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AdvaMedDx
A Division of the Advanced Medical Technology Association

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VIA e-mail: J1B.Policy@PalmettoGBA.com

Elaine K. Jeter, M.D.
Part B Medical Director
Palmetto GBA J1 Part B Medical Affairs
P.O. Box 1476
Augusta, GA 30903-1476

Re: Local Coverage Determination (LCD) for Molecular Diagnostic Tests (MDT)(DL32288)

Dear Dr. Jeter:

On behalf of AdvaMedDx, we are pleased to provide comments on Palmetto GBA's draft "Local Coverage Determination (LCD) for Molecular Diagnostic Tests (MDT) (DL 32288)."

AdvaMedDx member companies produce advanced *in vitro* diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and often reduce overall health care costs. Functioning as an association within the Advanced Medical Technology Association (AdvaMed), AdvaMedDx is the only multi-faceted policy organization that deals exclusively with issues facing *in vitro* diagnostic manufacturers both in the United States and abroad.

The above-referenced LCD is a key part of Palmetto's overall program relating to molecular diagnostic tests (MDTs) as announced in a series of postings on Palmetto's website. While only the LCD is formally open for comment, we are providing comments below relating more generally to the MDT program.

AdvaMedDx agrees that the Medicare program should be knowledgeable about the tests that are provided to the Medicare beneficiaries enrolled in the program. Given the number of tests available in the market, we can appreciate Palmetto's challenge to gather information systematically and to act on that information in an organized fashion. However, we believe that the developers and manufacturers of such tests would benefit from greater clarity and transparency regarding the tests that would be subject to Palmetto's MDT program and the

operation of the program. We urge Palmetto to provide the public with more specific information on this issue.

Additionally, more information is needed regarding McKesson's role in implementing the MDT program, particularly as it relates to the handling and dissemination of potentially proprietary information. Proprietary information submitted to the McKesson database must be protected, and AdvaMedDx urges Palmetto to clarify its intent with respect to the use, or limitations of use, of the information, and to provide assurances that such information will be kept confidential.

Which Tests Would Be Subject to the LCD?

The discussion in the LCD of which tests are non-covered is confusing. AdvaMedDx urges Palmetto to provide clear guidance on this issue so that providers and sponsors will know if their tests are subject to the proposed policy.

The draft LCD states that the non-coverage policy would apply to "all molecular diagnostic tests that are not explicitly covered by a National Coverage Determination (NCD), a Local Coverage Determination (LCD) or coverage article published by Palmetto." A definition of an MDT is then provided (this definition differs from that provided in the "Frequently Asked Questions" document posted by Palmetto on its website on November 2, 2011). The draft LCD then goes on to say:

> In addition to this definition, this non-coverage policy applies to all tests that:
> 1. Are Non-FDA cleared laboratory developed tests (LDTs), or
> 2. Are performed or marketed by a sole source, hospital, or reference laboratory, or
> 3. Have not received a specific AMA CPT code, or
> 4. Have not obtained an NCD or a coverage determination from Palmetto GBA (LCD or article)

AdvaMedDx is unclear as to whether Palmetto intends to have the non-coverage policy apply only to MDTs that meet criteria 1-4 or if the intended reach of the language in the LCD is broader and will apply to tests identified in criteria 1-4 in addition to MDTs that do not have an NCD, LCD, or Palmetto coverage article.

> As currently drafted the LCD could be interpreted to mean that any one of the four requirements noted above would result in non-coverage. This would mean that, in the absence of a coverage determination, a test cleared or approved by the FDA could be non-covered if it has not received a specific CPT code **or** if the test was ever performed by a single laboratory.[1]

[1] We assume this specification refers to an analyte-specific code, since CPT codes are not specific to particular tests. The intended meaning of the term "single-source, hospital or reference laboratory" is not fully clear. The MolDx program FAQ document provides a clearer statement, though it appears more inclusive. See "Molecular Diagnostic Services (MolDx) Program Frequently Asked Questions," updated November 2, 2011.

AdvaMedDx does not support application of increased scrutiny to tests that are FDA approved or cleared simply because they do not have a CPT code or are performed by a single laboratory. While most FDA cleared or approved tests are widely disseminated, some are initially offered by only one laboratory.

Therefore, AdvaMedDx requests that Palmetto clarify the intended application of its non-coverage policy.

