CHCPP NEWS

COMMISSION ON
HEALTH CARE POLICY AND PRACTICE

MEDICARE TO REIMBURSE FOR LUNG CANCER PET IMAGING

An important milestone in widening Medicare reimbursement for PET was reached on November 3, 1997, when Secretary of Health and Human Services Donna E. Shalala and Senator Ted Stevens (R-AK) agreed that Medicare would begin coverage for PET imaging for lung tumors, followed by fast-track review of other uses for PET within the next 18 months. (See letter below.)

"This is a huge victory for PET and for the thousands of patients who will benefit from PET scan technology in the diagnosis and treatment of illness," Senator Stevens stated.

The agreement between Shalala and Stevens was the result of negotiations stemming from passage of the Food and Drug Administration Modernization Act of 1997 (S.830). The PET provision in the Act revokes current agency guidance on the regulation of PET drug products and the regulations on good manufacturing practices for PET. It also requires that the FDA develop procedures for the regulation and approval of PET drugs within 2 years and allows the industry up to 2 years after such procedures are promulgated to submit new drug applications for compounded PET drugs.

Stevens, who has long urged that the federal government make PET scans more accessible and affordable, reported that Shalala had made a commitment to begin reimbursement for PET scans for the diagnosis and staging of lung cancer by the end of 1997.

Although the Health Care Financing Administration (HCFA) agrees that PET is accurate in the diagnosis of lung cancer, the effect of PET on patient care and Medicare costs is uncertain. For that reason, HCFA will conduct a prospective study on the effect of PET imaging on subsequent diagnostic surgical procedures. The study data will come from a series of HCPCS "G" codes, somewhat similar to the process that is currently being used in HCFA's assessment of PET myocardial perfusion imaging.

HCFA staff met with the PET Task Force, which consists of representatives of SNM, the American College of Radiology and the Institute for Clinical PET, on November 4, 1997. The task force is working with HCFA to develop coverage instructions for Medicare carrier medical directors and to assist HCFA in the analysis of the outcomes data. The task force drafted indications, definitions and G codes to assist HCFA in the retrospective assessment of the use of PET imaging for two clinical conditions: focal pulmonary lesions (solitary pulmonary nodules) and lung cancer staging. The coding will help in the evaluation of basic assumptions regarding the use of PET imaging in lung cancer. In addition, the task force supplied HCFA with diagnostic and therapeutic surgical procedure codes that will also aid in the tracking and analysis of PET imaging.

For additional information, contact Wendy Smith at (703) 708-9000, ext. 242, or by e-mail at wsmith@snm.org.

—Wendy J.M. Smith, MPH, is the SNM director of health care policy.

THE SECRETARY OF HEALTH AND HUMAN SERVICES
Washington, D.C. 20201

The Honorable Ted Stevens
Chairman
Committee on Appropriations
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

I am writing to clarify and confirm our commitment to carry out the administrative actions described below concerning Medicare coverage decisions with respect to Positron Emission Tomography (PET). I am aware of your interest in this technology and your leadership on the PET provision included in the Senate FDA reform bill (S.830).

As you know, the PET provision in S.830 makes a number of changes. It revokes current good industry guidance on the regulation of PET drug products and the regulations on good manufacturing practices for PET, requires that procedures be developed for the regulation and approval of PET drugs within two years, and allows the industry up to two years after such procedures are promulgated to submit new drug applications for compounded PET drugs.

During discussions on this provision, I understand that HHS staff committed the Health Care Financing Administration (HCFA) to undertake a series of administrative actions to move as expeditiously as possible, within the framework of the statute, to review and decide PET coverage under the Medicare program.

The following is a restatement of the commitments previously made and the actions taken to date in regard to each commitment:

1. Oncology

Previous Commitment

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At the August 1997 meeting of the Technology Advisory Committee (TAC) the technology assessments for the following oncology uses would be considered and the Committee would make coverage recommendations to HCFA. HCFA would make coverage determinations and issue the national coverage policy no later than 90 days after the TAC meeting and would report to the Committee Chairmen. Data deficiencies and research gaps would be noted for those uses where coverage is denied.

