

April 19, 2008

Steve Phurrough, M.D., M.P.A.
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Blvd., Mail Stop C1-09-06
Baltimore, MD 21244

Re: Support for Positron Emission Tomography NCD Reconsideration Request (CAG-00181N)

Dear Dr. Phurrough:

On behalf of the Academy of Molecular Imaging (AMI), I write to express our strong support for the extension of Medicare coverage to FDG-PET for use as a clinical management tool for patients with cancer.

The AMI understands that the Centers for Medicare & Medicaid Services (CMS) is reconsidering the current Coverage with Evidence Development (CED) data collection requirements for oncologic PET, and is considering revising the current National Coverage Determination (NCD) in order to provide Medicare coverage of FDG-PET for diagnosis, staging and restaging across all oncologic indications. The AMI believes that CMS should act favorably upon this reconsideration request.

The Academy of Molecular Imaging (AMI) is a national nonprofit organization whose mission is to advance the growing field of molecular medicine by encouraging advanced research in, and the innovative clinical application of, molecular imaging techniques. Through conferences, educational programs, and our peer-reviewed journal *Molecular Imaging and Biology*, the AMI seeks to bring together the top researchers and practitioners from the imaging, biological, physical and pharmaceutical science communities in order to promote and encourage greater understanding of how molecular imaging technology can benefit both patients and physicians.

The AMI has consistently advocated for the value of empirical evidence in assessing the benefits of cutting-edge applications of molecular imaging technologies. Because of this commitment, the AMI worked closely with CMS and the NOPR Working Group to develop and implement the CED NCD for oncologic PET. The AMI

Box 951735
Los Angeles, CA
90095-1735
T: 310.267.2614
F: 310.267.2617
ami@mednet.ucla.edu

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Pfizer Global Research
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Executive Director
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believes that the result of this collaboration -- a comprehensive nationwide data compilation of 22,975 PET studies spanning numerous cancer indications and the full spectrum of potential oncologic uses, as well as the analysis of these data as recently published in the *Journal of Clinical Oncology* -- speaks volumes.

The results published in the *Journal of Clinical Oncology* are both convincing and important. Of perhaps the most significance, the analysis of the NOPR Working Group demonstrated a 36.5% change in physicians' pre-PET treatment or no-treatment decision -- a figure that perhaps underestimates the clinical importance of PET because it considers only full changes between non-treatment and treatment. As the study further details, PET was associated with a management change in almost seventy-five percent of patients when the addition or deletion to specific modes of therapy were included.

Moreover, the NOPR data revealed that for patients with a pre-PET plan of biopsy, the post-PET plan had a significant impact on care, with such patients avoiding biopsy in approximately three-quarters of the cases analyzed. AMI believes that this finding is particularly valuable, as it demonstrates that PET provides physicians with an exceptionally valuable tool that can reduce the need for unnecessary surgery (and the attendant risks that such procedures may bring). Furthermore, the NOPR Working Group was careful to consider the impact of including or excluding in their analysis cases where the pre-PET treatment plan was *already* imaging. Yet even assuming that PET provided no advantages for those patients with pre-PET imaging plans, the NOPR Working Group's "worst-case estimate" (in their words) was that PET would nevertheless be associated with a major change in treatment in nearly twenty percent of patients.

These, of course, are merely some of the highlights of the thorough and meticulous analysis conducted by the NOPR Working Group. Indeed, having reviewed the data, the study, and the existing literature, the AMI echoes the position taken by the NOPR Working Group in their formal reconsideration request: that the clinical impact of PET "appears to be even greater than the impact of body CT when it was introduced thirty years ago."

On the basis of this data and analysis, the AMI is convinced that there exists a strong scientific and empirical justification for the recommendation that CMS terminate the current CED data collection requirements and authorize Medicare coverage for PET across all oncologic indications for diagnosis, staging, and restaging. The AMI strongly encourages CMS to act favorably upon the formal reconsideration request, and looks forward to working with CMS throughout the reconsideration process.

Sincerely,

Tim McCarthy
President