[0938-0968 Form #3]

Pre-PET Form
National Oncologic PET Registry

Comment to Clinician:

- You have requested an F-18 Fluoride PET scan, a test 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. 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***.

PATIENT INFORMATION

Date: _____/_____/_____ Social Security #: ___ ___ ___ — ___ ___ — ___ ___ ___ ___

Last name: _____ First name: _____

Date of Birth: _____/_____/_____ Patient's Zip Code: ___ ___ ___ ___ ___

REFERRING PHYSICIAN INFORMATION

UPIN #: _____ **or** NPI #:_____

Last name: _____ First name: _____

Office Telephone: (____) _____ Office Fax: (____) _____

1. SPECIFIC REASON FOR F-18 FLUORIDE PET STUDY

See page 6 of this form for definitions / instructions to assist you in completing Question 1.

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

☐ **Diagnosis** of suspected osseous metastatic disease ***in a patient without a pathologically proven diagnosis of cancer***
[If this option is selected, answer only questions 1.b, 2, 3, and 6. Also, note that guidance to help you answer parts a, b, and c of question 2 is provided on page 7 of this form.]

☐ **Initial staging** of newly diagnosed cancer

☐ **Suspected *new* osseous metastasis** as a site of recurrence or progression

☐ **Suspected progression of known osseous metastas**is

☐ **Monitoring Treatment Response** during chemotherapy (including biologic modifiers and hormonal therapy)

- ☐ **Monitoring Treatment Response** during radiation therapy
- ☐ **Monitoring Treatment Response** during combined modality therapy (e.g., chemotherapy ± radiation ± surgery)

b. Symptoms, signs, or other findings prompting F-18 fluoride PET bone imaging

- ☐ **NONE**
  *[If selected, go directly to Question 2; otherwise **select all of the following that apply**]*
- ☐ **Skeletal pain**
- ☐ **New focal neurologic signs or symptoms**
- ☐ **Findings on other imaging studies suggesting osseous metastatic disease**
- ☐ **Hypercalcemia**
- ☐ **Elevated or increasing tumor marker(s) (including alkaline phophatase)**
- ☐ **Evidence of new metastases in non-osseous sites**
  [Do not select this option if reason for study is "Diagnosis of suspected osseous metastatic disease in a patient without a pathologically proven diagnosis of cancer".]
- ☐ **Evidence of progression of known metastatic disease in non-osseous sites**
  [Do not select this option if reason for study is "Diagnosis of suspected osseous metastatic disease in a patient without a pathologically proven diagnosis of cancer".]

See page 7 of this form for guidance in the completion of Question 2 when the PET bone scan is requested for "Diagnosis of suspected osseous metastatic disease in a patient without a pathologically proven diagnosis of cancer"..

2. CANCER TYPE

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

a. Cancer Type - *check the one pathologically proven or strongly suspected cancer type that most closely relates to the specific reason for the PET study indicated in response to Question 1. (Check only one)*

- ☐ Lung
- ☐ Female breast
- ☐ Prostate
- ☐ Metastatic cancer of unknown primary origin (also answer question 2c below)
- ☐ Other

If other,
please describe cancer type**:** _____

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

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

c. Unknown primary: ***dominant site** of **pathologically proven** or **strongly suspected metastatic disease***

- ☐ Lymph node(s)
- ☐ Liver
- ☐ Bone/bone marrow
- ☐ Lung
- ☐ Brain
- ☐ Other

If other,
please describe cancer type**:** _____

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

a. Which of the following types of treatment is this patient now receiving?

(check all that apply)

- ☐ Radiation therapy
- ☐ Chemotherapy (including biologic modifiers and hormonal therapy)
- ☐ Immunotherapy (e.g., sipuleucel T (Provenge®) for prostate cancer)

b. What is your impression (before PET) of your patient's response to currently ongoing therapy?

