Pre-PET Form

National Oncologic PET Registry

- 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 <u>required to complete</u> 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.

PET Facility ID #:	Registry Case #:
PATIENT INFORMATION	
Date:/	
First Name:	Last Name:
Date of Birth/	
SSN#:	
REFERRING PHYSICIAN	
UPIN#: or NPI	[#:
First Name: La	sst Name: UPIN#:
Office Telephone: ()	Office Fax: ()

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.

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 <u>restaging</u> and <u>detection of suspected recurrences</u>:

- (1) <u>after</u> 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) <u>Restaging</u> 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 <u>during</u> the planned course of therapy (<u>i.e.</u>, <u>when a change in therapy is anticipated</u>).

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

1. SPECIFIC REASON FOR PET STUDY

Check the single <u>best</u> 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
\Box Monitoring Treatment Response during combined modality therapy (e.g., chemotherapy \pm 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 s patient's cancer is not listed, check the Other box and ente metastatic cancer of unknown primary origin, please also r metastatic disease in section 2c. 	r as text the cancer type. For a patient with			
A. Cancer Type (ICD-9 Code) - check the one cancer that most PET study indicated in response to Question 1. (Check only Note: The three-digit ICD-9 codes included on this form are for pur database, but the one selected is not necessarily the one that should	one) poses of identifying the cancer type in the NOPR			
☐ Stomach (151) ☐ Small Intestine (152) ☐ Anus (154) ☐ Liver and intrahepatic bile ducts (155) ☐ Gallbladder & extrahepatic bile ducts (156) ☐ Pancreas (157) ☐ Retroperitoneum and peritoneum (158) ☐ Lung, small cell (162) ☐ Pleura (163) ☐ Thymus, heart, mediastinum (164) ☐ Bone/cartilage (170) ☐ Connective/other soft tissue (171) ☐ Gastrointestinal stromal tumor (171) ☐ Non-melanoma skin (173) ☐ Kaposi's sarcoma (176) ☐ Uterus, unspecified (179)	 □ Cervix, initial treatment strategy, prior CT or MRI not performed before PET (180) □ Cervix, initial treatment strategy, prior CT or MRI performed before PET, but shows extrapelvic metastatic disease (180) □ Uterus, body (182) □ Prostate (185) □ Testis (186) □ Penis and other male genitalia (187) □ Bladder (188) □ Kidney and other urinary tract (189) □ Eye (190) □ Primary Brain (191) □ Leukemia (204-208) □ Neuroendocrine tumor (209) □ Metastatic cancer of unknown primary origin (answer question 2c below) 			
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 prov	ren or strongly suspected metastatic disease			
(196-199)				
☐ Lymph node(s)	☐ Brain			
Lung	☐ Bone/bone marrow			
☐ Liver				
Other, or not listed. Please describe metastatic site:				
and give the first 3 digits of the ICD-9 code. AXX [Acceptable responses are 196-199.]				

		UR WORKING SUMMARY STAGE FOR THE PATIENT BEFORE THE PET SCAN IS: ou 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. P	AT	TIENT PERFORMANCE STATUS
		eck the box best describing your patient's global functional status (ECOG Performance Score) (you must eck only one)
		☐ (0) Asymptomatic: fully active, able to carry on all activities without restriction.
	C	☐ (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: <i>capable of only limited self-care</i> , <i>confined to bed or chair 50% or more of waking hours</i> .
		(4) Bedridden: Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.
5. A	\D	DITIONAL RESPONSES REQUIRED ONLY IF THE SPECIFIC REASON FOR THE PET
S	TU	UDY 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? <i>(check one)</i>
		 □ 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: _____

PRA Disclosure Statement

Thank you for your assistance.

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.