Multiplex Pathogen Identification Panels for Infectious Disease

Humana

Medicaid Medical Coverage Policy

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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.

Expanded multiplex vaginitis/vaginosis pathogen panel is a laboratory test that uses molecular techniques like polymerase chain reaction (PCR) to simultaneously detect DNA and RNA from many microorganisms associated with vaginal infections like bacterial vaginosis (BV), vulvovaginal candidiasis (VVC), and trichomoniasis to help with diagnosis of vaginal symptoms using a single sample. **Bridge Women's Health Infectious Disease Detection Test** is an example of this type of testing. **(Refer to Coverage Limitations section)**.

Metagenomic next-generation sequencing (NGS) is an evolving, novel molecular technology proposed to detect pathogens for infectious disease and can potentially provide direct, unbiased analysis of microbial composition of specimens without reliance on traditional culture or targeted molecular tests. An example is

Johns Hopkins Metagenomic Next-Generation Sequencing Assay for Infectious Disease. **(Refer to Coverage Limitations section)**.

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

There are no covered indications; refer to Coverage Limitations Section.

Coverage Limitations

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

- Expanded multiplex vaginitis/vaginosis pathogen panels (Bridge Women's Health Infectious Disease Detection Test [0330U])[1,9,12,16,17]

- Metagenomic next-generation sequencing (NGS) (Johns Hopkins Metagenomic Next-Generation Sequencing Assay for Infectious Disease [0323U])[11,14]

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.

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
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	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
No code(s) identified		

References

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Change Summary

02/04/2025 New Policy.