

## Detection of Microorganisms Using Nucleic Acid Probes Utilization Guidelines (Adopted from Medicare Guidelines)

This policy contains information regarding utilization of and reimbursement for tests to identify microorganisms using nucleic acid probes.

### Background

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Over the past several years, the development and application of molecular diagnostic techniques has initiated a revolution in the diagnosis and monitoring of infectious diseases. Microbial phenotypic characteristics, such as protein, bacteriophage, and chromatographic profiles, as well as biotyping and susceptibility testing, are used in most routine laboratories for identification and differentiation. Nucleic acid techniques, such as plasmid profiling, various methods for generating restriction fragment length polymorphisms, and the polymerase chain reaction (PCR), are making increasing inroads into clinical laboratories. PCR-based systems to detect the etiologic agents of disease directly from clinical samples, without the need for culture, have been useful in rapid detection of unculturable or fastidious microorganisms. Additionally, sequence analysis of amplified microbial DNA allows for identification and better characterization of the pathogen. Subspecies variation, identified by various techniques, has been shown to be important in the prognosis of certain diseases. Other important advances include the determination of viral load and the direct detection of genes or gene mutations responsible for drug resistance. Increased use of automation and user-friendly software makes these technologies more widely available. In all, the detection of infectious agents at the nucleic acid level represents a true synthesis of clinical chemistry and clinical microbiology techniques.

### Reimbursement Requirements

To receive reimbursement for tests to detect microorganisms using nucleic acid probes, all of the following must be true. The test:

- Is ordered by a physician or eligible provider.
- Is reported promptly to the physician.
- Results are used by the physician in the management of the patient (“procedure to diagnosis” editing).
- Must be considered reasonable and necessary.
  - For a test to be considered reasonable and necessary the patient’s presenting problem and/ or symptoms must support the use of the test.

### Reimbursement Limitations

1. Medicaid does not reimburse for non-FDA approved tests. (See the provider manual at <http://health.utah.gov/Medicaid>, Section 1.)

2. Medicaid does not reimburse for laboratory studies currently in clinical trials where the study related laboratory tests are paid for under a current study grant.
3. Medicaid does not reimburse for a generic test when a CPT code is available for the organism under surveillance.
4. Medicaid does not reimburse for 87797-87799 if there is a specific CPT code. For example 87510 Direct Probe Technique for *Gardnerella vaginalis*.
5. 87800-87801- Should only be used for detection of multiple infectious agents not otherwise specified.
  - Example Chlamydia and Gonorrhea done together when there is not a specific code for running these together and obtaining a single result. See parenthetical statement under CPT code 87800.
6. In the event there is a need to test for an organism that is not currently accounted for in the CPT code family 87470-87801, then use code 87797 for one unit. Use 87797 when testing for separate, distinct organisms that are not part of any panel and there is not a specific code available. This is manually reviewed with documentation.
7. 87500 - No more than three units of service may be coded (and reimbursed) for the same date of service. This reflects the fact that no more than three genetic variants (e.g., Van A, Van B and/or Van C) should be necessary for the molecular evaluation of Vancomycin-resistant *Enterococcus*.
8. Code 87502 is reimbursed for typing or subtyping influenza.

### **Rapid Respiratory Panels**

The rapid respiratory panels are typically used for patients in the Emergency Department. These tests are designed to depict multiple organisms in a multiplex reaction. Since one procedure produces many results each of these CPT codes would be allowed reimbursement for one unit each. It is Medicaid of Utah policy that only the Infectious Agent Detection by Nucleic Acid or RNA multiple types or subtypes, 3-5 targets is a covered service.