



American
Clinical Laboratory
Association

October 9, 2009

Lawrence Schott, MD, MS
Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

**Re: Proposed Decision Memo
for Screening for HIV (CAG-00409N)**

Dear Dr. Schott:

On behalf of the American Clinical Laboratory Association (“ACLA”), I am pleased to submit these comments on the Proposed Decision Memo (“Proposed Decision”) for screening for HIV infection (CAG-00409-N). The Proposed Decision states that CMS has determined that the evidence is adequate to conclude that screening for HIV infection is reasonable and necessary for early detection of HIV and proposes Medicare coverage of the testing.

ACLA is an association of clinical laboratories throughout the country, including local, regional and national laboratories and we strongly support the decision of CMS to cover screening for HIV infection. ACLA is an organization devoted to educating the public and lawmakers about the vital role played by clinical laboratory testing in protecting the public health. Laboratory testing is crucial to the early detection of diseases, such as HIV, and early detection, in turn, is crucial to stemming the spread of such diseases, and to allowing patients to obtain early and effective treatment. ACLA applauds CMS for taking this important and significant step, which will benefit Medicare beneficiaries across the nation.

ACLA does have two comments, however, on the specifics of the Proposed Decision, which are set out below. First, CMS has erred in proposing to limit coverage to FDA approved tests for the reasons set out below. Second, ACLA urges CMS not to establish special HCPCS and screening codes to be used when billing for screening HIV services, as it has done with other services. Such codes simply create confusion and added burdens for all parties; therefore, CMS should simply use the current CPT code for billing purposes. These issues are set out in greater detail below.

**1. CMS Should Cover HIV Screening Performed
by LDTs, as well as by FDA Approved Kits.**

CMS states that it proposes to cover HIV screening performed “with an *FDA-approved* enzyme immunoassay (EIA), enzyme-linked immunosorbent assay (ELISA) or rapid HIV antibody

test.”¹ ACLA believes that this definition of covered testing is too narrow and would exclude many tests that are commonly used for detection of HIV.

While some laboratory testing is performed with FDA-approved or -cleared “test kits,” testing is also frequently performed with assays developed in-house by a clinical laboratory for use within that laboratory. Such tests, termed Laboratory-Developed Tests (“LDT”), are not subject to FDA clearance or approval; however, the laboratories performing such tests are subject to regulation by CMS under the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”). Laboratories performing LDTs must do their own validation of the tests to ensure their accuracy and establish other performance criteria.² FDA itself has recognized the value of LDTs and has stated that it will exercise its enforcement discretion with regard to many of these tests. In fact, in its Final Rule with regard to Analyte Specific Reagents, which are components of many LDTs, FDA stated that “the use of in-house developed tests has contributed to enhanced standards of medical care in many circumstances.”³

Many HIV screening tests performed by clinical laboratories will be done using LDT methodologies. If CMS limits coverage only to those tests that are FDA-approved or cleared, it could result in the denial of a significant number of tests. Traditionally, CMS has covered tests, regardless of whether they were performed using an FDA-cleared or -approved test kit or as an LDT validated by the performing laboratory in accordance with CLIA regulations. For example, when HIV viral load testing was first developed, CMS specifically noted that it was frequently done using “testing procedures developed in-house by individual laboratories and commonly referred to as ‘home brews.’” CMS specifically permitted coverage of these “home brew” tests.⁴ Thus, there is no basis for limiting the coverage in this situation either.

Further, there is no requirement in Medicare law that a test be FDA-approved or cleared before it can be covered. Medicare does exclude coverage of some devices that are deemed experimental;⁵ however, there is no basis for suggesting that HIV screening tests performed as LDTs would meet this criterion. As a result, there is no basis for excluding HIV screening tests from coverage, simply because they are performed using LDTs. Medicare should cover all HIV screening, regardless of whether it is done using an FDA approved or cleared kit or as an LDT.⁶ The language of the Proposed Decision should be changed to reflect this determination.

¹ Proposed Decision at 1. Technically, only tests for which a Pre-Market Approval (“PMA”) is submitted are “FDA-approved.” Tests for which a 510(k) request is submitted, i.e., those that are “substantially equivalent” to an existing device, are considered “FDA-cleared.”

² 42 C.F.R. § 493.1258(b)(2).

³ 62 Fed. Reg. at 62249 (Nov. 21, 1997).

⁴ HCFA, Program Memorandum No. AB-97-9 (June 1, 1997). Today, the term “Laboratory Developed Test” is usually used, rather than “home brew.”

⁵ 42 C.F. R. §411.15(o).

⁶ CMS has no way to determine in the usual instance whether a test is done using an LDT methodology or an FDA-approved or cleared kit. Theoretically, CMS could establish a special HCPCS code applicable to such testing; however, ACLA does not support such an approach for the reasons set out above.

2. To Avoid Confusion and Added Burdens, CMS Should Not Establish Unique Screening Codes for these Services.

ACLA has one additional comment with regard to the billing and payment for such tests. While we recognize that it does not specifically relate to the issue of coverage, we did want to highlight it as CMS moves forward with its consideration of this issue. CMS should not establish any special coding requirements for the new screening HIV test as it has done in certain other instances, because such special screening codes often create numerous billing and reimbursement problems.