The LCD would apply to all tests performed on or after February 27, 2012. AdvaMedDx has concerns regarding the amount of time that Palmetto is allocating for implementation of this new system and questions whether this time frame will provide a sufficient opportunity for manufacturers and others to obtain a Palmetto determination on their MDT. We understand that Palmetto senior staff has discussed phasing in the policy and possibly limiting its initial use to a limited number/type of tests. We urge Palmetto to more fully describe its planned approach for phasing-in this new system in the final LCD and accompanying guidance.

Lastly, AdvaMedDx has some concerns related to the applicability of the LCD to method-based, stacking, array, and cytogenetic codes. Over the past two years the AMA has worked to develop a number of new CPT codes to specifically describe MDTs. Many of these codes have already gone through the CPT process and a number of them are included in the 2012 edition of CPT. However, despite the incorporation of many of the new CPT codes in the 2012 edition of CPT, CMS has explicitly directed that the new molecular pathology codes that appear in the CPT book not be used to bill Medicare for services provided in 2012. Instead CMS has instructed that the stacking codes found in CPT continue to be used to bill for these molecular diagnostic procedures. Given these explicit directions from CMS and the historic use of these codes to bill for molecular pathology procedures, AdvaMedDx requests that Palmetto provide clarification and reconsider its position on non-covering molecular procedures billed using stacking and other codes in lieu of a Not Otherwise Classified (NOC) code.

The LCD discussion related to the use of NOC codes also states that Palmetto will only cover and reimburse MDTs that demonstrate analytical and clinical validity and clinical utility. However, the criteria that will be used to establish these utility and validity requirements, as explained in the article referenced in the LCD, are unclear. AdvaMedDx therefore requests that Palmetto provide additional clarification regarding the literature and/or other evidence requirements that will be used to determine analytical validity, clinical validity, and clinical utility as described in the LCD. We are particularly interested in clarification regarding the number and types of literature required to satisfy the validity and utility requirements

In sum, AdvaMedDx recommends that:

- Palmetto's final LCD clarify whether the non-coverage policy applies only to MDTs and clearly identify the types of MDTs that will be non-covered.

- Palmetto describe its planned approach for phasing in the MDT non-coverage policy.

- Palmetto clarify that the MDT non-coverage policy exclude FDA-cleared or approved tests that can be described by any CPT code including method-based, stacking, array, and cytogenetic codes, to be in alignment with the CMS policy included in the final CY 2012 Physician Fee Schedule regulation.

- The accompanying MDT LCD article clarify the literature and/or evidence requirements that will be used to establish clinical and analytical validity and clinical utility.

Development of a MolDx Program Using McKesson

Palmetto has also recently announced the expansion of its molecular diagnostics program. This new program will involve the development of Z-codes, developed by McKesson, to measure utilization, make coverage determinations, and facilitate reimbursement decision-making. AdvaMedDx has some concerns regarding the methods that will be used by McKesson and Palmetto to acquire the data used to develop the Z-codes. As discussed above, we also have concerns regarding the way in which McKesson, an organization with varied health care business interests, will utilize proprietary data that will be revealed during the Z-code development process.

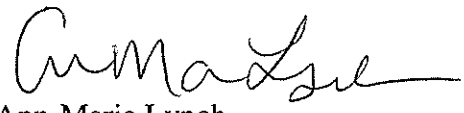
Many of the MDTs that are currently not assigned unique CPT codes, and would possibly be subject to the Z-code program, produce results that require analysis using a proprietary algorithm. We urge Palmetto to take steps to protect proprietary information as the Z-codes are developed and to clearly explain how it will maintain the confidentiality of this information. We further request that Palmetto clarify and limit the ability of McKesson to access and use proprietary information gained through its contract to develop Z-codes for any other purposes.

AdvaMedDx recommends that:

- If Palmetto intends to use McKesson to provide services in support of its MolDx program, Palmetto should ensure that:
    - McKesson does not acquire ownership of the information provided; and
    - McKesson has adequate firewalls in place to ensure against use of proprietary information for any purpose not related to this program.

AdvaMedDx appreciates the opportunity to comment on these issues. We would be happy to provide more information relating to any of the concerns we have raised. Please feel free to contact Chandra Branham at (202) 434-7219 or cbranham@AdvaMed.org if we can be of further assistance.

Sincerely,



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