Medical Coverage Policy | Identification of Microorganisms Using Nucleic Acid Probes

EFFECTIVE DATE: 01|01|2024
POLICY LAST REVIEWED: 09|06|2023

OVERVIEW

Nucleic acid probes are available for the identification of a wide variety of microorganisms. Nucleic acid probes can also be used to quantitate the number of microorganisms present. This technology offers advantages over standard techniques when rapid identification is clinically important, microbial identification using standard culture is difficult or impossible, and/or treatment decisions are based on quantitative results.

The following test(s) are addressed in this policy:

- MicroGenDX qPCR & NGS For Infection (MicroGenDX) CPT code 0112U
- ePlex BCID Fungal Pathogens Panel (GenMark Diagnostics, Inc.) CPT code 0140U
- ePlex BCID Gram-Positive Panel (GenMark Diagnostics, Inc.) CPT code 0141U
- ePlex BCID Gram-Negative Panel (GenMark Diagnostics, Inc.) CPT code 0142U

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

MicroGenDX qPCR & NGS For Infection (CPT code 0112U), ePlex BCID Fungal Pathogens Panel (CPT code 0140U), ePlex BCID Gram-Positive Panel (CPT code 0141U) and ePlex BCID Gram-Negative Panel (CPT code 0142U)

The use of nucleic acid testing using a direct or amplified probe technique (without quantification of viral load) may be considered medically necessary for the following microorganisms:

- Bartonella henselae or quintana
- Bordetella pertussis
- Candida species
- Chlamydia pneumoniae
- Chlamydia trachomatis
- Clostridium difficile
- Enterococcus, vancomycin-resistant (e.g., enterococcus vanA, vanB)
- Enterovirus
- Herpes simplex virus
- Human papillomavirus
- Influenza virus
- Legionella pneumophila
- Mumps
- Mycobacterium species
- Mycobacterium tuberculosis
- Mycobacterium avium-intracellulare
- Mycoplasma pneumoniae
- Neisseria gonorrhoeae
- Rubeola (measles)
- Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
- Staphylococcus aureus
- Staphylococcus aureus, methicillin-resistant

- Streptococcus, group A
- Streptococcus, group B
- Trichomonas vaginalis
- Zika virus

The use of nucleic acid testing using a direct or amplified probe technique (with or without quantification of viral load) may be considered medically necessary for the following microorganisms:

- Cytomegalovirus
- Hepatitis B virus
- Hepatitis C virus
- HIV-1
- HIV-2
- Human herpesvirus 6

The use of the following nucleic acid testing panel (without quantification of viral load) may be considered medically necessary

- Respiratory virus panel

PRIOR AUTHORIZATION

Medicare Advantage Plans and Commercial Products

Prior authorization is required for the following Proprietary Laboratory Analyses (PLA) tests:

- MicroGenDX qPCR & NGS For Infection (MicroGenDX) CPT code 0112U
- ePlex BCID Fungal Pathogens Panel (GenMark Diagnostics, Inc.) CPT code 0140U
- ePlex BCID Gram-Positive Panel (GenMark Diagnostics, Inc.) CPT code 0141U
- ePlex BCID Gram-Negative Panel (GenMark Diagnostics, Inc.) CPT code 0142U

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

The following Proprietary Laboratory Analyses (PLA) tests may be considered medically necessary when the medical criteria above has been met:

- MicroGenDX qPCR & NGS For Infection (MicroGenDX) CPT code 0112U
- ePlex BCID Fungal Pathogens Panel (GenMark Diagnostics, Inc.) CPT code 0140U
- ePlex BCID Gram-Positive Panel (GenMark Diagnostics, Inc.) CPT code 0141U
- ePlex BCID Gram-Negative Panel (GenMark Diagnostics, Inc.) CPT code 0142U

The use of nucleic acid testing with quantification of viral load is considered for microorganisms that are not included in the list of microorganisms above for which probes with or without quantification are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

The use of nucleic acid testing using a direct or amplified probe technique is considered for the following microorganisms not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome:

- Gardnerella vaginalis
- Hepatitis G

The use of the following nucleic acid testing panels (with or without quantification of viral load for viral panel elements) is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome:

- Central nervous system pathogen panel
- Gastrointestinal pathogen panel

Note: Laboratories are not allowed to obtain clinical authorization or participate in the authorization process on behalf of the ordering physician. Only the ordering physician shall be involved in the authorization, appeal or other administrative processes related to prior authorization/medical necessity.

