

The National Oncologic PET Registry (NOPR)

Patient Information Sheet

You are being invited to take part in a research study conducted by the National Oncologic PET Registry (NOPR). Before you decide whether or not to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to your family or friends about the study to help you decide whether or not you wish to take part. If you have any questions or if you would like more information after reading the information sheet, please go to the NOPR website, www.cancerpetregistry.org, or contact the NOPR staff by telephone toll free at 800-227-5463, ext. 4859. Your doctor who ordered the PET scan and the staff at the PET facility where your scan will be performed will not be able to answer your questions concerning this research study. The NOPR staff will be able to assist you and answer any questions you may have.

You are being asked to participate in this research study because you are a Medicare patient and your doctor has ordered a PET or a PET/CT scan for you that is currently not covered (paid for) by Medicare. The PET scan has been ordered to evaluate your cancer. Having the PET scan is not the research in this study. PET scans are part of routine clinical care. For the research, the NOPR will study how the information obtained from the PET scan is used by your doctor.

WHY IS THIS STUDY BEING DONE?

The Centers for Medicare and Medicaid Services (CMS), a Federal agency that manages the Medicare program, currently pays for PET scans that are ordered to evaluate cancer only for certain specific cancer types and reasons. CMS has a new policy called “coverage with evidence development” (CED) to pay for PET scans ordered for most other types of cancer and reasons. This means Medicare will pay for these additional PET or PET/CT scans in the same way that it pays for approved cancers and reasons.

CMS wants to determine if they should pay for PET scans for evaluating more types of cancer. In order to collect the information needed to make this decision, CMS will provide payment for the PET scans of patients who are properly registered with the National Oncologic PET Registry (NOPR). In addition, if you and your doctor agree to participate in the research, your information will be entered into the registry and will then be analyzed to determine how PET scans effect the way doctors plan treatment for their patients.

In order for Medicare to pay for your PET scan, Medicare is requiring that your doctor provide certain information about the reason for your scan and how the scan results may influence your treatment. This information will be sent by the PET facility to Medicare as a requirement for payment for your PET scan. In addition, the NOPR is requesting your consent to use this information for research. Specifically, the NOPR plans to study how PET scans affect the treatment plans of the doctors who order PET scans. Eventually, the results of this research may help to obtain coverage by Medicare and other insurers for a wider range of cancers.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

CMS will collect information about you from your doctor as a requirement of paying for your PET scan. Your personal information such as your name, date of birth, social security number, and your doctor’s information will be entered into NOPR database through a secure web site. All this information will be stored at the American College of Radiology Imaging Network (ACRIN). ACRIN is a national leader in clinical research involving cancer patients. This database is secure and meets the requirements for the protection of patient confidentiality as required by the U.S. Privacy Rule (HIPAA).

As part of Medicare requirement for payment, your doctor will be asked to complete a brief questionnaire regarding his/her request for PET or PET/CT scan and what the doctor would do if PET or PET/CT were not available. After the

PET scan is performed, your doctor will be asked to complete a second questionnaire about how the results of the scan affected your care. These forms must be completed and submitted to the NOPR within a specified period in order for the scan to be eligible for payment. NOPR will send your information to CMS so that your PET scan will be paid for by Medicare, like any other covered benefit.

If you agree to participate in the research part of the NOPR, you are giving permission to use your health information for research. However, your information will only be used by the NOPR for research if you and your doctor give permission to use it for research purposes.

WHAT OTHER OPTIONS ARE THERE?

You may choose not participate in this study. You can choose to have a PET or PET/CT scan without participating in the registry study. If you choose not to participate in the NOPR research study, the PET scan payment will not be affected.

ARE THERE POTENTIAL BENEFITS TO TAKING PART IN THE STUDY?

There is no immediate direct benefit to you for your participation in this research study. Whether or not you (or your doctor) agree to have your information used for the NOPR research study, Medicare will pay for the PET scan so long as your doctor provides the information Medicare requires for payment. If the research study leads to routine coverage by Medicare of your type of cancer (or the reason for your PET scan), you may benefit in the future if you need another PET scan. Other patients with cancer in the future may also be helped if the research leads to routine coverage of PET by Medicare or other health insurance providers.

WHAT ARE THE RISKS OF THE STUDY?

There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

WHAT ARE THE COSTS?

There are no additional costs to you associated with participating in the NOPR research study. Medicare will pay for the PET or PET/CT scan if your information is submitted within a specified timeframe by your doctor. You or your Medicare supplemental (Medigap) insurance will be responsible for any co-payment costs or deductible payments, just as occurs with any other medical service covered by Medicare.

WHAT ABOUT CONFIDENTIALITY?

Your information will be kept permanently in a secure electronic database at the ACRIN and may be used for future research. CMS, the NOPR working group and project staff, and the Center for Statistical Sciences at Brown University will have access to your information. They are responsible for making a recommendation to CMS on what types of PET scans should be paid for by Medicare. Your records may be reviewed in order to meet federal regulations. Your name will never be made public.

WHAT ARE MY RIGHTS?

Your participation in the NOPR research study is voluntary. You may choose not to be in the study. If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for research purposes.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits. You will continue to receive your usual medical care whether or not you decide to participate in this study. If you decide to withdraw from the study, you will need to let your doctor know in writing.

After you had a chance to read this information sheet and made a decision whether you want to participate, please let the staff at the PET facility know what you have decided. You are not required to sign a consent form to participate in this research, but you must let the PET facility staff know whether or not you wish to participate either before you leave the PET facility or at a later date but no more than two (2) working days after you have your PET scan. If you have any questions regarding the NOPR research study or the information sheet, please go to the NOPR website,

<http://www.cancerpetregistry.org/> and click on “Info for Patients”, or contact NOPR at (800) 227-5463, ext. 4859 or pet_registry@phila.acr.org. If you have any questions or concerns about your rights as a research subject or about harms related to this research, you can contact Maria Oh, the American College of Radiology (ACR) IRB coordinator, at (800) 227-5463, ext. 4160. You will be given a copy of this information sheet to take home with you.

Approved by the American College of Radiology Institutional Review Board on April 3, 2009.

A Spanish language translation of the NOPR Patient Information Sheet is available on the NOPR Web site at:
http://www.cancerpetregistry.org/pdf/patient_info_spanish.pdf