

April 3, 2009

NOPR Update: Changes to NOPR Patient Registration and Data Entry Procedures

The Centers for Medicare & Medicaid Services (CMS) announced a [new coverage policy](#) for oncologic PET scans < <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=218>>. NOPR has updated its data collection procedures to comply with this directive. Under this new policy, CMS has expanded coverage for the use of PET for initial treatment strategy evaluation (formerly diagnosis and initial staging) of patients with nearly all cancer types, and also will allow for use of PET in subsequent treatment strategy evaluations (formerly restaging, detection of suspected recurrence and treatment monitoring) for an expanded number of cancer types. However, for certain other cancers, the use of PET in initial treatment strategy evaluations and, particularly, in subsequent treatment strategy evaluations will still be covered by CMS only if patients are enrolled in an approved clinical trial or registry. The NOPR has obtained CMS approval to continue its data collection to allow for coverage of PET scans performed for these cancers and indications under this successor "coverage with evidence development" (CED) program.

In compliance with the new coverage policy, NOPR will launch a new version of the registry on Monday, April 6, 2009 at 9:00 AM ET. Access to the new registry will be through the current web site at <http://www.cancerPETRegistry.org>. The new registry portal is identified as NOPR 2009 and the old registry portal is identified as NOPR 2006. The following guidelines are provided to assist you in this transition:

New Facilities and New Patient Registrations

- All new patients will be registered in the new database (NOPR 2009).
- New facility registrations will only be accepted via the new database (NOPR 2009)
- Most of the data collection questions are the same or similar to the questions in the original registry, but there are some important differences, especially for PET studies being done for treatment monitoring. **On Monday April 6th**, facilities should download and review the new [Operations Manual](#) and new [case report forms \(CRFs\)](#), and the slightly revised [Patient](#) and [Referring Physician Information Sheets](#) (consent forms) that are available on the [NOPR Web site](#). **The new [Pre-PET Form and Patient Information Sheet](#) is available now** at <<http://nrdr.acr.org/PETRegistry/prePETwithConsent.pdf>>
- The new registry will require the referring physician to sign both the Pre-PET and the Post-PET forms submitted for each patient attesting to the accuracy of the data on the forms.

Previously Registered Patients

- Data for patients previously entered into the NOPR will continue to be stored and accessed through the 2006 Version.
- Patients currently registered in NOPR who had their PET performed on or before April 3, 2009 will remain in the current registry database (NOPR 2006) and their data will continue to be entered in that database. This will allow for data collection on open cases and report generation on all cases with scan completion dates prior to April 3, 2009.
- For patients registered in the current database (NOPR 2006) who did not have PET performed on or before April 3, 2009, the case registration should be cancelled and the patient should be re-registered in the new database (NOPR 2009). To be clear, the PET facility is responsible for canceling and re-registering these patients. Credits that are applied to accounts in NOPR 2006 after April 3, 2009 will be transferred to the facility's account in NOPR 2009.

Escrowed Funds

- All facility information and escrow balances will be transferred from the original database (NOPR 2006) to the new database (NOPR 2009). Facility staff who have been entering patients on the existing database will be able to enter new patients on the new database immediately.

OUTLINE OF NEW CMS COVERAGE POLICY (for further detail see the [Indications Table summarizing coverage](#)) <<http://nrdr.acr.org/PETRegistry/indications.pdf>>.

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.

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) of 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.