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RE: Draft Local Coverage Determination Molecular Diagnostic Tests (MDT) (DL33599)

Dear Dr. Jeter:

Thank you for the opportunity to comment on DL33599. AMP (Association for Molecular Pathology) is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry. AMP members are experts in molecular pathology, and the implementation of coverage policies for these services has a direct impact on their practice.

The College of American Pathologists (CAP) is a national medical specialty society representing more than 17,000 physicians who practice anatomic and/or clinical pathology. College members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities.

As such, AMP and the CAP are concerned about the impact of this draft LCD and Palmetto's MolDX coverage and payment policies have on the provision of molecular diagnostic testing in Jurisdiction 11.

Coverage and Payment for Molecular Pathology Testing During Technology Assessments (TA)

As written, this draft LCD continues the existing Palmetto policy of potentially stopping payment for a test until a technical assessment can be performed. The draft states:

Palmetto GBA will review all new test/assay clinical information to determine of a test meets Medicare's reasonable and necessary requirement. Labs must submit a comprehensive dossier on each new test/assay prior to claim submission. Palmetto GBA will only cover and reimburse tests that demonstrate analytical and clinical validity, and clinical utility at a level that meets the requirement of Reasonable and

Necessary. Prior to completion of this TA and published coverage determination, Palmetto will consider all claims for these tests on an individual consideration basis.

During the lengthy review process, patient access to these potentially lifesaving test could be jeopardized because of the uncertainty surrounding coverage and payment. While AMP and the CAP appreciate that Palmetto will not simply withdraw coverage during this period, the uncertainty this policy creates still jeopardizes the financial stability of labs dependent upon running these tests.

Content of LCDs and Associated Articles

LCDs should contain only "reasonable and necessary" information with CPT and ICD-9 codes included only when they are relevant or to clarify the items intended to be covered (or not covered) as outlined in PIM § 13.1.3. All MAC decisions about coverage status, specifically whether a service is considered to meet "reasonable and necessary" and will or will not be covered should be addressed in the LCD and go through the draft LCD process citing the supporting medical evidence and have the Notice and Comment period to allow review by and input from the public, especially the medical community about the service and criteria being proposed.

This is in contrast to the Article format, which is associated with a LCD and provides additional educational information about the LCD and the coding guidelines. The coding guidelines could include definitions of codes, lists of items that may be billed under a particular code and minimum requirements that providers must meet in order to bill using a certain code. It could also include a product classification list that would inform providers about which specific products meet the requirements of a specific code.

The draft LCD states the following: *Please refer to the MOLDX website www.palmettogba.com/MOLDX for covered and excluded tests' specific coding and billing information.*

As drafted, Palmetto again addresses the MOLDX requirements for both local coverage determinations related to "reasonable and necessary" criteria and the coding guidelines for molecular diagnostic tests in DL33599. However, determinations of what is "reasonable and necessary" and the specific coding guidelines for individual tests are not addressed in this draft LCD and Palmetto uses the process infrequently. Instead, providers are directed to the MOLDX website to access that specific information.

As outlined in the draft LCD, the review of tests in the MOLDX program includes a review of the clinical utility of these tests and a review of the medical evidence to determine of the "reasonable and necessary" criteria for coverage has been met. Because these are new decisions to cover tests under these criteria, they are subject to the LCD process for presentation and public comment before final implementation of coverage. The LCDs would include identification of the tests covered by CPT code or gene tested, the clinical indications, the patient selection limitations, the frequency of testing, the ICD-9 codes and reporting CPT codes, and presentation of the medical literature considered in making the determination.

The statements on Palmetto's website do not contain all of the information listed above or a section related to history and revisions. Without this information and a notice and comment period, these statements are insufficient to comply with the LCD process.

Another significant concern is that these webpage statements regarding coverage are not entered into the Medicare Coverage Database (MCD). All MACs are required to enter local coverage determinations into this publicly accessible database, which is a centralized repository through which providers and beneficiaries can access policies and coding instructions. The MCD also provides a tracking system that identifies the policies and coding instructions that were in place at the time a service was provided, which is critical for appeals and to maintain program integrity.

