of Tennessee

Policy

Reimbursement Policy

Identification of Microorganisms Using Nucleic Acid Probes

I. Policy Description

Nucleic acid hybridization technologies utilize complementary properties of the DNA double-helix structures to anneal together DNA fragments from different sources. These techniques are utilized in polymerase chain reaction (PCR) and fluorescent resonance energy transfer (FRET) techniques to identify microorganisms.[1]

A discussion of every infectious agent that might be detected with a probe technique is beyond the scope of this policy. Many probes have been combined into panels of tests. For the purposes of this policy, only individual probes are reviewed.

For guidance on nucleic acid identification of *Candida* in vaginitis, please refer to AHS-M2057-Diagnosis of Vaginitis.

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

Reimbursement Policy

1) The coverage status of nucleic acid identification using direct probe, amplified probe, or quantification for the microorganism's procedure codes is summarized in Table 1 below. "MCC" in the table below indicates that the test **MEETS COVERAGE CRITERIA**; while "DNMCC" tests indicates that the test **DOES NOT MEET COVERAGE CRITERIA**.

Microorganism	Direct Probe	Amplified Probe	Quantification
Bartonella henselae* or *quintana		87471 (MCC)	87472 (DNMCC)
Chlamydia pneumoniae	87485 (DNMCC)	87486 (MCC)	87487 (DNMCC)
Clostridium difficile		87493 (MCC)	
Cytomegalovirus	87495 (DNMCC)	87496 (MCC)	87497 (MCC)
***Enterococcus*, Vancomycin-resistant (e.g., enterococcus vanA, vanB)**		87500 (MCC)	
Enterovirus		87498 (MCC)	
Hepatitis G	87525 (DNMCC)	87526 (DNMCC)	87527 (DNMCC)
Herpes virus-6	87531 (DNMCC)	87532 (DNMCC)	87533 (MCC)
Legionella pneumophila	87540 (DNMCC)	87541 (MCC)	87542 (DNMCC)
Orthopoxvirus		87593 (MCC)	
Mycoplasma pneumoniae	87580 (DNMCC)	87581 (MCC)	87582 (DNMCC)
Respiratory syncytial virus		87634 (MCC)	
Staphylococcus aureus		87640 (MCC)	
***Staphylococcus aureus*, methicillin resistant**		87641 (MCC)	

2) Simultaneous ordering of amplified probe and quantification for the same organism in a single encounter **DOES NOT MEET COVERAGE CRITERIA.**

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: https://www.cms.gov/medicare-

coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

A list of current U.S. Food and Drug Administration[23] approved or cleared nucleic acid-based microbial tests is available at: https://www.fda.gov/medical-devices/vitro-diagnostics/nucleic-acid-based-tests.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
87471	Infectious agent detection by nucleic acid (DNA or RNA); Bartonella henselae and Bartonella quintana, amplified probe technique
87472	Infectious agent detection by nucleic acid (DNA or RNA); Bartonella henselae and Bartonella quintana, quantification
87485	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia pneumoniae, direct probe technique
87486	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia pneumoniae, amplified probe technique
87487	Infectious agent detection by nucleic acid (DNA or RNA); Chlamydia pneumoniae, quantification
87493	Infectious agent detection by nucleic acid (DNA or RNA); Clostridium difficile, toxin gene(s), amplified probe technique
87495	Infectious agent detection by nucleic acid (DNA or RNA); cytomegalovirus, direct probe technique
87496	Infectious agent detection by nucleic acid (DNA or RNA); cytomegalovirus, amplified probe technique
87497	Infectious agent detection by nucleic acid (DNA or RNA); cytomegalovirus, quantification
87498	Infectious agent detection by nucleic acid (DNA or RNA); enterovirus, amplified probe technique, includes reverse transcription when performed
87500	Infectious agent detection by nucleic acid (DNA or RNA); vancomycin resistance (eg, enterococcus species van A, van B), amplified probe technique

Reimbursement Policy

CPT	Code Description
87525	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis G, direct probe technique
87526	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis G, amplified probe technique
87527	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis G, quantification
87531	Infectious agent detection by nucleic acid (DNA or RNA); Herpes virus-6, direct probe technique
87532	Infectious agent detection by nucleic acid (DNA or RNA); Herpes virus-6, amplified probe technique
87533	Infectious agent detection by nucleic acid (DNA or RNA); Herpes virus-6, quantification
87540	Infectious agent detection by nucleic acid (DNA or RNA); Legionella pneumophila, direct probe technique
87541	Infectious agent detection by nucleic acid (DNA or RNA); Legionella pneumophila, amplified probe technique
87542	Infectious agent detection by nucleic acid (DNA or RNA); Legionella pneumophila, quantification
87580	Infectious agent detection by nucleic acid (DNA or RNA); Mycoplasma pneumoniae, direct probe technique
87581	Infectious agent detection by nucleic acid (DNA or RNA); Mycoplasma pneumoniae, amplified probe technique
87582	Infectious agent detection by nucleic acid (DNA or RNA); Mycoplasma pneumoniae, quantification
87593	Infectious agent detection by nucleic acid (DNA or RNA); orthopoxvirus (eg, monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each
87634	Infectious agent detection by nucleic acid (DNA or RNA); respiratory syncytial virus, amplified probe technique
87640	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, amplified probe technique
87641	Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, methicillin resistant, amplified probe technique

