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# Clinical Cytometry Society

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One Northbrook Place #5 Revere Drive, STE 200 Northbrook, IL 60062 USA • Tel 312.238.9068 • Fax 312.896.5614

Nita Collins  
Palmetto GBA  
J1 Part B Medical Affairs  
P.O. Box 1476  
Augusta, GA 30903-1476

February 25, 2010

Dear Ms. Collins,

This letter is a response from the Clinical Cytometry Society (CCS) to the draft LCD for Flow Cytometry DL30692.

The CCS is a non-profit professional organization dedicated to facilitating education and advancements world-wide in the application of flow cytometry to clinical needs, see <http://www.cytometry.org/>. It is the largest organization of its kind and its membership constitutes practicing physicians, medical technologists, and laboratory personnel focused on promoting the highest standards of clinical practice in this field. Many of the documents cited in the LCD were generated by members of our organization. Consequently, we believe we are uniquely qualified to provide guidance and commentary on the issues outlined in the LCD.

We welcome the recognition the document provides of the increasing importance of flow cytometry in the diagnosis and monitoring of a variety of medically important diseases, many of which are described under Indications. However, the focus in the document on diagnosis as the indication for testing differs from standard clinical practice. The physician who orders flow cytometric immunophenotyping typically does so on the basis of one or more signs and/or symptoms (e.g., cytopenias, leukocytosis, lymphadenopathy, monoclonal gammopathy, etc.) and it is on the basis of this Medical Indication that the laboratory determines which reagents are required. A recent consensus conference of experts in this field has endorsed a list of medical indications where flow cytometric testing is indicated, as well as situations in which flow cytometric testing is not indicated (see Davis, et al Cytometry B Clin Cytom 2007; 72 Suppl 1:S5-13). Put another way, the diagnosis is often not known at the time testing is performed; rather, the testing is being performed to establish the diagnosis. Consequently, it is not diagnosis but Medical Indication that should dictate reimbursement for this testing

As noted above, flow cytometric immunophenotyping is typically initiated on the basis of clinical or laboratory findings that may have a number of potential diagnostic possibilities, for instance pancytopenia, and testing is performed to assist in reaching a diagnosis, which might ultimately be the exclusion of a neoplastic diagnosis. In the latter situation, the effort required to confidently exclude a diagnosis of neoplasia approaches or may even exceed that needed to establish a neoplastic diagnosis. Even when a

diagnosis of neoplasia is ultimately rendered, significant effort is commonly required to exclude other diagnostic possibilities. This means that the total number of reagents required is not simply that directly relevant to the identification and characterization of the neoplastic population. This issue has recently been addressed by an international group of expert practitioners and optimal number of reagents suggested (see Wood, et al Cytometry B Clin Cytom 2007; 72 Suppl 1:S14-22). Additionally, there are certain primary diagnoses that are not acute leukemia or non-Hodgkin lymphoma where more than 10 antibodies are routinely required, for instance myelodysplastic syndromes. Consequently, the Limitation on p. 7 that “Palmetto GBA will not pay for more than 10 markers unless the diagnosis is NHL or acute leukemia” conflicts with established clinical practice and penalizes laboratories for using panels that have already been deemed appropriate by expert consensus. As suggested above, it would be better to link an appropriate level of reimbursement with the appropriate medical indication for which testing is being performed, irrespective of the diagnosis rendered.

The statement under Limitations on pages 6/7 that it is not considered reasonable and necessary to perform more than 21 markers in a panel also contradicts standard laboratory practice. While the immunophenotypes of leukemias and lymphomas are indeed well described, many of these evaluations are performed prior to the establishment of a diagnosis so the number of reagents required reflects the need to exclude other potential confounding diagnoses, identify the presence of the neoplastic population and provide appropriate characterization. As discussed above, a consensus strategy to perform these tasks has been published (see Wood, et al Cytometry B Clin Cytom 2007; 72 Suppl 1:S14-22). The number of reagents for initial evaluation varies depending on the Medical Indication with a subset requiring 22 unique reagents (see Tables 1, 2 and 3). If an abnormal population is identified, additional reagents will be required for characterization (see Table 4), the exact number will vary depending on the nature of the population identified, but 3 additional unique reagents is a reasonable estimate. Consequently, a limit of 25 antibodies on the total number reagents reimbursed would be more consistent with standard clinical practice.

We recognize the need for a rational and evidence-based reimbursement mechanism that allows patients and physicians access to this important technology while also controlling cost, which we take to be one intent of this document. It should be recognized that technology in this area continues to rapidly evolve with more powerful clinical analyzers being introduced and more challenging diagnostic questions being asked (e.g. myelodysplasia and minimal residual disease monitoring). The current model for reimbursement of the technical component, driven by billing on a per antibody basis, is ill-suited to the task. It generates unnecessary accounting work for both labs and payers, does not recognize redundant reagents required to perform these analyses, and diverts the focus from encouraging high quality practice. In addition, the lack of an upper limit on the number of antibodies that may be billed does not provide a deterrent for fraud and encourages the enactment of reimbursement caps that lack consistency between payers and which do not accurately reflect the nature of the work being performed..

In this context, we agree that a revision of the current reimbursement system is needed, and we would welcome the opportunity to work with you on such a revision. In broad outline, we would argue that reimbursement for flow cytometric testing should be focused on medical indication rather than the number of antibodies utilized, reflect the

resources required to perform the testing properly, and should be periodically revised as necessitated by changes in technology and practice. Such a system would simplify the process for all concerned, and address many of the limitations of the current system, while providing predictable and appropriate reimbursement. The CCS would be glad to work with you to implement and maintain this sort of change in reimbursement practice.

We are willing to discuss any of these issues with you in greater detail at any time, please do not hesitate to contact us with any concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Brent Wood". The signature is fluid and cursive, with the first name "Brent" and last name "Wood" clearly distinguishable.

Brent L Wood MD PhD  
President, Clinical Cytometry Society  
Professor, Dept of Laboratory Medicine  
University of Washington, Seattle

