

## Pre-PET Form

### National Oncologic PET Registry

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- You have requested a PET scan for an indication for which the Centers for Medicare and Medicaid Services (CMS) requires pre- and post-PET information from the referring physician as a condition for reimbursement. In order for the imaging center to be reimbursed this form must be completed and returned to the PET facility before the PET scan is performed.
  - **You will be required to complete a follow-up form in a timely fashion after the PET scan is done.** Thank you for your assistance completing the brief pre- and post-PET forms.
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PET Facility ID #: \_\_\_\_\_ Registry Case #: \_\_\_\_\_

#### PATIENT INFORMATION

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_

Date of Birth \_\_\_\_/\_\_\_\_/\_\_\_\_

SSN#: \_\_\_\_\_

#### REFERRING PHYSICIAN

UPIN#: \_\_\_\_\_ or NPI#: \_\_\_\_\_

First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_ UPIN#: \_\_\_\_\_

Office Telephone: (\_\_\_\_) \_\_\_\_\_ Office Fax: (\_\_\_\_) \_\_\_\_\_

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Comment to Clinician: The required follow-up questionnaire will be sent to you by the PET facility. **By requesting that this patient be entered on the NOPR you agree to also complete the post-PET follow-up form and return it to the PET scan facility within 30 days of the PET scan.**

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The following definitions/instructions are provided to assist you in the completion of Question 1 (“SPECIFIC REASON FOR PET STUDY”) on the next page of this form. This information is derived from the [Medicare National Coverage Determination for PET](#).

< <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=218> >

#### Covered Indications for PET Scans and Limitations/Requirements for Usage

##### Initial Treatment Strategy

PET performed as part of an evaluation for determination of an *initial treatment strategy* (formerly diagnosis and initial staging) is covered by CMS as an approved indication for PET with specific exceptions (see below):

PET is explicitly not covered by CMS for initial treatment strategy evaluation for three specific cancer types/indications: 1) diagnosis and axillary nodal staging of breast cancer; 2) assessment of regional lymph nodes in melanoma; and 3) diagnosis of prostate cancer and initial staging of newly diagnosed prostate cancer.

**However, PET for initial treatment strategy evaluation is covered only with participation in the NOPR for certain patients with suspected or proven cervical cancer and for patients with suspected or proven leukemia.**

**Note:** PET is covered only in clinical situations in which (1) the PET results may assist in avoiding an invasive diagnostic procedure, or in which (2) the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to doing a PET scan and therefore the scan is performed for staging rather than diagnosis.

PET is not covered as a screening test (i.e., testing patients without specific signs and symptoms of disease).

### **Subsequent Treatment Strategy**

PET is also a CMS-covered service when used in subsequent treatment strategy evaluation (formerly restaging, detection of suspected recurrence, and treatment monitoring) patients with the following cancers: breast, cervix, colorectal, esophageal, head and neck, lymphoma, melanoma, myeloma, non-small cell lung, ovary, and thyroid. For all other cancers, PET coverage for subsequent treatment strategy evaluation requires participation in this registry.

PET is covered for restaging and detection of suspected recurrences:

- (1) *after* completion of treatment for the purpose of detecting residual disease; or
- (2) for detecting suspected recurrence or metastasis; or
- (3) to determine the extent of a known recurrence;
- (4) if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.
- (5) *Restaging* applies to testing *after* a course of treatment is completed, and is covered subject to the conditions above.

*Comment: As noted above, PET is not covered as a screening test (i.e., testing patients without specific signs and symptoms of disease) and thus is not covered for surveillance of patients treated for cancer in whom there is no clinical reason to suspect recurrent disease.*

Treatment monitoring refers to use of PET to monitor tumor response to treatment during the planned course of therapy (i.e., when a change in therapy is anticipated).