REQUEST:

- As drafted, the process outlined in DL33599 will not conform to the standards for the LCD and Article coverage processes. Please separate local coverage determinations related to "reasonable and necessary" criteria for molecular diagnostic tests for specific conditions and their use for diagnosis and testing, addressed as LCDs and published on the MCD from content related to coding and guidance, which should be addressed in Articles, also published in MCD. This will allow the public to submit formal comments when appropriate. Posting decisions on coverage or non-coverage on the Palmetto website without a formal comment period does not satisfy these requirements.

- Palmetto should include the necessary information for all tests presented that have been deemed to meet the "reasonable and necessary" criteria, including indications, diagnosis, patient selection, and frequency for the tests under review that would be the basis of coverage decisions. Furthermore, Palmetto should provide the medical evidence for each test that supports the "reasonable and necessary" criteria and a positive decision for coverage. All of this information should be provided as part of a draft LCD subject to public review and comment.

Unique Test Identifier Requirement

AMP and the CAP continue to have significant concerns about the unique test identifier requirement and believe that it is duplicative of existing processes, including that of the AMA Current Procedural Technology (CPT) Editorial Panel. We would like to address the reasons Palmetto has offered for the creation of the unique identifier.

Difficulty Identifying the Tests Performed from the Claim Form

The draft LCD states, "*the language in the HCPCS and CPT manuals to describe the pathology and laboratory categories and the tests included in those categories are not specific to the actual tests provided.*" Because of this lack of specificity, Palmetto asserts the unique identifier is necessary.

We understand that challenges that existed under the old CPT codes of matching a lab test with a specific CPT code, but the new CPT codes are very specific for what is being tested and include the analyte in the name of the code. For Tier 2 codes, they have been grouped by Level to include those tests that represent similar levels of complexity and resources for testing. The specific analytes are listed and can be reported on the claim form in the same areas as would be used for the unique identifier. Given the specificity, we continue to question the need for a system that assigns a unique identifier for each test performed by a lab.

Need to Verify Analytic/Clinical Validity of Tests Performed

AMP and the CAP disagree with the position that a separate review of the analytic validity of each LDT or modified IVD by the Palmetto is needed. In order to be reimbursed by Medicare, the laboratory must be CLIA certified. CMS has already certified the laboratory (and all the tests it performs) under the CLIA program, which sets a standard for quality control for all tests performed. CMS notes in its brochure on CLIA that Medicare requires all laboratories performing tests be CLIA certified. It states CLIA "established quality standards for laboratories to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test is performed." Analytical validity is already addressed by CLIA regulations, which require laboratories to demonstrate analytical validity and regular proficiency testing.

Assuring clinical validity is not directly evaluated by CLIA. CLIA regulations under 42 CFR § 493.1445(e)(3)(i), however, require the laboratory director and technical supervisor to ensure that selected test methodologies are capable of providing the quality of results required for patient care. Implicit in this regulation is the responsibility of the laboratory director to use medically relevant test methodologies that have an effective clinical purpose—otherwise those methodologies could not be said to be "required for patient care."[i] Thus, the effective clinical purpose or clinical validity is typically documented by the laboratory in review of medical literature.

If a lab is not CLIA certified, the test cannot be paid for by Medicare. This should satisfy the requirement when obtaining a unique identifier, if one is needed. However, if there is doubt that these reviews do not adequately address analytic and clinical validity, tests that have been through the CPT process have had another review. For new molecular diagnostics tests, the CPT application process includes a review of analytic and clinical validity evidence to determine whether it is sufficient to support its position as part of medical practice. This added review ensures that all tests with a CPT code meet the requirements for analytic and clinical validity.

Ensure Claims Are Not Being Paid on Asymptomatic Persons

AMP and CAP agree with Palmetto that this remains an issue, but disagree that a unique identifier will adequately address the problem of when a test can be performed for many medical reasons in the symptomatic person. It may be possible to address this with specific information in the LCD, accompanying educational articles and requiring the appropriate HCPCS modifier be applied to the CPT code.