In no circumstance shall a laboratory or a physician/provider use a representative of a laboratory or anyone with a relationship to a laboratory and/or a third party to obtain authorization on behalf of the ordering physician, to facilitate any portion of the authorization process or any subsequent appeal of a claim where the authorization process was not followed and/or a denial for clinical appropriateness was issued, including any element of the preparation of necessary documentation of clinical appropriateness. If a laboratory or a third party is found to be supporting any portion of the authorization process, BCBSRI will deem the action a violation of this policy and severe action will be taken up to and including termination from the BCBSRI provider network. If a laboratory provides a laboratory service that has not been authorized, the service will be denied as the financial liability of the participating laboratory and may not be billed to the member.

Commercial Products
Some genetic testing services are not covered and a contract exclusion for any self-funded group that has excluded the expanded coverage of biomarker testing related to the state mandate, R.I.G.L. §27-19-81 described in the Biomarker Testing Mandate policy. For these groups, a list of which genetic testing services are covered with prior authorization, are not medically necessary or are not covered because they are a contract exclusion can be found in the Coding section of the Genetic Testing Services or Proprietary Laboratory Analyses policies. Please refer to the appropriate Benefit Booklet to determine whether the member's plan has customized benefit coverage. Please refer to the list of Related Policies for more information.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable laboratory benefits/coverage.

BACKGROUND

Nucleic Acid Probes
A nucleic acid probe is used to detect and identify species or subspecies of organisms by identifying nucleic acid sequences in a sample. Nucleic acid probes detect genetic materials, such as RNA or DNA, unlike other tests, which use antigens or antibodies to diagnose organisms.

The availability of nucleic acid probes has permitted the rapid direct identification of microorganism DNA or RNA. Amplification techniques result in exponential increases in copy numbers of a targeted strand of microorganism-specific DNA. The most used amplification technique is polymerase chain reaction (PCR) or reverse transcriptase PCR. In addition to PCR, other nucleic acid amplification techniques have been developed, such as transcription-mediated amplification, loop-mediated isothermal DNA amplification, strand displacement amplification, nucleic acid sequence-based amplification, and branched-chain DNA signal amplification. After amplification, target DNA can be readily detected using a variety of techniques. The amplified product can also be quantified to assess how many microorganisms are present. Quantification of the number of nucleic acids permits serial assessments of response to treatment; the most common clinical application of quantification is the serial measurement of HIV RNA (called viral load).

The direct probe technique, amplified probe technique, and probe with quantification methods vary based on the degree to which the nucleic acid is amplified and the method for measurement of the signal. The direct probe technique refers to detection methods in which nucleic acids are detected without an initial amplification step. The amplified probe technique refers to detection methods in which either target, probe, or signal amplification is used to improve the sensitivity of the assay over direct probe techniques, without quantification of nucleic acid amounts.

- Target amplification methods include PCR (including PCR using specific probes, nested or multiplex PCR), nucleic acid-based sequence amplification, transcription-mediated amplification, and strand displacement amplification. Nucleic acid-based sequence amplification and transcription-mediated amplification involve amplification of an RNA (rather than a DNA) target.
- Probe amplification methods include ligase chain reaction.
- Signal amplification methods include branched DNA (bDNA) probes and hybrid capture methods using an anti-DNA/RNA hybrid antibody.

The probe with quantification techniques refers to quantitative PCR or real-time PCR methods that use are porter at each stage of the PCR to generate absolute or relative amounts of a known nucleic acid sequence in the original sample. These methods may use DNA-specific dyes (ethidium bromide or SYBR green), hybridization probes (cleavage-based [TaqMan] or displaceable), or primer incorporated probes.

Direct assays will generally have lower sensitivity than amplified probes. In practice, most commercially available probes are amplified, with a few exceptions. For this evidence review, indications for direct and/or amplified probes without quantification are considered together, while indications for a probe with quantification are considered separately.

Classically, identification of microorganisms relies either on the culture of body fluids or tissues or identification of antigens, using a variety of techniques including direct fluorescent antibody technique and qualitative or quantitative immunoassays. These techniques are problematic when the microorganism exists in very small numbers or is technically difficult to culture. Indirect identification of microorganisms by immunoassays for specific antibodies reactive with the microorganism is limited by difficulties in distinguishing between past exposure and current infection.

