

NOPR Letter for Referring Physicians

The National Oncologic PET Registry (NOPR) was approved by the Centers for Medicare and Medicaid Services (CMS) and opened on May 8, 2006. As most of you are aware, Medicare has provided coverage for FDG-PET for certain specific indications for a number of cancers for several years, but many other cancers and some indications remained noncovered. With the opening of the NOPR, essentially all of these other cancers and indications were covered for patients who have Medicare as their primary insurance (including those with Medicare Advantage managed care plans). This coverage is provided by CMS under a program known as "coverage with evidence development."

During nearly three years of operation, over 100,000 patients have undergone PET under NOPR's mechanism that allows for Medicare coverage of these scans. The NOPR investigators have published several peer-reviewed manuscripts (<http://jco.ascopubs.org/cgi/reprint/JCO.2007.14.5631v1>) documenting the impact of PET on referring physicians' intended management in patients with cancer. Based in part on these results, the NOPR investigators asked CMS in March 2008 to reconsider its coverage policy for PET. On April 3, 2009, CMS announced a new coverage policy (<http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=218>). Under this new policy, CMS expanded coverage for the use of PET for initial evaluation of patients with cancer to nearly all types of cancer and also allows for use of PET in subsequent treatment strategy evaluations for an expanded number of cancers. However, for many other cancers, the use of PET in subsequent treatment strategy evaluations will still be covered by CMS only if patients are enrolled in an approved clinical trial or registry such as the NOPR.

Patient entry in the NOPR requires that referring physicians provide certain additional information to the PET facility when such a study is requested, as well as additional information after the PET scan has been completed. The PET facility will submit this information to the NOPR database. The data submitted from PET facilities across the country will be used to assess the impact of PET on referring physicians' intended patient management. Ultimately, the goal of this data collection is to obtain standard Medicare coverage for all remaining cancer imaging indications, or as many as possible. Detailed information about the NOPR can be found on the NOPR Web site at <http://www.cancerPETregistry.org>.

From a practical viewpoint, obtaining a PET or PET/CT study on a Medicare patient eligible for inclusion in the NOPR will require some additional effort for referring physicians and their staff by comparison with a non-Registry study, but the NOPR has tried to make this process as easy as possible. Specifically, it will be necessary for the referring physician's office to complete the NOPR Pre-PET Form (http://www.cancerpetregistry.org/pdf/nopr_prepet_form.pdf) at the time the PET or PET/CT scan is requested and to submit this along with the standard oncologic PET request form. The PET facility must receive this form no later than the day of the PET study. After the PET or PET/CT scan is completed and the report has been distributed, a NOPR Post-PET Form will be sent to the referring physician's office. This form will need to be completed and sent back to the PET facility by fax, mail, or hand delivery as quickly as possible. The PET facility is required to enter the data from this post-PET form into the NOPR database no later than 30 days after the scan is completed (or the facility will not be able to bill Medicare for the study). Both the Pre- and Post-PET Forms must be signed by the referring physician to attest to the accuracy of the submitted data. Coverage by Medicare for a NOPR PET study is the same as for any other covered service; the patient or the patient's MediGap insurance will be responsible for any deductible or co-pay amount. The charges for a NOPR PET or PET/CT study are the same as for a non-Registry study.

Note that although the NOPR data collection is considered research, the only entity considered to be engaged in research is the NOPR itself. The PET facility and staff, as well as referring physicians and their staff, are not considered to be engaged in research. The American College of Radiology IRB has approved the NOPR, and the Federal Office of Human Research Protections has indicated that the procedures of the NOPR are in compliance with applicable regulations relating to protection of human subjects. In order for the NOPR to use the collected data for research purposes, BOTH the patient and the referring physician must give their consent (since both are research subjects). Patients will be provided with an information sheet either before their appointment or when they arrive for their PET scan. They will be asked to tell PET facility staff whether or not they consent; the usual requirement for written consent documentation has been waived. Referring physicians will provide their consent for use of the data in research by way of a checkbox on the Post-PET Form. **Please note that the collected data will be sent to CMS under any circumstances as a condition of payment for the PET scan; the required consents are only for the additional use of the data in research by the NOPR.**