*Comment: As an example, PET performed under NOPR may be covered for monitoring after 2 or 3 of a planned 6 cycles of chemotherapy in a patient considered not to be responding as expected.*

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## **1. SPECIFIC REASON FOR PET STUDY**

Check the single best match for the reason for the PET (*you must check only one of the following*)

- Restaging** after completion of therapy
- Suspected Recurrence** of a previously treated cancer
- Monitoring Treatment Response** during chemotherapy (including biologic modifiers)
- Monitoring Treatment Response** during radiation therapy
- Monitoring Treatment Response** during combined modality therapy (e.g., chemotherapy ± radiation ± surgery)
- Diagnosis (Cervical Cancer and Leukemia Only):** To determine if a suspicious lesion is cancer (answer 2a and 2b)
- Diagnosis/Paraneoplastic (Cervical Cancer and Leukemia Only):** To detect a primary tumor site in a patient with a presumed paraneoplastic syndrome (answer 2a and 2b)
- Initial Staging (Cervical Cancer and Leukemia Only)** of histologically confirmed, newly diagnosed cancer (answer 2a and 2b)

## 2. CANCER TYPE

- Please mark the corresponding box of the cancer type in section 2a and answer question 2b. If your patient's cancer is not listed, check the Other box and enter as text the cancer type. For a patient with metastatic cancer of unknown primary origin, please also mark the corresponding box of the site of metastatic disease in section 2c.

### a. Cancer Type (ICD-9 Code) - check the one cancer that most closely relates to the specific reason for the PET study indicated in response to Question 1. (Check only one)

Note: The three-digit ICD-9 codes included on this form are for purposes of identifying the cancer type in the NOPR database, but the one selected is not necessarily the one that should be used for claim submission.

- |  |   |
|--|---|
| <input type="checkbox"/> Stomach (151)                               | <input type="checkbox"/> Cervix, initial treatment strategy, prior CT or MRI not performed before PET (180)                                       |
| <input type="checkbox"/> Small Intestine (152)                       | <input type="checkbox"/> Cervix, initial treatment strategy, prior CT or MRI performed before PET, but shows extrapelvic metastatic disease (180) |
| <input type="checkbox"/> Anus (154)                                  | <input type="checkbox"/> Uterus, body (182)   |
| <input type="checkbox"/> Liver and intrahepatic bile ducts (155)     | <input type="checkbox"/> Prostate (185)   |
| <input type="checkbox"/> Gallbladder & extrahepatic bile ducts (156) | <input type="checkbox"/> Testis (186)   |
| <input type="checkbox"/> Pancreas (157)                              | <input type="checkbox"/> Penis and other male genitalia (187)   |
| <input type="checkbox"/> Retroperitoneum and peritoneum (158)        | <input type="checkbox"/> Bladder (188)  |
| <input type="checkbox"/> Lung, small cell (162)                      | <input type="checkbox"/> Kidney and other urinary tract (189)   |
| <input type="checkbox"/> Pleura (163)                                | <input type="checkbox"/> Eye (190)  |
| <input type="checkbox"/> Thymus, heart, mediastinum (164)            | <input type="checkbox"/> Primary Brain (191)  |
| <input type="checkbox"/> Bone/cartilage (170)                        | <input type="checkbox"/> Leukemia (204-208)   |
| <input type="checkbox"/> Connective/other soft tissue (171)          | <input type="checkbox"/> Neuroendocrine tumor (209)   |
| <input type="checkbox"/> Gastrointestinal stromal tumor (171)        | <input type="checkbox"/> Metastatic cancer of unknown primary origin (answer question 2c below)   |
| <input type="checkbox"/> Non-melanoma skin (173)                     |   |
| <input type="checkbox"/> Kaposi's sarcoma (176)                      |   |
| <input type="checkbox"/> Uterus, unspecified (179)                   |   |

Other, or not listed. Please describe cancer type: \_\_\_\_\_

and give the first 3 digits of the ICD-9 code. .XX

[Acceptable responses are 159, 165, 181, 183, 184, 192 - 195, and 235-238. Note: Ovarian cancer is a covered indication; use 183 only for other adnexal cancers.]

