

*InsideHealthPolicy.com - Nov. 10, 2008*

## **Oft-Debated PET Scans May Be Months Away From Broader CMS Coverage**

The physician group that requested CMS reconsider its national coverage determination (NCD) for PET scans in the spring is optimistic the agency will respond in January by proposing to dismiss the need for more research before expanding coverage of the cancer-detecting scans.

Despite some concerns from insurance companies and other groups about overuse, the opinions received by CMS in the comment period that ended last week support broadened coverage for PET scans. PET -- positron emission tomography, a non-invasive imaging used to assess metabolic activity -- can show doctors signs of malignancy by comparing differences between adjacent tissues.

Since May 2006, a group called the National Oncologic PET Registry (NOPR) has been operating under guidance from CMS and in conjunction with a host of clinical colleges and societies. The NOPR, in its letter dated March 25 and signed by four co-chairs of the group's working group, asks CMS to end data collection requirements for PET for brain, cervical, ovarian, pancreatic, small cell lung and testicular cancers. The quartet also requested CMS provide a kind of omnibus coverage of PET -- across all oncologic indications for diagnosis, staging and restaging/suspected recurrence purposes.

A draft decision memo is expected from CMS this January, before another comment period leads to a final decision.

"I think they like [the request], based on informal conversations," said Barry Siegel, a professor of radiology at Washington University School of Medicine and a NOPR working group co-chair. "Overall, we're very hopeful we can finally work our way out of a process that's been going on for 10 years."

The PET NCD -- one of the first to employ the innovative "coverage with evidence development" policy -- has so far allowed coverage of PET with F-18 fluorodeoxyglucose (FDG) for certain indications and cancers as long as the coverage is paired with a means to collect evidence that would let CMS develop a policy. NOPR, which serves as that evidence development mechanism, used nearly 23,000 cases to form its study, which was presented at a meeting of the Radiological Society of North America in November, 2007 before being published in the *Journal of Clinical Oncology*.

In 2004, a bipartisan group of 37 senators signed off on a letter that described PET as "an incredibly powerful tool" and called on CMS to lift the scans' national non-coverage status and leave coverage of PET up to local Medicare carrier medical policy. One of those senators was Sen. Ted Stevens (R-AK), a stalwart supporter of PET, who in 2006 included language in the Deficit Reduction Act, which cut certain Medicare payments for imaging services, to urge the National Cancer Institute to push for PET expansion.

NOPR's data showed PET having a significant impact on physician medical decision making, with a 36.5 percent change in doctors' pre-PET treatment or no-treatment decision. Of the 36.5 percent, PET findings prompted a change from a non-treatment to a treatment plan 28 percent of the time, three times the chance of non-treatment (8 percent). PET was associated with illustrating a greater cancer burden or more sites of disease more often than with a reduction of the seriousness of the cancer. The 36.5 percent figure only considers full changes between non-treatment and treatment, which NOPR states underestimates the clinical impact of PET imaging.

These changes include potential oncologic uses of PET such as diagnosis, initial staging, restaging and detection of suspected recurrence.

"PET was actually associated with a management change in almost three-quarters of patients when the addition of deletion to specific modes of therapy are included, and as well as alterations in the type of non-treatment care recommended," the co-chairs write.

The analysis finds that if PET is unavailable the top second choice is other imaging, 41 percent of the time. Patients planning on a biopsy before PET avoided that biopsy about three-quarters of the time. And referring physicians reported that PET let them avoid additional tests or procedures as often as 80 percent of the time, according to the request.

NOPR summed up by saying more than one-third of patients undergoing PET for one of the cancer types covered under Medicare's CED policy had a major change in intended management, including type of treatment.

"The clinical impact of PET appears to be even greater than the impact of body CT when it was introduced thirty years ago," the request states, before asking CMS to end the evidence collection requirements as condition of PET coverage and to support the omnibus coverage policy.

Though he admitted feeling anxious awaiting the result, Edward Coleman, professor of radiology at Duke University and another NOPR co-chair, said, "With the data we have, and the other literature out there, I'm optimistic we'll end up with some kind of omnibus coverage." Coleman said the decision will hopefully go a long way toward dispelling current confusion over what's covered and what's not. But he added that he wouldn't be surprised if CMS ruled against some of the requested cancer coverages, such as diagnosis of prostate cancer. With the literature not as supportive, the exception "wouldn't be a shock," Coleman said.

The encouraged expectations from NOPR as CMS prepares for its decision memo stems in part from a CMS memo from 2005 that said the agency would have "continued adding coverage for specific clinical use of FDG PET in cancer as each of these potential uses was shown through well-designed clinical trials to influence patient management and alter patient outcomes."

While the report indicates that CMS could save money through the reduction of other tests, it does not specifically address whether patient outcomes are improved through the use of the technology.

Expanding PET now is seen as largely uncontroversial, sources say, with some minor push-back from insurance companies that have worried patients will ask for the expensive scans simply for peace of mind. NOPR agrees with the insurers, including Blue Cross, that CMS needs to pay more attention to the issue, Siegel said.

“They need to make their guidance clearer,” Siegel said of CMS. “Physicians shouldn’t be ordering PET scans for asymptomatic patients when the evidence suggests the difference made is minimal to none. PET should be reserved for circumstances where conventional imaging doesn’t give enough information or where it can be completely substituted for traditional imaging.”

Concerns of overuse are also mitigated because PET involves injecting the FDG into a patient, which makes it more difficult to just crank out scans like is possible in other imaging. In any case, NOPR leaders said their data showed an increase in utilization of 10 percent of the Medicare population, a substantial figure but one Coleman described as “not opening up the floodgates.”

CMS approved coverage of PET performed on Medicare beneficiaries on a case-by-case basis for nine malignancies from 1998 and 2005, when the academic research community, professional societies, imaging industry and CMS got together to design the NOPR. The registry was created in response to a CMS proposal to expand coverage for PET with FDG to include cancers and indications that were otherwise ineligible for Medicare. Among the exceptions in the coverage was breast cancer diagnoses.

Medicare coverage can be obtained as long as the patient’s referring doctor and provider submit data to a clinical registry to assess the impact of PET. The NOPR national data registry with information from all Medicare-eligible PET facilities from physicians requesting the PET and from interpreting doctors’ PET reports began accepting facility registrations in late November 2005 and patient registration began in May 2006.

The work by NOPR has been unusually collaborative with CMS, Siegel said. “If nothing else, 120,000 patients have had PET scans” that they otherwise would have had to pay for, Siegel said. “The coverage with evidence development provides both access and evidence. And both of those are good.” -- *Seth Freedland (sfreedland@iwppnews.com)*

**Date: November 10, 2008**

**© Inside Washington Publishers**