ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
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April 16, 2026

Blue Cross and Blue Shield of Alabama
Attn: Health Management - Medical Policy
P.O. Box 995
Birmingham, AL 35298-0001

Re: BCBS Alabama coverage policy *Identification of Microorganisms Using Nucleic Acid Probes*

Dear Dr. Richard Embrey

The Association for Molecular Pathology (AMP) appreciates the opportunity to review and comment on the Blue Cross Blue Shield Alabama's recently published draft medical policy titled *Identification of Microorganisms Using Nucleic Acid Probes*. AMP is an international medical and professional association representing approximately 3,100 physicians, doctoral scientists, and medical laboratory professionals involved in molecular diagnostics, including infectious disease testing, genetics, and genomics. Our members work across government, academic, hospital-based, and commercial laboratories, as well as within the in vitro diagnostics industry. As experts in molecular diagnostics, we are committed to ensuring patient access to high-quality, evidence-based testing and welcome the opportunity to collaborate on the development and refinement of coverage policies.

We have significant concerns regarding the current policy, particularly due to scientific inaccuracies that we believe may cause confusion and ultimately delay patient care. Below, we have outlined our concerns and recommendations for changes within the policy.

Title of Policy

The title of the policy is "Identification of Microorganisms Using Nucleic Acid Probes", AMP believes this is unclear because a negative test result does not lead to organism identification but is considered clinically relevant for the patient. Of note, an "organism" specifically called out in the policy, Bacterial vaginosis, is detected though a composite of bacterial detections and/or lack of detections. **As such, AMP recommends that the policy be renamed to "Testing for Detection of Microorganisms or Associated Syndromes ".**

Microorganism List

AMP appreciates the list of Microorganisms that are identified as medically necessary. However, AMP is concerned with the policy statement at the top of the micro-organism list: "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 (see table at the end of this section for details on coding)". AMP would like to point out the many of the organisms included in the list do not have a viral load and the mention of "without quantification of viral load" implies there is a potential

viral load in the bacterium mentioned below. **AMP is extremely concerned about this implication leading to scientific inaccuracy and requests that the language "without quantification of viral load" be removed from the policy.**

AMP also appreciates the addition of Bacterial Vaginosis (BV) testing to the policy; however, the policy specifically notes that BV testing is only covered in symptomatic individuals, which AMP agrees with, but there is no such distinction for any other target. For example, it is also standard to test for Bartonella henselae or quintana only in symptomatic individuals; yet this notation is not mentioned in the policy. To maintain consistency within the policy, **AMP believes that the addition of "in symptomatic individuals" to be overly-specific for this individual test and requests its removal in the policy.**

Clarification of investigational panels

Within the policy, the panels listed below are deemed investigational. However, it is unclear how each panel is defined. **AMP requests further clarification for the definitions of "Bacterial Vaginosis expanded panel", "Infectious Disease (fungus and/or bacteria) Panel", and "Genitourinary Pathogen Panel"**

The use of nucleic acid testing expanded panels using a direct or amplified probe technique with or without quantification of viral load is considered investigational for the following microorganisms, including, but not limited to:

- *Bacterial Vaginosis expanded panel*
- *Infectious Disease (fungus and/or bacteria) Panel*
- *Genitourinary Pathogen Panel*

Respiratory Virus Panels

AMP agrees that the expanded respiratory virus panels are not typically needed in an average risk, non-immunocompromised individual. However, this information is difficult to ascertain from the policy. AMP requests clarification that usage of limited panels, involving 5 targets or less, is considered medically necessary in average risk individuals.

Additionally, AMP disagrees with the determination that use of expanded panels involving 6 or more targets is not medically necessary. The usage of expanded respiratory virus panel testing is essential for immunocompromised individuals. IDSA guidelines recommend that clinicians should test high-risk, immunocompromised patients using panels for respiratory pathogens results[1]. This is due to the high impact on patient care in both inpatient and outpatient settings, potentially avoiding hospitalization of immune-compromised individuals. **AMP requests that BCBSAL notate that expanded respiratory panels are medically necessary for immuno-compromised individuals.**

Recommended Changes for Table 1: CPT Codes for Nucleic Acid Probes

- *Infectious Disease (fungus and/or bacteria) Panel*

[1] https://doi.org/10.1093/cid/ciz044

Under the pathogen type labeled "Infectious Disease (fungus and/or bacteria) Panel" there are many codes labeled as not meeting the medically necessary criteria. The information below breaks down the testing and cites information that the medical necessity of this type of panel testing.