Where a screening benefit is established under Medicare, CMS has sometimes established a separate HCPCS code to distinguish the screening test from other diagnostic uses of the test. It has done this in the case of screening Pap smears covered by Medicare as well as screening PSAs. At the same time, CMS often also sets up a specific ICD-9 code or codes to be used to show the purpose of the test was for screening. For example, in the case of PSAs, the test is to be billed using the screening HCPCS code (G0103) and the ICD-9 code, V76.44 (special screening for malignant neoplasms, prostate). ACLA is concerned that CMS may consider doing the same thing with regard to coverage of HIV screening.

The creation of such special billing requirements for screening services creates numerous billing problems for physicians, laboratories, patients and for the contractors who pay the claims. First, in order to determine whether to use the usual CPT code or the special screening HCPCS code, laboratories must somehow determine the physician's purpose in ordering the service. Laboratories have developed numerous approaches to deal with this issue, but they all create their own problems. For example, with PSA, laboratories may have two separate offerings on their requisition, a diagnostic and a screening PSA. However, physicians often do not understand the billing and payment implications of the two different types of PSAs; therefore, they may order a screening PSA with a diagnostic ICD-9 code, and a diagnostic PSA with a screening ICD-9 code. All of these situations require the laboratory to make separate inquiries to the physician to obtain the appropriate information for billing purposes.

The directive to use a particular ICD-9 code in order to indicate that a test is for screening, which CMS has also done for PSA testing, creates even more opportunities for confusion. As a matter of compliance, laboratories bill the ICD-9 code that is submitted with the testing from the physician. When CMS established a specific code for a screening PSA, laboratories had to educate physicians and their staffs to use that one code when ordering the screening PSA. However, not surprisingly, given the other demands on physicians and their staffs, it is fairly common for a laboratory to receive an order for a screening PSA with the wrong ICD-9 code, including the wrong screening diagnosis code, which can result in the test being denied and the patient being liable.

For example, sometimes a physician orders a PSA test, but instead of submitting V76.44, the specific code for a screening PSA, the physician submits the code for routine medical examination. This is not unusual because the physician or his staff may know the PSA is a screening service, but may not know to use a special code. When the laboratory receives that order, it will bill using the screening code received from the physician. Since the Medicare billing system only recognizes one code to demonstrate a screening PSA, it rejects other screening codes as a non-covered screening service, which can result in patient liability. The patient will then receive a bill for a non-covered

screening service, which is a nonsensical given that the screening service is actually a covered benefit. This creates unnecessary stress and confusion for the patient, and frustration for his physician, the laboratory, and the contractor, as they attempt to set things right.

ACLA is concerned that if CMS does approve HIV as a screening service, there will be a replay of the confusion detailed above. As ACLA has noted in the past, there is a simple solution that will avoid this situation, and we strongly urge CMS to implement it, rather than to create a new set of screening HCPCS and ICD-9 codes. As ACLA has noted in the past, it would be preferable and less confusing for all, if CMS neither assigned new HCPCS codes nor defined specific screening ICD-9 codes to be used to identify the screening services. Where a screening benefit exists, such as HIV screening, the laboratory should simply bill the standard CPT code applicable to the service, and submit the diagnosis code provided by the physician. If the code submitted is a diagnosis code, then it would be paid as a diagnostic service; if the code submitted is one of the numerous existing screening codes, then it would be paid as a screening service. The actual payment does not vary in either case. In other words, the very same adjudication logic in the payment system that currently determines when HIV testing is to be denied as a routine screening service should be used in the future to allow the claim to be covered and paid on the basis of routine screening under the new benefit. This approach would alleviate much of the confusion, claims denials, resubmissions, and beneficiary anxiety that currently exist. As a result, we urge CMS neither to establish new HCPCS codes for the HIV screening services nor to define screening specific ICD-9 codes, if they are covered by the Medicare program.

As noted, our strong preference is for there to be no new HCPCS or screening codes specified if HIV screening is covered. However, if—despite the reasons set out above—CMS follows its past practice and does establish new HCPCS codes for HIV screening tests, then CMS should help to prevent the type of confusion and wasted effort detailed above. Therefore, it must provide sufficient explanation and background to laboratories and physicians to explain how the new codes should be used with other existing codes and modifiers for HIV testing. Further, if CMS is going to require a screening diagnosis code to indicate that the test is a covered screening service, then CMS should establish a broad list of codes that it will recognize as demonstrating that the test is a covered screening service. When CMS only establishes a single code, it almost guarantees confusion in billing and frustration for beneficiaries. As a result, CMS should establish a broad list of specific ICD-9 diagnosis codes, similar to the screening codes used in the laboratory coverage policies resulting from the Laboratory Negotiated Rulemaking that could be used to as support for an HIV screening test. An adequate subsequent public comment period should also be offered for responses to any such coding proposals.

We hope you find these comments useful. If you have any questions or comments, please do not hesitate to contact us.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Alan Mertz". The signature is fluid and cursive, with a large initial "A" and "M".

Alan Mertz
President