NOPR Study Confirms PET Benefit in Patient Management

According to a study of data collected by the National Oncologic PET Registry (NOPR) and published online in the *Journal of Clinical Oncology* on March 24, management decisions are changed on the basis of results of ^{18}F-FDG PET in more than a third of patients who undergo such imaging. Lead author Bruce E. Hillner, MD, from Virginia Commonwealth University (Richmond) and a consortium of researchers from the Mallinckrodt Institute of Radiology (St. Louis, MO), Brown University (Providence, RI), Wayne State University (Detroit, MI), the American College of Radiology (ACR; Reston, VA), and Duke University School of Medicine (Durham, NC) coordinated the analysis of PET data from more than 1,500 facilities and nearly 23,000 patients. They found that physicians changed their intended management in 36.5% of cases after PET.

The NOPR was launched in May 2006 in response to the Centers for Medicare and Medicaid Services (CMS) Coverage with Evidence Development policy, which allows for the collection of data through a clinical registry to inform future coverage determination decisions for currently noncovered cancer indications. NOPR is sponsored by the Academy of Molecular Imaging and managed by the ACR and the ACR Imaging Network. The registry was designed to collect questionnaire data from referring physicians on intended patient management before and after ^{18}F-FDG PET imaging.

As a result of this positive data, the NOPR has formally asked CMS to reconsider the current National Coverage Decision on ^{18}F-FDG PET and to end data collection requirements for diagnosis, staging, and restaging. CMS would then review the data and issue a decision on reimbursement for PET scans currently covered only through the NOPR.

The authors of the *Journal of Clinical Oncology* article noted that "the data collected by NOPR fulfills an unmet need with its primary scientific aim of measuring the impact of PET on patient management in a manner that is minimally intrusive to care providers." They also stated that "our findings are representative of Medicare patients for whom PET would be ordered if it were covered by CMS for the expanded indications."

More information about the NOPR is available at www.cancerpetregistry.org.

National Oncologic PET Registry

CMS Denies New PET Coverage for Infection, Inflammation

The Centers for Medicare and Medicaid Services (CMS) released on March 19 a Decision Memorandum stating that "based upon our review CMS has determined that the evidence is inadequate to conclude that FDG PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin improves health outcomes in the Medicare populations." This decision, which signaled continued noncoverage for ^{18}F-FDG PET in these indications, also included specific language excluding coverage for these indications under the Coverage with Evidence Development paradigm on which the National Oncologic PET Registry is based (see Newsline article, above).

The final ruling was not unexpected and followed a December 2007 CMS recommendation to decline reimbursement. At that time, the agency asked for the submission of new evidence accrued since the original formal request for coverage of these indications was received in June 2007 from Abass Alavi, MD, chief of the nuclear medicine section at the University of Pennsylvania (Philadelphia), and Javad Parvizi, MD, associate professor of orthopedic surgery at Thomas Jefferson University (Philadelphia).

The Decision Memorandum (www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=207&) summarized the evidence presented, criteria used to determine coverage status, and reasons for declining coverage. Language in the Decision Memorandum indicated that negative factors in the decision included the absence of "any systematic reviews" in the literature evaluating the use of ^{18}F-FDG PET for the requested indications, a paucity of data supporting the ability of PET imaging to improve treatment or enhance long-term outcomes, and the absence of evidence-based guidelines for the use of PET in the requested indications. Articles submitted for support of expanded approval were criticized for small sample sizes and methodologic and statistical flaws.

A "lack of interest" was also cited by CMS as a negative factor: ". . .we note the marked paucity of expressed interest on this issue by practicing orthopedic surgeons or their professional societies. Similarly we note the lack of expressed interest from those physicians, generally infectious disease specialists, who would routinely be asked to consult in cases of fever of unknown origin. This leads us to reasonably determine that the interest in the use of PET for these indications is narrow and does not apparently include the physicians who routinely manage the care of beneficiaries who have these conditions."

Centers for Medicare and Medicaid Services