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MEDICARE CHANGES POSITION ON PET SCAN

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Four months ago, several University of Tennessee Medical Center doctors, along with the president of a local manufacturing firm, were worried.

Dr. Gary Smith, director of nuclear medicine and PET at the hospital, and Terry Douglass, president of CTI Inc., were afraid Food and Drug Administration regulation would strangle a new noninvasive diagnostic imaging technique known as positron emission tomography.But in the last week both the Health Care Financing Administration and Congress brightened PET's future.

Sen. Ted Stevens, R-Alaska, announced Nov. 6 that Medicare would start reimbursing for PET scans used in the diagnosing and staging of lung cancer as of the end of the year.

"This is great news," said Douglass, whose Knoxville-based company is solely devoted to building PET equipment and holds 70 percent of the world market.

Positron emission tomography is a technique used to map an organ's activity. In contrast, MRIs (magnetic resonance imaging) and CTs (computer-aided tomographs) show what an organ looks like.

For example, while an MRI can show a surgeon the dimensions of a tumor, PET will indicate if the tumor is "hot" and growing aggressively, or if it's merely dead scar tissue. The technique is used to diagnose, plan treatments and save unnecessary surgery in cancer, heart disease, brain disorder and muscle graft viability cases.

Dr. Karl Hubner, director of clinical research at UT Medical Center, said in July that using PET in only five procedures could save $5.3 billion in U.S. health-care costs.

About 50 sites are doing clinical PET scans in the United States, and one is at UT Medical Center.

Despite the apparent promise of PET, proponents of the technique have been fighting a 25-year battle. The imaging process begins when a patient is injected with a radioactive tracer known as FDG, or fluoro-deoxyglucose. The FDG has to be made on-site in a cyclotron and injected within two hours of its manufacture.

Because the FDA has not yet approved the way the tracer is manufactured, HCFA and Medicare also haven't approved it. Most private insurance companies follow Medicare's lead -- which means patients have had to foot the bill themselves for a $2,200 PET scan. And because the technology is so expensive, many surgeons are hesitant to saddle patients with that kind of expense, although they recognize its value.

But all that is about to change, at least for lung cancer patients. Stevens' staff, along with Douglass and several members of the PET industry, have been negotiating for months with HCFA to unravel the reimbursement tangle. Last week Stevens, who is also chairman of the Senate Appropriations Committee, met with Donna Shalala, secretary of Health and Human Services. In a Nov. 3 letter, she assured him of her commitment to HCFA's moving "as expeditiously as possible" on PET reimbursement. What this means to patients is that within 45 days from Stevens' and Shalala's meeting, HCFA will start cutting checks for PET scans for lung cancer. In addition, the agency also has agreed to a fast-track review of other uses of PET.

"It's fantastic -- it's what our industry has been looking for," said Ruth Tesar, who's on the board of directors of the Sacramento, Calif.-based Institute for Clinical PET.

In a related development, Stevens and Sen. Bill Frist, R Tenn., sponsored a provision in the Senate FDA Reform bill to speed up FDA approval of PET materials and ease insurance reimbursement. That bill passed Sunday and next moves to President Clinton's desk for his signature. Both Lee Rawls, chief of staff for Frist, and Liz Connell, legislative aide to Stevens, said Monday that Clinton will sign the bill within the next 10 days.

Smith of UT Medical Center is somewhat concerned the FDA Reform Bill could actually slow down new drug applications. "It

remains to be seen if FDA Reform is a good thing (for PET), but the HCFA (announcement) is certainly good news," he said Friday.

Tesar agreed new drug applications may be slowed down temporarily but said, "The intent of all this was to come up with a new, innovative way to work with the FDA. This legislation will allow breathing space for innovation to come."

Specifically, the bill revokes restrictions FDA put on PET in 1995 that, according to Smith, were almost impossible for PET sites to meet.

Connell summed up the events by saying, "The best thing about this package deal is that finally, from the secretary of Health and Human Services on down, we've legitimized PET. It won't go backwards. PET will be a recognized part of medicine. "The heartwarming part of all this is that it will benefit so many thousands of people."