b. Has this cancer diagnosis been pathologically proven?  Yes  No

c. Unknown primary: dominant site of pathologically proven or strongly suspected metastatic disease (196-199)

- |   |   |
|---|---|
| <input type="checkbox"/> Lymph node(s)  | <input type="checkbox"/> Brain            |
| <input type="checkbox"/> Lung   | <input type="checkbox"/> Bone/bone marrow |
| <input type="checkbox"/> Liver  |   |
| <input type="checkbox"/> Other, or not listed. Please describe metastatic site: _____ |   |

and give the first 3 digits of the ICD-9 code. .XX [Acceptable responses are 196-199.]

### 3. YOUR WORKING SUMMARY STAGE FOR THE PATIENT BEFORE THE PET SCAN IS:

(you must check only one)

- No evidence of disease / In remission
- Localized only
- Regional by direct extension or lymph node involvement or both
- Metastatic (distant) with a single suspected site
- Metastatic (distant) with multiple suspected sites
- Unknown or uncertain

### 4. PATIENT PERFORMANCE STATUS

Check the box best describing your patient's global functional status (ECOG Performance Score) (you must check only one)

- (0) Asymptomatic: *fully active, able to carry on all activities without restriction.*
- (1) Symptomatic, fully ambulatory: *restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature.*
- (2) Symptomatic in bed <50% of the day: *ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.*
- (3) Symptomatic in bed >50% of the day, but not bedridden: *capable of only limited self-care, confined to bed or chair 50% or more of waking hours.*
- (4) Bedridden: *Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.*

### 5. ADDITIONAL RESPONSES REQUIRED ONLY IF THE SPECIFIC REASON FOR THE PET STUDY IS MONITORING TREATMENT RESPONSE

- a. Is the currently ongoing treatment intended to be:
  - Curative
  - Palliative
- b. What is your current impression (before PET) of your patient's response to currently ongoing therapy? (check one)
  - Clearly responding, but uncertain about degree of response
  - Possible partial response, but uncertain about degree of response
  - Suspect no response
  - Suspect progressive disease
- c. If you were to continue your management of your patient without doing any other testing first (e.g., PET, CT, MRI, biopsy), what would be your treatment plan today? (check one)
  - Continue and complete currently ongoing therapy
  - Modify dose or schedule of currently ongoing therapy
  - Switch to another therapy or add another mode of therapy
  - Stop therapy and switch to supportive care

## 6. MANAGEMENT PLAN

If PET were not available, your current **management strategy** would be? (*you must check only one*)

- Observation** (with close follow-up)
- Additional Imaging** (CT, MRI) or other non-invasive diagnostic tests
- Tissue Biopsy** (surgical, percutaneous, or endoscopic).

**Note:** If concurrent biopsy and total surgical resection are planned, then mark “surgical” treatment below.

- Treatment (see additional required responses below)**

**Treatment Goal:** (*check one*)

- Curative
- Palliative

**Type(s):** (*check all that apply*)

- Surgical
- Chemotherapy (including biologic modifiers)
- Radiation
- Other
- Supportive care

**Will treatment be directly provided by you?** (*check one*)

- Yes
- No

## 6. NAME OF PERSON WHO COMPLETED THE PAPER FORM

First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_ Date \_\_\_\_\_

## PHYSICIAN ATTESTATION OF DATA ACCURACY

By signing below I verify that, to the best of my knowledge, the information on this form is accurate.

Physician Signature: \_\_\_\_\_ Date \_\_\_\_\_

Printed Name of Physician: \_\_\_\_\_

Thank you for your assistance.

### PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0968. The time required to complete this information collection is estimated to average five (5) minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

## 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](http://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](mailto: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](http://www.cancerpetregistry.org/pdf/patient_info_spanish.pdf)