01/17/2008

Re: Comments on Proposed Decision for Positron Emission Tomography (FDG) for Infection and Inflammation (CAG-00382N)

Dear Dr. Phurrough:

On behalf of the Academy of Molecular Imaging (AMI), I am writing to express the AMI's disappointment in the conclusion of CMS that there is inadequate evidence to warrant a positive National Coverage Determination (NCD) for the use of PET for infection and inflammation. While we recognize and understand the concerns expressed by CMS in its proposed decision memorandum, the AMI believes that there is sufficient evidence in both the peer-reviewed scientific literature and the extensive clinical experience of our investigators to support the issuance of an NCD at this time, particularly for the indications of chronic osteomyelitis, infection associated with hip arthroplasty, and fever of unknown origin.

Nevertheless, we are encouraged by CMS's request for comments concerning the potential for providing limited coverage for these indications under the Coverage with Evidence Development (CED) paradigm. As the president of the AMI, I have direct knowledge of the highly effective collaboration of AMI with the Centers for Medicare & Medicaid Services (CMS) in the development and implementation of the National Oncologic PET Registry (NOPR), which has operated successfully pursuant to the innovate Coverage with Evidence Development (CED) paradigm since May 2006. If CMS does not believe a positive NCD can be issued on the basis of existing evidence, we strongly believe that - if feasible - a CED registry similar to the NOPR would enable CMS to acquire the data necessary to support the issuance of a favorable NCD on PET for infection and inflammation.

National Infection PET Registry (NOPR) Option

There are a number of advantages to the development of a National Infection PET Registry ("NOPR"), which we believe could operate in a manner similar to the current NOPR. For instance, CMS would have the assurance on the implementation level of the proven success of the NOPR in systematically acquiring PET scans for analysis. Additionally, the relevant potential stakeholders in such an endeavor (including the AMI, CMS, the NOPR, the American College of Radiology (ACR), and Society of Nuclear Medicine (SNM)) would bring to the project a level of prior familiarity with the implementation of a registry that would prove invaluable in enabling the NOPR to begin operation quickly and efficiently.

A CED for NOPR will, however, require the commitment of substantial technical and financial resources. To minimize such costs, the AMI would propose drawing upon the existing NOPR system as both a template and a foundation for the NOPR. From our experience in developing the NOPR, we believe that the costs of setting up a stand-alone second registry, developing data processing operations, registering sites, and gaining CMS recognition would outweigh any potential benefits of a distinct second registry. However, we do not believe that the existing NOPR study design will be entirely transferable to a registry for infection/inflammation imaging: for instance, entirely new pre-PET and post-PET forms would need to be developed and tested. Additionally, and in contrast to the NOPR, there are no single-site predecessor studies that conclusively demonstrate the feasibility of acquiring useful data in the setting of infection/inflammation. For this reason, we believe that many NOPR protocols would need to be developed de novo.

The viability of a NOPR also depends on the availability of adequate funding. The NOPR is currently funded on a per-scan basis through the CMS CED. Based on the success of the NOPR, the NOPR Working Group intends to request that CMS lift its CED requirement on PET across all cancer types for diagnosis, staging, and restaging/suspected recurrence purposes. Should CMS issue a NCD for oncologic PET indications, as we hope that it will, the CED funding for these scans - and thus, a substantial portion of the funding for the NOPR - will disappear. While such an NCD would be welcome news for the thousands of Medicare cancer patients who will benefit from PET, it would leave NOPR with substantially fewer financial resources available to cover its overhead and operations costs.

Although the NOPR expects to continue operating in order to gather data on PET for oncologic treatment monitoring, it is unclear whether the added financial burden of developing new protocols for PET for infection

could be overcome if PET for infection were added to the NOPR framework. If CMS elects to pursue a CED for PET for infection using the NOPR as a foundation, we would strongly encourage CMS to recognize and incorporate these additional resource needs into its decision.

Conclusion

In summary, the AMI continues to believe that FDG-PET is clinically effective in diagnosing suspected chronic osteomyelitis, infection associated with hip arthroplasty, and fever of unknown origin, among many other infectious and inflammatory conditions. We strongly urge CMS to establish a CED for PET for infection and inflammation, as we believe that such a CED would provide CMS with the additional data it feels are necessary to support the issuance of an NCD for these indications.

We appreciate your attention to this issue, and look forward to working closely with CMS to reach a positive determination on PET for infection and inflammation. If we can provide any additional information, please do let us know.

Sincerely,

Tim McCarthy, PhD
President
Academy for Molecular Imaging