeted respiratory infection multiplex pathogen identification panel (2-5 pathogen targets [eg, influenza, SARS-CoV-2]) performed prior to expanded panel and is negative[2]; **AND**
- Individual is immunocompromised and/or considered high-risk for serious complications and includes any of the following[2]:
    - Currently receiving cancer treatment[2,4]; **OR**
    - Currently receiving chronic glucocorticoid therapy[2]; **OR**
    - Diagnosed with human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS)[2]; **OR**
    - Diagnosed with inherited disease that affects the immune system (eg, agammaglobulinemia, selective IgA deficiency)[2]; **OR**
    - Organ transplant recipient[2,4]

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **NeXGen Fungal/AFB NGS Assay (0531U)**.

A review of the current medical literature shows that there is **no evidence** to determine that this service is standard medical treatment. There is an absence of current, widely-used treatment guidelines or

acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Humana members may **NOT** be eligible under the Plan for the following:

- Combination pathogen identification and antibiotic resistance or sensitivity (eg, Respiratory Pathogen with ABR [RPX] [0373U])
- Expanded multiplex vaginitis/vaginosis pathogen panels (Bridge Women's Health Infectious Disease Detection Test [0330U])[1,14,20,28,29]
- Metagenomic next-generation sequencing (NGS) including the following:
    - Cell-free DNA (cfDNA) metagenomic NGS (Karius Test [0152U])[13]
    - Johns Hopkins Metagenomic Next-Generation Sequencing Assay for Infectious Disease (0323U)[19,22]

A review of the current medical literature shows that the **evidence is insufficient** to determine that these services are standard medical treatments. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

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	

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	
87632	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 6-11 targets	
87633	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets	
0115U	Respiratory infectious agent detection by nucleic acid (DNA and RNA), 18 viral types and subtypes and 2 bacterial targets, amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected	
0152U	Infectious disease (bacteria, fungi, parasites, and DNA viruses), microbial cell-free DNA, plasma, untargeted next-generation sequencing, report for significant positive pathogens	
0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected	
0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected	

0225U	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected	
0323U	Infectious agent detection by nucleic acid (DNA and RNA), central nervous system pathogen, metagenomic next-generation sequencing, cerebrospinal fluid (CSF), identification of pathogenic bacteria, viruses, parasites, or fungi	
0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab	
0373U	Infectious agent detection by nucleic acid (DNA and RNA), respiratory tract infection, 17 bacteria, 8 fungus, 13 virus, and 16 antibiotic-resistance genes, multiplex amplified probe technique, upper or lower respiratory specimen	
0528U	Lower respiratory tract infectious agent detection, 18 bacteria, 8 viruses, and 7 antimicrobial-resistance genes, amplified probe technique, including reverse transcription for RNA targets, each analyte reported as detected or not detected with semiquantitative results for 15 bacteria	New Code Effective Date 01/01/2025
0531U	Infectious disease (acid-fast bacteria and invasive fungi), DNA (673 organisms), next-generation sequencing, plasma	**New Code Effective Date 04/01/2025**
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
No code(s) identified		

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Change Summary

02/04/2025 New Policy.
04/01/2025 Update, Coverage Change. Provider Claims Codes Update.
08/05/2025 Update, Coverage Change. Provider Claims Codes Update.