- staging lung cancer
- pulmonary nodule diagnosis of lung cancer
- colorectal cancer
- head and neck cancer
- melanoma
- breast cancer
- Hodgkin's lymphoma
- ovarian cancer

Action to Date

At the August 1997 meeting of the Technology Advisory Committee (TAC), a technology assessment done by Blue Cross and Blue Shield on non-central nervous system cancers was considered. Of the more than 30 uses of PET scans subject to the assessment, two uses (detection and staging of lung cancer) were favorably reported. The Department of Veterans' Affairs (VA), however, was also present at the TAC meeting and discussed an assessment that they had done, which raised significant doubts regarding the effectiveness of PET scans, including the quality of the evidence reviewed in the Blue Cross assessment.

After the TAC meeting, the PET industry informed HCFA that the Institute for Clinical PET had commissioned an additional assessment by ECRI, which was in the final stage of development. In view of the fact that there was another significant review of the technology almost completed, and that the results of the two other assessments were in conflict, HCFA determined it essential to see the results of the ECRI study prior to making a final coverage decision.

In the interim, HCFA is prepared to begin making payment for PET scans for lung cancer diagnosis and staging. This coverage will be provided in a manner consistent with decision models provided by PET representatives and in a way that will provide useful information regarding the impact on patient outcomes and Medicare costs. HCFA staff will meet with representatives of the PET industry as soon as it can be arranged to present and receive feedback on this approach. HCFA will then begin making payment no later than 45 days after this meeting.

2. Brain Cancer and Cardiac Indications

Previous Commitment

HCFA would, upon enactment of the FDA reform bill, request a technology assessment for two PET uses, brain cancer and myocardial viability. These studies are conducted by either Blue Cross or the Agency for Health Care Policy and Research. HCFA would request completion of the studies within 6 months and would put these two uses on the agenda for the next quarterly meeting of the TAC. Upon review by the TAC, the agency would make the coverage determinations and report to the Committee Chairmen within 3 months of the TAC meeting.

Action to Date

HCFA requested technology assessments for both brain cancer and myocardial viability. Following completion and staff review, these two uses will be placed on the agenda for the next TAC meeting.

3. Priority List

Previous Commitment

HCFA would conduct a thorough review of scientific literature, consult with the PET industry and develop a priority list for PET scan uses. The list would be published in the Federal Register within 6 months. It would be available for public comment, would be maintained by HCFA and periodically reviewed and updated as new uses and scientific information become available. HCFA would send a letter to the Committee Chairmen each six months to report recent actions on PET coverage determinations and other relevant issues and activities of the agency.

Action to Date

After consultations with the PET industry, HCFA has developed a draft priority list of PET scan uses for the purpose of making coverage determinations. This list has been shared with the PET industry and will be published in the Federal Register within 6 months of the enactment of the FDA reform bill.

4. Industry Guidance

Previous Commitment

Within 6 months, HCFA would issue a guidance describing the processes for making coverage decisions for PET scans and similar technologies, the relevant issues considered by the TAC, the types of research studies and other evidence that are required or useful in resolving such issues, and any other information that would inform or assist the industry in meeting the expectations of the agency with respect to the coverage determination. The guidance would be subject to public comment and the document could be revised by the agency following the comment period.

Action to Date

HCFA has developed the draft guidance document describing the evidence necessary to assess coverage for PET scans. Within 6 months of enactment of the FDA reform bill, the guidance will be released and be subject to public comment and may be revised if HCFA considers such revisions appropriate.

You have my assurance that we will work deliberately to carry out the administrative steps as outlined above. If you have questions, please contact Richard Tarplin, the Assistant Secretary for Legislation.

Sincerely,
Donna E. Shalala