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

1. Khan A. Rapid Advances in Nucleic Acid Technologies for Detection and Diagnostics of Pathogens. *J Microbiol Exp*. 2014;1(2)doi:10.15406/jmen.2014.01.00009

2. Mothershed EA, Whitney AM. Nucleic acid-based methods for the detection of bacterial pathogens: present and future considerations for the clinical laboratory. *Clinica chimica acta; international journal of clinical chemistry*. Jan 2006;363(1-2):206-20. doi:10.1016/j.cccn.2005.05.050
3. WHO. Monkeypox. Updated August 26, 2024. https://www.who.int/news-room/fact-sheets/detail/mpox
4. Miller JM, Binnicker MJ, Campbell S, et al. A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2018 Update by the Infectious Diseases Society of America and the American Society for Microbiology. *Clinical Infectious Diseases*. 2018:ciy381-ciy381. doi:10.1093/cid/ciy381
5. Miller JM, Binnicker MJ, Campbell S, et al. Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2024 Update by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM) ∗. *Clinical Infectious Diseases*. 2024;doi:10.1093/cid/ciae104
6. CDC. Identification of Candida auris. Updated June 27, 2024. https://www.cdc.gov/candida-auris/hcp/laboratories/identification-of-c-auris.html
7. CDC. Laboratory Testing for Chlamydia pneumoniae. Updated January 30, 2024. https://www.cdc.gov/cpneumoniae/php/laboratories
8. CDC. Clinical Testing and Diagnosis for CDI. Updated March 6, 2024. https://www.cdc.gov/c-diff/hcp/diagnosis-testing/
9. CDC. Laboratory Testing for CMV and Congenital CMV. Updated April 15, 2024. https://www.cdc.gov/cytomegalovirus/php/laboratories/index.html
10. CDC. Mpox Case Definitions. Updated September 12, 2024. https://www.cdc.gov/mpox/hcp/case-definitions/
11. CDC. Mpox Clinical Testing. Updated August 27, 2024. https://www.cdc.gov/mpox/hcp/diagnosis-testing/
12. CDC. Laboratory Testing for Methicillin (oxacillin)-resistant Staphylococcus aureus (MRSA). Updated April 12, 2024. https://www.cdc.gov/mrsa/php/laboratories/index.html
13. CDC. Laboratory Testing for Mycoplasma pneumoniae. Updated December 27, 2023. https://www.cdc.gov/mycoplasma/php/laboratories
14. CDC. Laboratory Testing for Non-Polio Enterovirus. Updated April 16, 2024. https://www.cdc.gov/non-polio-enterovirus/php/laboratories/index.html
15. CDC. Diagnostic Testing for RSV. Updated August 30, 2024. https://www.cdc.gov/rsv/hcp/clinical-overview/diagnostic-testing.html
16. CDC. Laboratory Testing for Legionella. Updated January 29, 2024. https://www.cdc.gov/legionella/php/laboratories
17. CDC. Clinical Guidance for Bartonella henselae. Updated May 15, 2024. https://www.cdc.gov/bartonella/hcp/bartonella-henselae/
18. AAP Committee on Infectious Diseases. *Red Book® 2018*. 2018.

19. ECDC. *Risk assessment: Monkeypox multi-country outbreak*. 2022. https://www.ecdc.europa.eu/en/publications-data/risk-assessment-monkeypox-multi-country-outbreak
20. ECDC. *Interim advice on Risk Communication and Community Engagement during the monkeypox outbreak in Europe, 2022*. 2022. https://www.ecdc.europa.eu/sites/default/files/documents/Joint-ECDC-WHO-interim-advice-on-RCCE-for-Monkeypox-2-June-2022.pdf
21. UKHSA. Monkeypox: diagnostic testing. Updated April 4. https://www.gov.uk/guidance/monkeypox-diagnostic-testing
22. HHV-6 Foundation. Overview on Testing for HHV-6 infection. 2024;
23. FDA. Nucleic Acid Based Tests. Updated March 05. https://www.fda.gov/medical-devices/vitro-diagnostics/nucleic-acid-based-tests

VI. Revision History

06/04/2025	Reviewed and Updated: Updated background, guidelines, and evidence-based scientific references. Literature review necessitated the following changes in coverage criteria: Removed "Non-vaginal Candida species" and associated codes from the table, as the codes for all Candida species are the same and appropriate ordering scenarios for NAAT testing for Candida are addressed in M2057 and M2172. Direct probe testing for Chlamydia pneumoniae, Cytomegalovirus, Legionella pneumophila, and Mycoplasma pneumoniae all changed from "MCC" to "DNMCC". All direct probes in policy do not meet coverage criteria. Change of direct probe management in CC1 results in removal of direct probe from CC2 and reorganization of the criteria to describe the exclusion of same day ordering. Now reads: "2) Simultaneous ordering of amplified probe and quantification for the same organism in a single encounter DOES NOT MEET COVERAGE CRITERIA." Removed CPT code 87480, 87481, 87482