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Published on Diagnostic Imaging (http://www.diagnosticimaging.com)

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September 14, 1994 | Nuclear Imaging [1], Practice Management [2], Vendors [3]

PET may also get a boost from FDA certification of FDG

The sound you hear may be gridlock breaking. Positron emission tomography passed two regulatory milestones last month that could help breathe life into moribund sales of this high-end nuclear imaging technique. A long-awaited evaluation of rubidium-82 PET imaging was passed to the Health Care Financing Administration (HCFA) early in August for Medicare reimbursement review of this procedure.

Shortly thereafter, the Food and Drug Administration certified Downstate Clinical PET Center's new drug application for the marketing of 18-fluorodeoxyglucose (FDG-18) for use with PET in locating epileptic seizure foci in the brain. The FDA's go-ahead for this agent could also lead to Medicare reimbursement. Ultimately, however, PET's market prospects hinge on convincing both private and public insurance payors that the modality offers both positive clinical outcomes and relative cost-effectiveness.

"This is a step forward," said Benjamin F. Armbruster, manager of marketing services for Siemens' nuclear medicine division in Hoffman Estates, IL. "It signifies at long last a recognition on the part of the federal government that at least PET should be made available to a large portion of the population that heretofore was unable to receive it because of the Medicare reimbursement question."

HCFA is evaluating a report on the use of rubidium in cardiac PET imaging that was prepared by the Office of Health Technology Assessment (OHTA), according to Janice M. Flaherty, director of the division of medical services coverage policy in HCFA's bureau of policy development.

"They (OHTA) found PET could be used to evaluate myocardial perfusion in most patients referred to cardiac centers. Previously, we had considered it experimental and investigational. This gives us the opportunity to look at it for coverage purposes, which we are doing," Flaherty told SCAN. "We plan on providing coverage, but first we have to look at different related issues, such as patient and facility selection criteria. We are looking at this as quickly as we possibly can."

Industry and government sources agree that Medicare reimbursement for PET could arrive by this month or next -- in time for the five-year anniversary of rubidium's market certification by the FDA. Squibb's CardioGen-82, a generator-based PET agent, was given the FDA go-ahead in January 1990 (SCAN 1/31/90).

Rubidium had been the only FDA-approved PET agent until the FDG decision last month. That statement is somewhat misleading, however. FDG has been widely used in clinical PET imaging for years. Until the FDA showed a desire to review FDG in 1989, certification of the agent was not required. FDG, as a cyclotron-based radiopharmaceutical, was classified under the practice of pharmacy rather than as a drug.

This regulatory authority issue is still under debate in the clinical community. Although the FDA has approved FDG for the epilepsy indication, there is no formal policy on whether institutions with cyclotrons are required to receive FDA certification for the agents they produce, said Michael McGehee, president of the Institute for Clinical PET in Washington, DC. Most PET centers, in fact, continue to operate under the jurisdiction of state boards of pharmacy.

Ironically, it was bureaucratic wheel-spinning over FDG that caused the holdup on rubidium and Medicare reimbursement.

"The FDA indicated that it wanted to regulate cyclotron-based tracers," McGehee told SCAN. "HCFA's initial request to OHTA for (PET) assessment did not make a distinction between rubidium and cyclotron-based tracers. So the people at OHTA refused to make that distinction and separate out
those two types of PET tracers. As a result, rubidium has been hampered by this anchor of FDA approval of a cyclotron-based tracer for five years."

Helped by members of Congress with PET centers in their districts, pressure was put on the regulatory apparatus to break the PET tracer logjam. In March, HCFA requested that OHTA separate rubidium from FDG in its study. This resulted in the August report.

Private insurance carriers and even the U.S. military insurance system have not waited for Medicare reimbursement. Payments are being made for PET exams, although positive statements by both the FDA and Medicare could help speed private payments for PET, McGehee said.

"This (FDA certification of FDG safety and efficacy) will make it easier for third-party payors that have in past wanted to pay for PET scans but said they had to wait for FDA approval because of legal concerns," he said.

PET camera sales have stagnated over the past two years. There are 73 PET facilities and 82 cameras installed in the U.S., McGehee said. The number of facilities was around 60 two years ago (SCAN 11/18/92).

Both wider reimbursement and the introduction of less expensive cameras, such as Siemens' ECAT ART selling for under $1 million (SCAN 6/15/94), should help stimulate PET sales, he said.

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