



FAQS ON THE NATIONAL ONCOLOGIC PET REGISTRY FOR REFERRING PHYSICIANS

1. What is the National Oncologic PET Registry and why was it developed?

The National Oncologic PET Registry (NOPR) was developed in response to the Centers for Medicare & Medicaid Services' (CMS) announcement of expanded coverage for FDG-PET scans. In January 2005, CMS issued a National Coverage Determination (NCD) that extended coverage of PET scans using Fluoro-D-Glucose (FDG-PET) to essentially all cancers and indications not previously reimbursed by the Medicare program if the scan was conducted in conjunction with a "clinical study...designed to collect additional information at the time of the scan to assist in patient management," such as a registry.

Reimbursement for PET scans may now be made if the patient's referring physician submits data to the NOPR. The registry is designed to collect information regarding the impact of the PET on patient management. Data will be reviewed and assessed by CMS to make ongoing coverage determinations on PET scans.

Details relating to Medicare's expanded coverage can be found in section 220.6.15 of Medicare's National Coverage Determinations Manual at http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part4.pdf.

2. Who is managing the NOPR?

The NOPR is sponsored by the Academy of Molecular Imaging (AMI) and the American College of Radiology (ACR). The registry's database will be managed by the American College of Radiology Imaging Network (ACRIN).

CMS does not have a role in directly managing the NOPR but has certified that NOPR meets its criteria for coverage under the January 2005 NCD.

3. Which cancers and indications will now be covered when data is submitted to the NOPR?

For a complete listing of the cancers and indications that are eligible for Medicare reimbursement under the NOPR visit http://www.cancerpetregistry.org/indications_facilities.htm.

4. When did the NOPR open?

The NOPR began accepting patient data on May 8, 2006. PET facilities have been able to register since November 2005.

5. As an oncologist, how does the oncologic PET Registry apply to me?

Medicare has expanded the coverage of FDG-PET when used for certain cancer indications. Therefore, a FDG-PET scan that you order for your patient may now be a covered benefit for your patient under Medicare.

6. Is participation in the oncologic PET Registry mandatory?

No, participation in the PET Registry is voluntary.

7. What is the referring oncologist required to do?

If you are referring a patient with one of the identified cancer indications for a FDG-PET scan, you will be asked to complete 2 forms – a pre-PET and a post-PET data collection form. The forms include questions relating to the management of your patient’s treatment.

The physician referring the patient for a FDG-PET should complete a pre-PET form and send it to the registered PET facility (one that has registered with NOPR) with the FDG-PET referral. If the pre-PET form is not submitted with the referral, the facility should contact the referring physician to complete the pre-PET form. The completed pre-PET form can be returned by e-mail, fax, mail, or hand delivered.

Once the PET is performed, the facility sends a report to the referring physician. Seven days after the report is sent, the NOPR will send the referring physician a patient specific post-PET form to be completed. The completed post-PET form needs to be returned to the PET facility.

8. What do the forms look like?

There is one standard pre-PET form for use with all patients enrolled in the registry. Physicians participating in the initiative will also have to complete one post-PET form specific to the patient’s status (suspected cancer, unknown primary tumor/paraneoplastic syndrome, initial staging, restaging cancer, suspected cancer recurrence, or treatment monitoring).

The pre- and post-PET forms can be found and downloaded from the NOPR website at www.cancerPETregistry.org.

9. What are the time frames for submitting this paperwork?

The pre-PET form must be returned to the PET facility no later than the scheduled date of the PET scan. The post-PET form must be returned to the facility no later than 30 days after the PET scan took place.

10. Will I receive payment for completing the PET registry forms?

There will be no Medicare payment to the referring physician for completing the pre- and post-PET forms. Medicare reimbursement will be provided to the PET facility that conducts the PET scan and to the physician who interprets the scan.

11. When can claims be submitted to Medicare?

The PET facility or a physician providing an interpretation can bill Medicare only after the NOPR has received and entered data from the pre- and post-PET forms. The NOPR will notify the PET facility when this has occurred.

12. How do we enroll in the oncologic PET registry?

The PET facility is the only entity that needs to register for the NOPR. Any PET facility that can bill Medicare for either technical or global charges can participate in the NOPR.

13. Is there a list of registered PET facilities?

Yes. The CMS website has a listing of PET facilities that have registered with NOPR and is updating that list regularly. The list can be viewed at <http://www.cms.hhs.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage>.

14. Does participation in the NOPR comply with HIPAA requirements for privacy of health information?

Yes, but the PET facility must enter into a Business Associate Agreement with ACR. The NOPR provides the following information to its site regarding HIPAA

“The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires that providers (Covered Entities as that term is defined under HIPAA) have in place an agreement with any Business Associate if the parties in their business dealings exchange Protected Health Information (PHI), as that term is defined in the HIPAA regulations. Under the regulations, submission of claims data by a PET facility (Covered Entity) to the ACR (Business Associate) requires execution of a business associate agreement.

This business associate agreement (BAA) serves the purpose of obtaining satisfactory assurance that the Business Associate will appropriately safeguard any PHI received from the Covered Entity. With this agreement in place, the exchange of information between the Covered Entity and the Business Associate will meet HIPAA requirements without disruption of the business arrangement.”

The American College of Radiology has developed a Business Associate Agreement (BAA) that can be used by PET facilities to comply with HIPAA privacy requirements.

15. Does the referring physician need to obtain patient consent?

The NOPR website provides the following information consent and IRB approval:

“Individual PET facilities and referring physicians and their staff are not engaged in research and therefore are not required to have IRB approval for their participation in the activities of the NOPR. Submission of the information for the registry (pre-PET and post-PET case report forms and the PET scan report) is required by CMS for payment for PET studies for all Medicare-insured patients with cancer indications included in the registry. Additionally, CMS is not conducting research. The subjects of the NOPR research, patients and referring physicians, can consent (or not) to allow their data to be used for purposes of the research being conducted at NOPR. The dataset used by NOPR investigators for research will contain only the data of patients and physicians when **both** have consented to have the data included.”

The NOPR has received a waiver to the requirement that the consent be in writing. The patient and the referring physician, however, will be provided with the ACR IRB information sheets that explain what the data will be used for. More information on IRB approval and the waiver of written consent can be found on the NOPR website. To view this information, go to http://www.cancerpetregistry.org/pdf/nopr_regulatory.pdf.

16. Can you explain why CMS is collecting data on PET scans?

Medicare has begun a new initiative to permit, in certain circumstances, coverage and payment for drugs and services when provided with data regarding their use. This initiative is known as coverage with evidence development, or CED. CMS intends to use the data collected by the registry to make coverage determinations on the use of PET scans.

17. Where can I locate additional information about the NOPR?

More detailed information for physicians, PET facilities, and patients can be found on the NOPR web site at www.cancerpetregistry.org.