- PLA code 0480U is a metagenomic sequencing assay in CSF with demonstrated clinical utility in cases of meningitis and encephalitis[2][3]. This testing method is routinely used for complex cases that are not diagnosed by conventional methods and should not be considered investigational.
- PLA codes 0140U-0142U are individual codes for the yeast, gram-negative and gram-positive organism identification panels manufactured by GenMark (Roche) and FDA cleared for use on positive blood culture bottle broth. They are widely used clinically and are considered standard of care for management of patients with sepsis, and thus are not investigational[4]. The CDC's Core Elements of Hospital Antibiotic Stewardship Programs also recommends the use of panels like these[5].
- CPT code 87594 is used for the detection of *Pneumocystis jirovecii*, a fungal pathogen that causes life threatening pneumonia in immunocompromised hosts. Molecular detection is standard of care in most settings that care for immunocompromised patients and is not investigational according to the Infectious Diseases Society of America and the American Society for Microbiology's joint, peer-reviewed guidance[6].
- PLA code 0152U is the Karius Test which is now recommended by the Duke International Society for Cardiovascular Infections[7] as means of diagnosis of infective endocarditis, thus it is not investigational.

AMP requests that PLA codes 0480U, 0140U, 0141U, 0142U, 0152U and CPT code 87594 be notated with the signifier "Med Nec" to demonstrate clinical utility for this type of testing and that it is medically necessary.

Additional Recommended Changes within Table 1

- To address our concerns in adding the Epstein Barr Virus Testing to the microorganism list**, we encourage the addition of the corresponding CPT codes 86663, 86664, 86665, 87495, 87496, and 87497 to be included within Table 1.** These tests are essential in the testing for Epstein-Barr virus and need to be labeled medically necessary.
- Under the pathogen type named "Genitourinary Pathogen Panel", the PLA codes listed are for urinary tract infection panels. Due to potential confusion, **AMP suggests changing the name to Urinary Tract Infection panel as genitourinary implies sexually transmitted infections or**

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[2] https://pubmed.ncbi.nlm.nih.gov/39533109/
[3] https://pubmed.ncbi.nlm.nih.gov/31189036/
[4] https://pubmed.ncbi.nlm.nih.gov/27080992/
[5] The Core Elements of Hospital Antibiotic Stewardship Programs
[6] Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2024 Update by IDSA/ASM
[7] 2023 Duke-International Society for Cardiovascular Infectious Diseases Criteria for Infective Endocarditis: Updating the Modified Duke Criteria | Clinical Infectious Diseases | Oxford Academic

women's health testing. This could lead to confusion as a patient might believe their needed testing is non covered.

- Under the Pathogen labeled "Central Nervous System Pathogen Panel" the PLA Code 0323U is listed as "quantitative". This is the PLA code for the Johns Hopkins metagenomic sequencing assay. This assay is similar other metagenomics assays that are well established in terms of clinical utility (e.g. UCSF, Mayo Clinic, which is referenced above as PLA 0480U, and Delve Bio). AMP would like to point out that PLA code 0323U is not quantitative and should be removed from that column. Furthermore, PLA code 0323U is labeled under the policy as considered investigational. Due to its similarity to other well-established tests that have proven clinical utility, AMP does not consider PLA code 0323U as investigational. **We recommend PLA code 0323U be notated with the signifier "Med Nec" to show that this type of testing has clinical utility and is medically necessary.**
- Under the Pathogen labeled "Unlisted (infectious agent detection by nucleic acid, DNA or RNA, not otherwise specified)" CPT codes 87797, 87798, 87800 and 87800 are noted to not meet the medically necessary criteria. In many cases, these unlisted codes may be used for clinically relevant testing that is not captured by a more specific CPT code or PLA code. Examples would include the UCSF's metagenomic sequencing test on Cerebral Spinal Fluid, or broad range bacterial or fungal PCR and sequencing offered by University of Washington, as these methods are routinely used for diagnosis of critically important infections. **AMP recommends CPT codes 87797, 87798, 87800 and 87800 be notated with the signifier "Med Nec" to show that this type of testing has clinical utility and is medically necessary.**

Thank you for providing the opportunity to comment on this policy. AMP would welcome the opportunity to work with BCBSA in the development of future applicable coverage policies. Should you have additional questions or require our expertise, please direct your correspondence to Samantha Pettersen, Manager, Public Policy & Advocacy at spettersen@amp.org.

Sincerely,

Jay Patel, MD,

Chair of the Economics Affairs Committee

Association for Molecular Pathology