Performing 3 or More Tests Creates a "New Test" to be Reviewed for Medical Necessity

This can present in 1 of 2 ways in clinical practice:

1. Individual tests done in sequence or combination, reported separately: AMP is in agreement that every test ordered must be for the diagnosis or treatment for a symptomatic patient. However, there is a difference between a lab creating a "panel" of tests for a condition, which are identified on an ordering form to assist in ordering tests. The form must be clear so that physicians understand which tests are being included in the panel and each test must be clinically necessary. It can also be stated that if the tests are done in sequence, the order of testing is to be determined by the results from a previous test. This is common practice with cultures for infectious disease. There is a way for the physician to order the fluid specimen for gram stain, then culture and further testing for sensitivity is only performed based on the previous results. Each step in the testing is clinically indicated. Being able to indicate that the

intention of the physician is to have the full sequence done if the first test is positive. This allows the lab to proceed without requiring a delay imposed by informing the physician of the first result and requiring a new order to proceed, or even requiring a new specimen. The result of each of the tests is independent and reported. Tests ordered as a "panel" because they are related, done in sequence and each clinically indicated do not constitute a new test that must be reviewed to determine if it meets "reasonable and necessary" criteria.

2. A single test composed of individual tests with a new composite result: This is very different from the new testing capabilities in which multiple tests can be performed and their results combined and analyzed with an algorithm to create a new and different result which is the only thing reported, e.g. a risk score. AMP and the CAP agree this type of combining tests where the report from the whole panel is different information and should be addressed as a new and different test distinctly different and separate from the individual component tests. The MAAA tests are an example of this type of new testing. It is appropriate to review the combined test result/report to determine if it meets "reasonable and necessary" criteria.

Need to Address Clinical Utility of a Test

The unique identifier process should not include an evaluation of clinical utility. This is essentially an evaluation of the medical literature and a decision as to whether a test meets the "reasonable and necessary" criteria for a specific condition. This should not be done by an outside organization. As per the PIM Chapter 13, it should go through the LCD process, which requires presentation of the medical evidence and Palmetto's conclusions to be subject to review and public comment by the medical community. Palmetto is currently not adhering to this process.

Furthermore, as stated above, molecular diagnostic tests that have gone through the CPT process and received a CPT code have been subject to an assessment of clinical validity and utility during that process, making them unique from many other services with CPT code. Evaluating the clinical utility of tests already assigned a CPT code is redundant.

REQUEST:

- Recognize that CPT codes are sufficient to identify the tests performed and limit the unique identifier system to those tests without an assigned CPT code. Any assigned unique identifiers should be reviewed on an annual basis and removed once a CPT code has been assigned.

- Recognize the CMS administered CLIA program as sufficient to ensure the accuracy, reliability and timeliness of patient test results.

- Consider including information in the LCD about testing in asymptomatic persons, the reasons for denial and use of a modifier for claim submission. Publish an accompanying article to reinforce appropriate billing using the modifiers.

- Separate the clinical utility of a test for a condition from the unique identifier system. As a decision about whether the test is considered to meet "reasonable and necessary" criteria for coverage purposes, clinical utility should be addressed within the already defined and required LCD process.

Status of FDA Approved Tests: Applicable Tests/Assays

This draft LCD fails to address its application to FDA approved tests. We respectfully request that Palmetto address the following questions:

- Would existing coverage determinations (LCDs) apply to FDA approved tests?
- Are FDA approved tests recognized for their approved indications?
- Does the unique identifier program apply to FDA approved tests? Will there by an Article accompanying this LCD with information for billing? How should a laboratory indicate on the claim that a test being billed under a specific code is done with an FDA approved test and not one that requires a unique identifier?

We respectfully ask that you consider these comments which were prepared by a consortium of providers in the Palmetto jurisdiction as well as other members of AMP and the CAP, laboratory directors, staff and consultants who provide service to Medicare beneficiaries covered by Palmetto. We are happy to be of assistance in providing additional clinical information, references, contacts, or whatever is needed to assist you with this DLCD. Please direct your correspondence to Mary Steele Williams, AMP Executive Director, at mwilliams@amp.org or Jennifer Madsen, Senior Director, Economic and Regulatory Affairs, at jmadsen@cap.org.

Sincerely,

Association for Molecular Pathology
College of American Pathologists

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[i] U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services, Report of the Secretary's Advisory Committee on Genetics, Health, and Society, April2008