Potential reasons for a nucleic acid probe to be associated with improved clinical outcomes compared with standard detection techniques include the following (note: in all cases, for there to be clinical utility, making a diagnosis should be associated with changes in clinical management, which could include initiation of effective treatment, discontinuation of other therapies, or avoidance of invasive testing):

- Significantly improved speed and/or efficiency in making a diagnosis.
- Improved likelihood of obtaining any diagnosis in cases where standard culture is difficult. Potential reasons for difficulty in obtaining standard culture include low numbers of the organisms (e.g., HIV), fastidious or lengthy culture requirements (e.g., Mycobacteria, Chlamydia, Neisseria species), or difficulty in collecting an appropriate sample (e.g., herpes simplex encephalitis).
- There is no way to definitively make a diagnosis without nucleic acid testing.
- The use of nucleic acid probe testing provides qualitatively different information than that available from standard cultures, such as information regarding disease prognosis or response to treatment. These include cases where quantification of viral load provides prognostic information or is used to measure response to therapy.

The risks of nucleic acid testing include false-positive and false-negative results, inaccurate identification of pathogens by the device, inaccurate interpretation of test results, or incorrect operation of the instrument.

- False-positive results can lead to unnecessary treatment, with its associated toxicities and side effects, including allergic reaction. In addition, true diagnosis and treatment could be delayed or missed altogether.
- False-negative results could delay diagnosis and initiation of proper treatment.
- It is possible that these risks can be mitigated by the use of a panel of selected pathogens indicated by the clinical differential diagnosis while definitive culture results are pending.

For individuals who have signs and/or symptoms of meningitis and/or encephalitis who receive a nucleic acid-based central nervous system pathogen panel, the evidence includes a systematic review and a pivotal prospective study. Relevant outcomes include test accuracy and validity, other test performance measures, medication use, symptoms, and change in disease status. Access to a rapid method that can simultaneously

test for multiple pathogens may lead to the faster initiation of more effective treatment and conservation of cerebrospinal fluid. The available central nervous system panel is highly specific for the included organisms, but the sensitivity for each pathogen is not well-characterized. More than 15% of positives in the largest clinical validity study were false-positives. A negative panel result does not exclude infection due to pathogens not included in the panel. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have signs and/or symptoms of gastroenteritis who receive a nucleic acid-based gastrointestinal pathogen panel, the evidence includes prospective and retrospective evaluations of the tests' sensitivity and specificity and prospective studies on utility. Relevant outcomes include test accuracy and validity, other test performance measures, medication use, symptoms, and change in disease status. The evidence suggests that pathogen panels are likely to identify both bacterial and viral pathogens with high sensitivity, compared with standard methods. Access to a rapid method for etiologic diagnosis of infections may lead to more effective early treatment and infection control measures. However, in most instances, when a specific pathogen is suspected, individual tests could be ordered. There may be a subset of patients with an unusual presentation who would warrant testing for a panel of pathogens at once, but that subset has not Been well defined.

The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. For individuals who have signs and/or symptoms of respiratory infection who receive a nucleic acid-based respiratory pathogen panel, the evidence includes a systematic review and 2 randomized controlled trials(RCTs). Relevant outcomes include test accuracy and validity, other test performance measures, medication use, symptoms, and change in disease status. The systematic review reported that all 3 reviewed multiplex polymerase chain reaction systems were highly accurate. One RCT and 1 quasi-RCT evaluated utility of a respiratory panel and found benefits in time-to-treat and length of hospital stay. In addition, 1 subanalysis found fewer antibiotics being prescribed for patients diagnosed with the panel. The panel did not significantly affect duration of antibiotic use, readmission, or mortality rates. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) are covered for Medicare Advantage Plans and Commercial Products when medical criteria above are met:

This code can be used for MicroGenDX qPCR & NGS For Infection (MicroGenDX)

0112U Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-resistance gene

This code can be used for ePlex BCID Fungal Pathogens Panel (GenMark Diagnostics, Inc.)

0140U Infectious disease (fungi), fungal pathogen identification, DNA (15 fungal targets), blood culture, amplified probe technique, each target reported as detected or not detected

This code can be used for ePlex BCID Gram-Positive Panel (GenMark Diagnostics, Inc.)

0141U Infectious disease (bacteria and fungi), gram-positive organism identification and drug resistance element detection, DNA (20 gram-positive bacterial targets, 4 resistance genes, 1 pan gram-negative bacterial target, 1 pan Candida target), blood culture, amplified probe technique, each target reported as detected or not detected

This code can be used for ePlex BCID Gram-Negative Panel (GenMark Diagnostics, Inc.)

0142U Infectious disease (bacteria and fungi), gram-negative bacterial identification and drug resistance element detection, DNA (21 gram-negative bacterial targets, 6 resistance genes, 1 pan gram-positive bacterial target, 1 pan Candida target), amplified probe technique, each target reported as detected or not detected

RELATED POLICIES
Biomarker Testing Mandate
Proprietary Laboratory Analyses (PLA)

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