



If you have questions regarding the National Oncologic PET registry, please call (609) 652-3375

Frequently Asked Questions

What is the NOPR?

The National Oncologic PET Registry (NOPR) was developed in response to the Centers for Medicare and Medicaid Services (CMS) proposal to expand coverage for positron emission tomography with F-18 fluorodeoxyglucose (PET) to include cancers and indications not presently eligible for Medicare reimbursement. Medicare reimbursement for these cancers can now be obtained if the patient's referring physician and the provider submit data to a clinical registry to assess the impact of FDG-PET on cancer patient management. The NOPR is implementing this registry for CMS. The NOPR is sponsored by the Academy of Molecular Imaging (AMI) and managed by the American College of Radiology (ACR) through the American College of Radiology Imaging Network (ACRIN).

Has the NOPR Been Approved by the Medical Community?

The NOPR received input from, and is endorsed by, the American College of Radiology (ACR), the American Society of Clinical Oncology (ASCO), and the Society for Nuclear Medicine (SNM). The NOPR worked with the Centers for Medicare and Medicaid Services (CMS) to develop this registry.

When Did the NOPR Open?

The NOPR began accepting facility registrations in late November 2005 but patient registration did not begin until May 8, 2006.

Does my Site Need IRB Approval to Participate in the NOPR?

The only entity engaged in research is the registry itself (i.e., NOPR); the NOPR intends to use the data it is collecting for research purposes when both the patient and the referring physician have consented to the use of the information for this purpose. The ACR IRB has granted approval for the NOPR to engage in research using these data (see Appendix IV of the Operations Manual for more details).

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.

Any participating PET facility may nevertheless elect to have its local IRB review its participation in the NOPR. Some IRBs require, as a matter of institutional policy, that they review all research conducted in the institution, even if only to determine that the facility is not engaged in the research. Materials are provided in Appendix I to assist in this process. The Office of Human Research Protections (OHRP) has reviewed the NOPR procedures for protection of human research subjects and finds them to be in compliance with the applicable DHHS

regulations. Any individual IRBs with questions can contact OHRP.

What Patients are Eligible for the NOPR?

Medicare beneficiaries, including those with conventional Medicare coverage and those enrolled in with a Medicare Advantage plan, who are referred for PET for essentially all oncologic indications that are not currently reimbursable under Medicare are eligible to participate in the NOPR. The Indications tables list the cancers and indications that will and will not be accepted in the Registry.

Patients with insurance coverage other than Medicare, including Medicaid, are not eligible to participate in the NOPR. Patients enrolled in a managed Medicare health plan are eligible for the NOPR. Medicare or a managed Medicare plan must be the primary insurance.

Does NOPR Apply to Oncologic PET performed with Radiopharmaceuticals other than FDG?

No.

What are the PET Facility's Responsibilities?

The PET facility is responsible for collecting and entering patient data into the Registry database through a web application at www.cancerPETregistry.org. Below is a brief summary of the data collection procedure.

- When a patient eligible for entry into the NOPR presents at the PET facility, the facility contacts the referring physician and obtains confirmation that the physician will submit the pre- and post-PET data requirements.
- The facility registers the patient on the NOPR via a Web form, at which time a Registry case number is assigned.
- The NOPR will send confirmation to the PET facility and e-mail a request for the pre-PET data to the referring physician.
- The referring physician must complete and return the Pre-PET Form to the PET facility and **the PET facility must enter the Pre-PET Form into the NOPR database by midnight of the day of the PET scan.**
- At some time before the PET study, or when the patient arrives for the PET scan, the PET facility will provide the patient with the ACR IRB-approved standard NOPR Patient Information Sheet that is posted on the NOPR Web site. The patient will be able to contact the NOPR directly for more information, if necessary. The patient will indicate his or her consent verbally to staff at the PET facility, either on the day of the PET study or within two working days after the PET study is completed. Written consent is not required. The PET facility will note in the database, on the PET Report Form, if the patient gave or withheld consent for use of his or her data in future NOPR research.
- After the PET scan is performed, the PET facility sends the PET report to the physician, enters the study completion date into a Web form, and submits the report text electronically to the NOPR database. **Note that the PET scan must be completed and the PET Scan Completion Form must be entered into the database with in 14 days of case registration or the case will be marked as ineligible.**
- Within 7 days after the PET scan, the database will send the physician a patient-specific Post-PET Form. This form will also include an ACR IRB approved Referring Physician Information Sheet. The physician will indicate on the Post-PET Form whether consent for use of the response data in future NOPR research has been given or withheld. All data will be sent to CMS, but 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. This form must be completed, returned to the PET facility, and entered into the NOPR database within 30 days of the PET scan.