(check one)

- ☐ Probable complete response
- ☐ Possible partial response, but uncertain about degree of response
- ☐ Suspect no response (stable disease)
- ☐ Suspect progressive disease

c. If you were to continue your patient's management 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

5. MANAGEMENT PLAN

If the F-18 fluoride PET bone scan were not available, which ONE of the following would be the next step in your current management strategy?

[Note: For purposes of this question, you should assume that neither an F-18 fluoride PET bone scan nor a conventional bone would be available as the next step.]

(check only one)

☐ **Observation** (with close follow-up)

☐ **Additional Imaging** (CT, MRI, FDG-PET)
[Note: Do not check this option if you would order a conventional bone scan if the F-18 fluoride PET bone scan were not available.]

☐ **Tissue Biopsy** (surgical, percutaneous, or endoscopic).
Note: If concurrent biopsy and a surgical procedure are planned, then mark "treatment" below.

☐ **Supportive care only** (e.g., pain management, hospice care)

☐ **Treatment for the cancer**

If treatment is selected, please also answer the following (1, 2 and 3):

a. Treatment Goal:

(check one)

☐ Curative

☐ Palliative

b. Treatment will be directed to:

(check all that apply)

☐ Primary tumor and/or locoregional disease

☐ Non-osseous distant metastatic disease

☐ Osseous distant metastatic disease

c. Type(s):

(check all that apply)

☐ Surgery

☐ Radiation

☐ Chemotherapy (including biologic modifiers)

☐ Hormonal therapy

☐ Bisphosphonate therapy

☐ Immunotherapy (e.g., sipuleucel T (Provenge®) for prostate cancer)

- ☐ Radiopharmaceutical therapy (strontium-89, samarium-153, etc.)
- ☐ Other
  Specify type: _____

6. NAME OF PERSON WHO COMPLETED THE PAPER FORM

First Name: _____ Last Name: _____ Date: ____/____/____

7. 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.

ADDITONAL INSTRUCTIONS FOR COMPLETING PRE-PET FORM QUESTION 1

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 F-18 Fluoride PET.

< http://www.cms.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=233&**>**

Indications for F-18 Fluoride PET Scans and Limitations/Requirements for Usage

Initial Treatment Strategy

F-18 Fluoride PET performed as part of an evaluation for determination of an *initial treatment strategy* is covered by CMS only with participation in this registry. F-18 fluoride PET may be used both for diagnosis of strongly suspected bone metastases in a patient without a pathologically proven diagnosis of cancer and as part of initial staging in a patient with a pathologically proven cancer.

Note: F-18 fluoride 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 bone 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

F-18 fluoride PET is also covered by CMS only with participation in this registry when used in ***subsequent treatment strategy*** to identify bone metastases in a patient with a pathologically proven cancer.

F-18 fluoride 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, F-18 fluoride 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

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, F-18 fluoride 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.

ADDITIONAL INSTRUCTIONS FOR COMPLETING PRE-PET FORM QUESTION 2

The following guidance is provided to assist you in answering Questions 2a, b, and c when the PET bone scan is requested for "Diagnosis of suspected osseous metastatic disease in a patient without a pathologically proven diagnosis of cancer".

Below are several common clinical scenarios that serve as illustrations.

- A man with back pain, a markedly elevated PSA and sclerotic lesions in several vertebrae on a recent chest radiograph. Answer "Prostate (185)" to question 2a and "No" to question 2b. Do not answer question 2c.
- A woman with a long smoking history, now with a left upper lobe mass, mediastinal adenopathy, and an adrenal nodule on CT. Answer "Lung, non-small cell lung (162)" to question 2a and "No" to question 2b. Do not answer question 2c.
- A man with multifocal bone pain and several ill-defined lytic osseous lesions on a recent chest, abdomen and pelvis CT (with no evidence of a primary tumor on the CT study). Answer "Metastatic cancer of unknown primary origin" to question 2a, "No" to question 2c, and "Bone/bone marrow" to question 2c.
- A woman with severe headache and multiple enhancing lesions on brain MRI. Answer "Metastatic cancer of unknown primary origin" to question 2a, "No" to question 2c, and "Brain" to question 2c.