What are the Referring Physician's Responsibilities?

The patient's referring physician must agree to complete pre- and post-PET data collection forms consisting of

approximately 5 questions regarding the patient's planned management.

- The Pre-PET Form must be completed by the referring physician and returned to the PET facility prior to the patient's PET scan. A blank Pre-PET Form can be downloaded from the NOPR Web site and sent to the PET facility at the time of patient referral. If the form is not submitted with the referral a patient-specific form will be e-mailed to the referring physician. The Pre-PET Form can be returned to the PET facility via FAX, mail, or hand delivery.
- After the PET study is performed, a patient-specific Post-PET Form will be e-mailed to the referring physician for completion within 30 days. This form will also include an ACR IRB approved Referring Physician Information Sheet. The physician will indicate on the Post-PET Form whether consent for use of the response data in future NOPR research has been given or withheld. All data will be sent to CMS, but 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. This form can also be returned to the PET facility via FAX, mail, or hand delivery.

The patient's PET study is eligible for CMS reimbursement only if the Pre-PET Form is completed and returned to the PET facility prior to the PET scan and the Post-PET Form is completed and returned within 30 days of the PET scan.

Can a Nurse or Nurse Practitioner Complete the Pre- and Post-PET Forms?

We anticipate that ancillary personnel often will complete much of both the pre-PET and post-PET forms, but will ask the referring physician to provide the answer to the intended management question and to review the other responses for accuracy.

Medicare Medlearn Matters

The Medicare Claims Processing Manual for PET (Transmittal 527):

The National Coverage Determinations Manual Transmittal 31:

Medicare Medlearn Matters

We caution PET facilities, especially those with automated billing systems, to set up in advance, internal mechanisms to hold these claims until all of the required case data for the NOPR have been entered and this has been acknowledged by the NOPR database. Each PET facility can check on the status of its patients at any time via the reporting tools available on the NOPR Web site.

Does the NOPR Apply to Hospitalized Medicare Inpatients?

Yes. Note that the technical charge for a PET study on a Medicare inpatient is not billed directly, but rather is considered to be covered by the Diagnostic Related Grouping (DRG) payment to the hospital for that patient. Inclusion of the patient in the NOPR is necessary, however, for professional component reimbursement for the PET study.

Will a Medicare Patient's Medigap Insurance Cover the Cost of the Co-payment for a Registry PET Scan?

Yes, Medigap insurance should cover the co-payment, as for any other Medicare covered service.

Will Medicare Advantage Plans Reimburse for Patients Entered in the Registry?

Managed Medicare Advantage plans should pay any claims that would be covered by Medicare. If the managed Medicare plan does not have a NOPR-participating facility in its network, patients can be referred to an out-of-network facility without incurring an out-of-network co-payment. Pre-authorization/certification may be

required depending upon the plan's guidelines.

Is Pre-Authorization Still Needed for Patients in Managed Medicare Plans?

Yes, providers will still need to follow HMO guidelines for pre-authorization.

Will Non-Medicare Insurers Reimburse for Patients Entered in the Registry?

No, there are no non-Medicare insurers who have elected to reimburse for patients entered in the registry. Patients with Medicaid and other types of insurance coverage other than Medicare are not eligible to participate in the NOPR.

Who Has Access to NOPR Data?

The members of the NOPR working group, NOPR project staff at the American College of Radiology (ACR) and the Center for Statistical Sciences at Brown University, and staff of the Centers for Medicare and Medicaid Services (CMS).

Who Owns the NOPR Data?

The Academy of Molecular Imaging, as an Agent of the Centers for Medicare and Medicaid Services (CMS), will maintain ownership of the data collected by American College of Radiology (ACR) for the NOPR. The data will reside in an electronic database at the ACR.

Why Can't We Attach Our PET Scan Report as a Word Document?

In an effort to minimize the spread of computer viruses, the PET Report Submission Form will accept only PDF and JPEG files as uploaded attachments. Text from Microsoft Word documents, or any other type of text file, can be cut and pasted into the text field on the form.